INSTITUTE
OF PHARMACOVIGILANCE

Pharmacovigilance Career Framework Guideline

Version 2 — DRAFT for review

Institute of Pharmacovigilance · *with the ISoP SIG on PV Professional Qualification Framework*

20 July 2026

Draft for review — not published content. This document renders the complete proposed v2 revision of the Career Framework: all 75 roles, with tightened job descriptions and a verified citation attached to every competency-knowledge claim. It is generated from the same data that drives the reviewer toggle on gppc.cloud, so its content is identical to what reviewers see online. Every citation was verified against the issuing body (EUR-Lex, EMA, ICH, CIOMS, MedDRA/MSSO, WHO-UMC, ISPE, MHRA, FDA) on 12 July 2026.

About this v2 revision

Version 0.3 defined the roles of the pharmacovigilance profession. This v2 keeps that taxonomy and the intent of every role, and improves the content in two ways:

1. Job descriptions are tightened for clarity, consistency and current terminology. Eight flagship roles carry hand-authored rewrites; where a role section is headed “v0.3 wording retained”, the v2 pass deliberately kept the original text.
2. Competency claims (the knowledge topics for each role) each carry a verified citation to the governing standard or publication, so the framework's claims are traceable to their source. Citations were verified against the issuing bodies and refreshed to the in-force versions.

How to read the review markers: **CURRENCY** — the source was updated to the current in-force version (e.g., GVP Module XVI Rev 2 → Rev 3, 2024); **NEW CITATION** — a previously uncited topic is now anchored to a named publication (confirm the source choice); **WORDING UPDATED** — the claim text itself was clarified; **MANAGEMENT COMPETENCY** — a genuine duty with no external regulatory source to cite; **VERIFY FIT** — the generated claim may be the wrong template fit for this role and should be re-authored on review. Routine version/date refinements carry no marker.

What this pass covered — and did not. It improved job-description *wording* and attached a verified *source* to each knowledge topic. It did ***not*** re-set the proficiency *levels* (Basic / Intermediate / Expert), the *prerequisites*, or the *KSA* mappings — those remain as in v0.3 and are not reproduced in this document. Competency standards remain **DRAFT** (authored for review) except where marked PUBLISHED. The healthcare “PV Awareness for Healthcare Professionals” certificate is a published standard and appears with its original content.

Knowledge proficiency scale

Every knowledge claim in this guideline uses the four-level scale below (unchanged from v0.3).

Level	Score	Expected knowledge
N/A	0	No knowledge required.
Basic	1	Elementary knowledge of the specific regulation; fundamental understanding of the terms and definitions used, a basic understanding of the concept of the regulation, a general overview of what it covers and where it can be found; passive/delegated usage of the regulation.
Intermediate	2	Very good knowledge of the specific regulation; comprehensive understanding of the terms and definitions and of the concept and context of who/when/where/why/how it applies; active usage of the regulation when required.
Expert	3	Excellent knowledge of the specific regulation; in-depth understanding of the concept and of how and why its sections should be implemented and followed, including outcomes

Level	Score	Expected knowledge
		and responsibilities for all relevant stakeholders; active usage of the regulation on a daily basis.

Role index

The 75 roles of the framework, grouped by career category. Role codes follow the v0.3 taxonomy (Category.Sector.Area).

Leadership

1. Head of Safety **L.I.HS**
2. EU QPPV **L.I.R.EUQP**
3. Global/HQ QPPV **L.I.GQP**
4. UK QPPV **L.I.R.UKQP**
5. PV Policy Lead **L.I.PVPL**
6. Head of PV **L.RA.HPV**
7. PV Policy Lead **L.RA.PVPL**
8. Head of PV Academic Program **L.A.HPVP**

Managerial

9. Head of PV Operations **M.I.HPVO**
10. Head of Quality Assurance PV **M.I.HQA**
11. Head of Medical PV **M.I.HMPV**
12. Head of PV Data Science **M.I.HPVDS**
13. Head of PV Pharmacoepidemiology **M.I.HPVPE**
14. PV Project Manager **M.I.PVPM**
15. PV Vendor Manager **M.I.PVVM**
16. Head of Signal Management **M.RA.HSM**
17. Head of PV Medical Assessment **M.RA.HPVMA**
18. Head of Data Management **M.RA.HDM**
19. Head of Risk Management **M.RA.HRM**
20. Head of PV Inspectorate **M.RA.HPVI**
21. Team Leader in PV **M.RA.TLPV**
22. PV Academic Program Manager **M.A.PVPM**
23. PV Academic Project Manager **M.A.PVPM2**

Scientific

24. Pharmacovigilance Awareness for Healthcare Professionals
25. Medical Reviewer **S.I.DM.MR**
26. Signal Evaluator **S.I.SM.SE**
27. PV Data Supervisor **S.I.DM.DS**
28. PV Data Scientist **S.I.DM.DSC**
29. Medical Evaluator **S.I.SM.ME**
30. Risk Management Scientist **S.I.RM.RMS**
31. Quality Assurance Scientist **S.I.QA.QAS**
32. PV Systems Architect **S.I.PVS.SA**
33. PV Medical Writer **S.I.MW.MW**
34. PBRER Writer **S.I.MW.PBRER**
35. RMP Writer **S.I.MW.RMP**
36. REMS Writer **S.I.MW.REMS**
37. DSUR Writer **S.I.MW.DSUR**
38. PV Pharmacoepidemiologist **S.I.DCS.PE**
39. PV Biostatistician **S.I.DCS.BS**
40. PV Medical Assessor **S.RA.MA**
41. PV Scientific Assessor **S.RA.SA**
42. PV Inspector **S.RA.INSP**
43. Senior Researcher **S.A.SR**
44. PV Scientist **S.A.SC**
45. PV Data Scientist **S.A.DSC**

46. PV Pharmacoepidemiologist **S.A.PE**
47. PV Lecturer **S.A.PVL**
48. Medication Safety Officer **S.H.MSO**

Technical

49. Safety Database Specialist **T.I.DM.ITS.SDS**
50. IT PV Systems Supervisor **T.I.DM.ITS.ITSS**
51. Data Entry Specialist **T.I.DM.DE.DES**
52. Terminology Coder **T.I.DM.DE.TC**
53. Product Coder **T.I.DM.DE.PC**
54. Data Entry Supervisor **T.I.DM.DE.DESUP**
55. Signal Management Administrator **T.I.SM.SMA**
56. Risk Management Administrator **T.I.RM.RMA**
57. PV Quality Assurance Administrator **T.I.QA.QAA**
58. PV Auditor **T.I.QA.AUD**
59. PSMF Administrator **T.I.PVS.PSMF**
60. SDEA Administrator **T.I.PVS.SDEA**
61. Local Responsible Person **T.I.PVS.LRP**
62. PV Studies Administrator **T.I.DCS.SA**
63. Safety Database Specialist **T.RA.DM.ITS.SDS**
64. IT PV Systems Supervisor **T.RA.DM.ITS.ITSS**
65. Data Entry Specialist **T.RA.DM.DE.DES**
66. Terminology Coder **T.RA.DM.DE.TC**
67. Product Coder **T.RA.DM.DE.PC**
68. Data Entry Supervisor **T.RA.DM.DE.DESUP**
69. Signal Management Administrator **T.RA.SM.SMA**
70. Risk Management Administrator **T.RA.RM.RMA**
71. PSMF Assessor **T.RA.PVS.PSMF**
72. PV Inspector **T.RA.QA.INSP**
73. Data Quality Reviewer **T.RA.QA.DQR**
74. PV Research Administrator **T.A.RA**
75. PV Assistant Lecturer **T.A.AL**

Leadership

Roles accountable for pharmacovigilance governance, strategy and the overall PV system.

8 roles

1. Head of Safety

Code **L.I.HS** *Leadership · Industry* **DRAFT** competency standard

Also known as: Head of Group Health and Safety; Head of Patient Safety; Director of Drug Safety

v2: Proposed citation mapping: each topic is paired with a source drawn from the verified base (all sources checked against their issuing body, 2026-07-12) and refreshed to the in-force version — confirm each topic→source fit on review. Blank-note gaps are filled and misfit template topics flagged. Job description and proficiency levels are unchanged from v0.3 for this role.

Job description (v0.3 wording retained)

- Ensure the establishment and maintenance of PV governance within the organisation.
- Establish a clear vision, action plan, and processes to bridge PV Operations, Medical Safety, and Safety Science.
- Accountable for compliance, documentation, and training of processes with ongoing assessment of continuous process improvement.
- Lead the development and compliance of annual safety reports, investigator communications, product labelling, etc.
- Responsible for the development of risk management, minimisation plans and strategies, and the assessment of risk for drugs in development through commercialisation.
- Ensure consistency and standardisation of roles and procedures throughout the organisation.
- Build the PV strategy and timelines and plan the budget for the division.
- Support and facilitate communication in responding to safety questions from regulatory authorities, as well as audits and inspections with corrective action plans.
- Ensure oversight and management of all outsourced or insourced PV activities, including key quality and compliance metrics.
- Ensure accurate and current PV agreements and Safety Data Exchange Agreements are in place with all licence partners, vendors and third parties.

Competency claims with verified sources

General Knowledge

Competency claim (knowledge topic)	Level	Verified source
Pharmacovigilance legislation and Good Pharmacovigilance Practices (GVP) overview **NEW CITATION**	**Expert**	Dir 2001/83/EC (as amended by Dir 2010/84/EU); Reg (EC) 726/2004 (as amended by Reg (EU) 1235/2010); EMA GVP Module I (2012)
The PV system and Pharmacovigilance System Master File (PSMF) **NEW CITATION**	**Expert**	EMA GVP Module II (Rev 2, 2017); Comm. Impl. Reg (EU) 520/2012, as amended
Roles and responsibilities of the QPPV and the PV organisation **NEW CITATION**	**Expert**	EMA GVP Module I (2012); Comm. Impl. Reg (EU) 520/2012, as amended
Quality management systems and data integrity principles **NEW CITATION**	**Intermediate**	EMA GVP Module I (2012); MHRA 'GXP' Data Integrity (2018); FDA Data Integrity (2018) — ALCOA+

Role-Specific Knowledge

Competency claim (knowledge topic)	Level	Verified source
Risk management: RMP / REMS and risk minimisation measures **NEW CITATION**	**Expert**	EMA GVP Module V (Rev 2, 2017); EMA GVP Module XVI (Rev 3, 2024); FDA REMS — FDAAA 2007, FD&C

Competency claim (knowledge topic)	Level	Verified source
		Act §505-1
Aggregate safety reporting (PBRER/PSUR, DSUR) **NEW CITATION**	**Expert**	EMA GVP Module VII (Rev 1, 2013); ICH E2C(R2) (PBRER); ICH E2F (DSUR, Step 4 2010)
Signal management (detection, validation, assessment) **NEW CITATION**	**Expert**	EMA GVP Module IX (Rev 1, 2017)
Audit and inspection readiness; CAPA management **NEW CITATION**	**Expert**	EMA GVP Module IV (Rev 1, 2015); EMA GVP Module III (Rev 1, 2014)
Safety Data Exchange Agreements and vendor/partner oversight **NEW CITATION**	**Intermediate**	EMA GVP Module I (2012); EMA GVP Module II (Rev 2, 2017)
PV budgeting, resourcing and business continuity planning **MANAGEMENT COMPETENCY (NO EXTERNAL REGULATORY SOURCE)**	**Intermediate**	—

2. EU QPPV

Code **L.I.R.EUQP** *Leadership · Industry · Regional QPPV* **DRAFT** competency standard

Also known as: Qualified Person Responsible for Pharmacovigilance (EU)

> *v2: Job description tightened (active voice; governing legislation named); every knowledge topic now carries a verified citation, with base laws cited "as amended".*

Job description — v2 (revised wording)

- Reside and operate in the EU/EEA.
- Act as the single pharmacovigilance contact point for the national competent authorities and the EMA on a 24-hour basis, and as the contact point for pharmacovigilance inspections.
- Establish and maintain the EU pharmacovigilance system in accordance with Directive 2001/83/EC (as amended by Directive 2010/84/EU) and the Good Pharmacovigilance Practices (GVP).
- Have oversight of the functioning of the pharmacovigilance system in all relevant aspects, including its quality system.
- Maintain an overview and awareness of medicinal-product safety profiles and of any conditions or obligations adopted as part of the marketing authorisations.
- Have sufficient authority over the pharmacovigilance system and the content of risk management plans (RMPs).
- Be involved in the review and sign-off of protocols of post-authorisation safety studies (PASS) conducted in the EU.
- Ensure submission of pharmacovigilance documents in accordance with legal requirements, and ensure the necessary quality, correctness and completeness of pharmacovigilance data.
- Ensure full and prompt responses to any request from the national competent authorities and the EMA.
- Maintain a matrix of local QPPVs and equivalents (in-house and outsourced) across all relevant countries.

Competency claims with verified sources

General Knowledge

Competency claim (knowledge topic)	Level	Verified source
EU pharmacovigilance legislation — Directive 2001/83/EC (as amended by Dir 2010/84/EU) and Regulation (EC) No 726/2004 (as amended by Reg (EU) No 1235/2010) **WORDING UPDATED**	**Expert**	EUR-Lex, consolidated versions
Good Pharmacovigilance Practices (GVP) modules	**Expert**	EMA, GVP
Pharmacovigilance System Master File (PSMF)	**Expert**	EMA GVP Module II (Rev 2, 2017); Comm. Impl. Reg (EU) 520/2012, as amended
Quality-system requirements for the PV system	**Expert**	EMA GVP Module I (2012); Reg (EU) 520/2012, as amended

Regional Regulatory-Specific Knowledge *EU/EEA variant.*

Competency claim (knowledge topic)	Level	Verified source
EMA and national competent authority interactions	**Expert**	Reg (EC) No 726/2004, as amended
EudraVigilance and ICSR reporting obligations	**Intermediate**	EMA GVP Module VI (Rev 2, 2017); ICH E2B(R3)
PRAC procedures and referrals	**Intermediate**	Reg (EC) No 726/2004, as amended by Reg (EU) 1235/2010

Role-Specific Knowledge

Competency claim (knowledge topic)	Level	Verified source
Risk management plans (RMPs) and risk minimisation CURRENCY	**Expert**	EMA GVP Module V (Rev 2, 2017); Module XVI (Rev 3, 2024)
Post-authorisation safety studies (PASS/PAES)	**Intermediate**	EMA GVP Module VIII (Rev 3, 2017)
Aggregate reporting (PSUR/PBRER)	**Intermediate**	EMA GVP Module VII (Rev 1, 2013); ICH E2C(R2)
Signal management in the EU regulatory context	**Intermediate**	EMA GVP Module IX (Rev 1, 2017)

3. Global/HQ QPPV

Code **L.I.GQP** *Leadership · Industry* **PUBLISHED** competency standard
Also known as: Global Safety Leader

Job description (v0.3 wording retained)

- Implement global PV services and oversee successful service delivery from an operational perspective.
- Have oversight of the functioning of the PV systems in all relevant aspects, including its quality system.
- Ensure that processes are efficient, high quality, and in compliance with the global legislation.
- Supervise PV systems, including review and revision of documented procedures (e.g. SOP) and identify a need for development or revision of existing documented procedures.
- Where required, take responsibility for, and lead the receipt, processing, reporting, follow-up, and reconciliation of adverse event reports from any source like clinical trials, literature, post-marketing, and pharmaceutical-technical complaints.
- Have awareness of relevant PSMF, RMPs, risk minimisation activities, and periodic aggregate safety reports (e.g., PBRERs, PSURs, DSURs).
- May also manage activities related to clinical trials, e.g., development of Safety Management Plans.
- Implement and evaluate global literature searches.
- Lead client audits and inspections.
- Ensure a suitably organised and managed PV team.
- Support relevant management staff.
- Ensure that information about all relevant suspected adverse reactions are reported to the company and affiliates, as defined in agreements, is collected, collated and is accessible within the PV system.
- Ensure all periodic reports and medical variation applications are planned, tracked and obtained in a timely manner.
- Develop and implement relevant PV training.
- Ensure continuous improvement of resources and materials provided.
- Engage in continuous improvement of the processes.
- Support company governance of business ethic compliance and its implementation.

Knowledge

Pharmacovigilance

Knowledge topic	Level
Pharmacovigilance aim, scope, and history	**Expert**
PV glossary and definitions	**Expert**
Ethics and leadership in pharmacovigilance	**Expert**
Societal burden of adverse reactions to medicines	**Intermediate**
The global PV-relevant regulatory landscape (including data privacy)	**Intermediate**
Architecture of pharmacovigilance system (industry, regulators, other)	**Intermediate**

Knowledge topic	Level
Industry-specific knowledge	Expert

Sciences and Technologies

Knowledge topic	Level
Mechanisms underlying adverse reaction to medicines	Basic
Information Technology systems applied to pharmacovigilance	Intermediate
Collection, processing, and medical evaluation of safety data	Basic
Detection and management of safety signals. Benefit vs Risk evaluation	Expert
Risk management planning and risk minimisation methods	Expert
Safety decision making (including labelling variation)	Expert
Pharmacoepidemiology and safety data generation	Basic
Generation, distribution, and evaluation of safety regulatory documents	Intermediate
Quality Management of PV-Relevant processes (QC, QM, QA, A&I)	Expert
Product quality safety management	Expert

Local regulation

Knowledge topic	Level
Local applicable regulations	Intermediate

Skills

Assessed on the usage-based skill scale: Basic — passive/delegated usage; Intermediate — active usage when required, often in collaboration with other specialists; Expert — active usage on daily basis, usually responsible person, or leader of activities.

Collection and reporting

Skill	Level
Collecting spontaneous adverse drug reaction reports	Basic
Collecting reports using active surveillance	Basic
Reporting of suspected adverse reaction	Basic

Analysis and assessment

Skill	Level
Data management in pharmacovigilance	Expert
Signal management in pharmacovigilance	Intermediate
Interaction between PV and product quality defect systems	Expert
Benefit-Risk evaluation of authorized medicinal products	Intermediate
Periodic Benefit-Risk Evaluation reporting	Expert

Skill	Level
Risk management of medicinal products	**Intermediate**

Taking measures

Skill	Level
Safety Variations	**Expert**
Safety Communication to competent authorities	**Expert**
Safety Communication to healthcare professionals and patients	**Expert**
Management of post-authorisation pharmacovigilance commitments	**Expert**

General skills

Skill	Level
Business continuity of pharmacovigilance systems	**Expert**
Good Documentation Practices	**Expert**
Good Clinical Practices	**Expert**
Data Privacy Protection	**Expert**

Attitude

Cognitive competencies

- Strategic thinking
- Analysis and use of information
- Decision making

Intrapersonal competencies

- Ethical
- Independent
- Professional
- Performance oriented

Interpersonal competencies

- Leadership
- Influencing
- Communication

Official standard: *ISoP Global Competency Standard for Qualified Person in Pharmacovigilance (QPPV), v1.0 — jointly developed by ISoP, the ISoP SIG on PV Professional Qualification Framework and the Institute of Pharmacovigilance — https://pharmacovigilance.institute/res/pages/files/66216-a9-isop-global-qppv-competency-standard-v1.0.pdf*

4. UK QPPV

Code **L.I.R.UKQP** *Leadership · Industry · Local QPPV* **DRAFT** competency standard

> *v2: Proposed citation mapping: each topic is paired with a source drawn from the verified base (all sources checked against their issuing body, 2026-07-12) and refreshed to the in-force version — confirm each topic→source fit on review. Blank-note gaps are filled and misfit template topics flagged. Job description and proficiency levels are unchanged from v0.3 for this role.*

Job description (v0.3 wording retained)

- Resides and operate in the UK or EU/EAA.
- Responsible for establishing and maintaining the PV system.
- Act as a single PV contact point for MHRA regulators on a 24-hour basis and as a contact point for PV inspections.
- Ensure a tracking system for PV audits and related CAPA is in place and ensure implementation of such CAPA plans.
- Responsible for setting up a PV system that ensures accurately, timely, and complete submissions.
- Implement and evaluate local literature searches.
- Provide input into the preparation of regulatory action in response to emerging safety concerns (e.g., variations, urgent safety restrictions, communication to patients and healthcare professionals).
- Involved and consulted in due diligence that may have an impact on the PV system.
- Ownership of UK PSMFs.
- Responsible for ensuring suitable managed and up to date PV Business Continuity Plans that suitably covers the needs of the UK PSMF.
- Develop and implement relevant PV training.
- Ensure continuous improvement of resources and materials provided.
- Engage in continuous improvement of the processes.
- Support company governance of business ethic compliance and its implementation.

Competency claims with verified sources

General Knowledge

Competency claim (knowledge topic)	Level	Verified source
Pharmacovigilance principles and Good Pharmacovigilance Practices (GVP) overview	**Expert**	EMA GVP Module I (2012); Dir 2001/83/EC (as amended by Dir 2010/84/EU); Reg (EC) 726/2004 (as amended by Reg (EU) 1235/2010)
The pharmacovigilance system and Pharmacovigilance System Master File (PSMF)	**Expert**	EMA GVP Module II (Rev 2, 2017); Comm. Impl. Reg (EU) 520/2012, as amended
Individual case safety report (ICSR) management and regulatory reporting timelines	**Expert**	EMA GVP Module VI (Rev 2, 2017); ICH E2D(R1) (in force EU 18 Mar 2026); ICH E2B(R3) (v5.02, 2016)

Role-Specific Knowledge *Includes topics derived from this role's job description.*

Competency claim (knowledge topic)	Level	Verified source
PV governance, strategy and the PV system	**Expert**	EMA GVP Module I (2012)
PV legislation and GVP across regions	**Expert**	Dir 2001/83/EC (as amended by Dir 2010/84/EU); Reg (EC) 726/2004 (as

Competency claim (knowledge topic)	Level	Verified source
		amended by Reg (EU) 1235/2010)
Risk management and aggregate reporting oversight	**Expert**	EMA GVP Module V (Rev 2, 2017); EMA GVP Module VII (Rev 1, 2013)
Audit, inspection readiness and CAPA	**Intermediate**	EMA GVP Module IV (Rev 1, 2015); EMA GVP Module III (Rev 1, 2014)
Budgeting, resourcing and business continuity **MANAGEMENT COMPETENCY (NO EXTERNAL REGULATORY SOURCE)**	**Intermediate**	—
Audits and regulatory inspections	**Expert**	EMA GVP Module IV (Rev 1, 2015); EMA GVP Module III (Rev 1, 2014)
CAPA (corrective and preventive action) management	**Expert**	EMA GVP Module IV (Rev 1, 2015)
Literature monitoring and review	**Intermediate**	EMA GVP Module VI (Rev 2, 2017) — literature monitoring
Training, education and capacity building	**Intermediate**	WHO PV Core Curriculum for University Teaching (van Eekeren et al., Drug Saf 2018)
PSMF and Safety Data Exchange Agreements (SDEA)	**Expert**	EMA GVP Module II (Rev 2, 2017); EMA GVP Module I (2012)

5. PV Policy Lead

Code **L.I.PVPL** *Leadership · Industry* **DRAFT** competency standard

> *v2: Proposed citation mapping: each topic is paired with a source drawn from the verified base (all sources checked against their issuing body, 2026-07-12) and refreshed to the in-force version — confirm each topic→source fit on review. Blank-note gaps are filled and misfit template topics flagged. Job description and proficiency levels are unchanged from v0.3 for this role.*

Job description (v0.3 wording retained)

- Coordinate the exchange of policy-related information and disseminate it across other teams and ensure all the resources provided are available to implement relevant policies.
- Maintain regular contact with other divisions and give feedback with regards to policy-related changes for the successful enforcement of the policies.
- Support relevant management staff.
- Engage with Training and Quality teams regularly to ensure robust and consistent enforcement and correct understanding of internal policies.
- Flag resource constraints, policy issues or inconsistencies timely.
- Gather insights and offer policy suggestions based on the direct application of the policies.
- Ensure continuous improvement of resources and materials provided.
- Engage in continuous improvement of the processes.
- Support company governance of business ethic compliance and its implementation.

Competency claims with verified sources

General Knowledge

Competency claim (knowledge topic)	Level	Verified source
Pharmacovigilance principles and Good Pharmacovigilance Practices (GVP) overview	**Expert**	EMA GVP Module I (2012); Dir 2001/83/EC (as amended by Dir 2010/84/EU); Reg (EC) 726/2004 (as amended by Reg (EU) 1235/2010)
The pharmacovigilance system and Pharmacovigilance System Master File (PSMF)	**Expert**	EMA GVP Module II (Rev 2, 2017); Comm. Impl. Reg (EU) 520/2012, as amended
Individual case safety report (ICSR) management and regulatory reporting timelines	**Expert**	EMA GVP Module VI (Rev 2, 2017); ICH E2D(R1) (in force EU 18 Mar 2026); ICH E2B(R3) (v5.02, 2016)

Role-Specific Knowledge *Includes topics derived from this role's job description.*

Competency claim (knowledge topic)	Level	Verified source
PV governance, strategy and the PV system	**Expert**	EMA GVP Module I (2012)
PV legislation and GVP across regions	**Expert**	Dir 2001/83/EC (as amended by Dir 2010/84/EU); Reg (EC) 726/2004 (as amended by Reg (EU) 1235/2010)
Risk management and aggregate reporting oversight	**Expert**	EMA GVP Module V (Rev 2, 2017); EMA GVP Module VII (Rev 1, 2013)
Audit, inspection readiness and CAPA	**Intermediate**	EMA GVP Module IV (Rev 1, 2015); EMA GVP Module III (Rev 1, 2014)
Budgeting, resourcing and business continuity **MANAGEMENT**	**Intermediate**	—

Competency claim (knowledge topic)	Level	Verified source
COMPETENCY (NO EXTERNAL REGULATORY SOURCE)		
Training, education and capacity building	**Intermediate**	WHO PV Core Curriculum for University Teaching (van Eekeren et al., Drug Saf 2018)
PV policy, legislation and guideline development	**Expert**	Dir 2001/83/EC (as amended by Dir 2010/84/EU); Reg (EC) 726/2004 (as amended by Reg (EU) 1235/2010)

6. Head of PV

Code **L.RA.HPV** *Leadership · Regulatory Authority* **DRAFT** competency standard

Also known as: Head of Safety Surveillance

> *v2: Proposed citation mapping: each topic is paired with a source drawn from the verified base (all sources checked against their issuing body, 2026-07-12) and refreshed to the in-force version — confirm each topic→source fit on review. Blank-note gaps are filled and misfit template topics flagged. Job description and proficiency levels are unchanged from v0.3 for this role.*

Job description (v0.3 wording retained)

- Build and manage a high-growth PV team and communicate departmental information effectively to the team.
- Provide global strategic leadership by setting clear expectations and providing hands-on leadership for PV, promoting collaboration and team cohesiveness.
- Oversee all PV-related activities performed by external suppliers/consultants, ensure appropriate documentation and governance frameworks are in place
- Interact with internal and external staff to develop programs and processes to meet regulatory reporting requirements.
- Lead process improvement within global PV – including technology assessment and implementation.
- Collaborate with appropriate clinical, medical, quality, and regulatory counterparts to provide input and oversight for all safety and PV issues, as appropriate.
- Support relevant management staff.
- Oversee assessment of aggregate reporting, management of risk-benefit profiles for clinical and post-marketing compounds.
- Contribute to transparency and communication initiatives through the provision of scientifically rigorous and consistent information to promote the safe and effective use of medicines.
- Liaise with and provide technical information, advice and guidance on PV matters to other colleagues, pharmaceutical companies, relevant national and international bodies, healthcare professionals and members of the public.
- Support external compliance monitoring with PV obligations.
- Participate at all levels (internally and externally) in the formulation, and preparation of regulatory policies, guidelines, legislation, and opinions.
- Develop and implement relevant training.
- Ensure continuous improvement of resources and materials provided.
- Engage in continuous improvement of the processes.
- Support regulatory authority governance of ethic compliance and its implementation.

Competency claims with verified sources

General Knowledge

Competency claim (knowledge topic)	Level	Verified source
Pharmacovigilance principles and Good Pharmacovigilance Practices (GVP) overview	**Expert**	EMA GVP Module I (2012); Dir 2001/83/EC (as amended by Dir 2010/84/EU); Reg (EC) 726/2004 (as amended by Reg (EU) 1235/2010)
The pharmacovigilance system and Pharmacovigilance System Master File (PSMF)	**Expert**	EMA GVP Module II (Rev 2, 2017); Comm. Impl. Reg (EU) 520/2012, as amended
Individual case safety report	**Expert**	EMA GVP Module VI (Rev 2, 2017);

Competency claim (knowledge topic)	Level	Verified source
(ICSR) management and regulatory reporting timelines		ICH E2D(R1) (in force EU 18 Mar 2026); ICH E2B(R3) (v5.02, 2016)

Role-Specific Knowledge

Includes topics derived from this role's job description.

Competency claim (knowledge topic)	Level	Verified source
PV governance, strategy and the PV system	**Expert**	EMA GVP Module I (2012)
PV legislation and GVP across regions	**Expert**	Dir 2001/83/EC (as amended by Dir 2010/84/EU); Reg (EC) 726/2004 (as amended by Reg (EU) 1235/2010)
Risk management and aggregate reporting oversight	**Expert**	EMA GVP Module V (Rev 2, 2017); EMA GVP Module VII (Rev 1, 2013)
Audit, inspection readiness and CAPA	**Intermediate**	EMA GVP Module IV (Rev 1, 2015); EMA GVP Module III (Rev 1, 2014)
Budgeting, resourcing and business continuity **MANAGEMENT COMPETENCY (NO EXTERNAL REGULATORY SOURCE)**	**Intermediate**	—
Aggregate safety reports (PBRER/PSUR, DSUR)	**Expert**	EMA GVP Module VII (Rev 1, 2013); ICH E2C(R2) (PBRER); ICH E2F (DSUR, Step 4 2010)
Training, education and capacity building	**Intermediate**	WHO PV Core Curriculum for University Teaching (van Eekeren et al., Drug Saf 2018)
Benefit–risk assessment methodology	**Expert**	ICH E2C(R2) (PBRER)
PV policy, legislation and guideline development	**Expert**	Dir 2001/83/EC (as amended by Dir 2010/84/EU); Reg (EC) 726/2004 (as amended by Reg (EU) 1235/2010)

7. PV Policy Lead

Code **L.RA.PVPL** *Leadership · Regulatory Authority* **DRAFT** competency standard

> *v2: Proposed citation mapping: each topic is paired with a source drawn from the verified base (all sources checked against their issuing body, 2026-07-12) and refreshed to the in-force version — confirm each topic→source fit on review. Blank-note gaps are filled and misfit template topics flagged. Job description and proficiency levels are unchanged from v0.3 for this role.*

Job description (v0.3 wording retained)

- Coordinate the exchange of policy-related information and disseminate it across other teams, and ensure all the resources provided are available to implement relevant policies.
- Maintain regular contact with other divisions and give feedback with regards to policy-related changes for the successful enforcement of the policies.
- Support relevant management staff.
- Engage with Training and Quality teams regularly to ensure robust and consistent enforcement and correct understanding of internal policies.
- Flag resource constraints, policy issues or inconsistencies timely.
- Gather insights and offer policy suggestions based on the direct application of the policies.
- Contribute to transparency and communication initiatives through the provision of scientifically rigorous and consistent information to promote the safe and effective use of medicines.
- Liaise with and provide technical information, advice, and guidance on relevant PV matters to other regulatory colleagues, pharmaceutical companies, relevant national and international bodies, healthcare professionals and members of the public.
- Support external compliance monitoring with PV obligations.
- Participate at all levels (internally and externally) in the formulation and preparation of regulatory policies, guidelines, legislation, and opinions.
- Ensure continuous improvement of resources and materials provided.
- Engage in continuous improvement of the processes.
- Support regulatory authority governance of ethic compliance and its implementation.

Competency claims with verified sources

General Knowledge

Competency claim (knowledge topic)	Level	Verified source
Pharmacovigilance principles and Good Pharmacovigilance Practices (GVP) overview	**Expert**	EMA GVP Module I (2012); Dir 2001/83/EC (as amended by Dir 2010/84/EU); Reg (EC) 726/2004 (as amended by Reg (EU) 1235/2010)
The pharmacovigilance system and Pharmacovigilance System Master File (PSMF)	**Expert**	EMA GVP Module II (Rev 2, 2017); Comm. Impl. Reg (EU) 520/2012, as amended
Individual case safety report (ICSR) management and regulatory reporting timelines	**Expert**	EMA GVP Module VI (Rev 2, 2017); ICH E2D(R1) (in force EU 18 Mar 2026); ICH E2B(R3) (v5.02, 2016)

Role-Specific Knowledge *Includes topics derived from this role's job description.*

Competency claim (knowledge topic)	Level	Verified source
PV governance, strategy and the	**Expert**	EMA GVP Module I (2012)

Competency claim (knowledge topic)	Level	Verified source
PV system		
PV legislation and GVP across regions	**Expert**	Dir 2001/83/EC (as amended by Dir 2010/84/EU); Reg (EC) 726/2004 (as amended by Reg (EU) 1235/2010)
Risk management and aggregate reporting oversight	**Expert**	EMA GVP Module V (Rev 2, 2017); EMA GVP Module VII (Rev 1, 2013)
Audit, inspection readiness and CAPA	**Intermediate**	EMA GVP Module IV (Rev 1, 2015); EMA GVP Module III (Rev 1, 2014)
Budgeting, resourcing and business continuity **MANAGEMENT COMPETENCY (NO EXTERNAL REGULATORY SOURCE)**	**Intermediate**	—
Training, education and capacity building	**Intermediate**	WHO PV Core Curriculum for University Teaching (van Eekeren et al., Drug Saf 2018)
PV policy, legislation and guideline development	**Expert**	Dir 2001/83/EC (as amended by Dir 2010/84/EU); Reg (EC) 726/2004 (as amended by Reg (EU) 1235/2010)

8. Head of PV Academic Program

Code **L.A.HPVP** *Leadership · Academia* **DRAFT** competency standard

> *v2: Proposed citation mapping: each topic is paired with a source drawn from the verified base (all sources checked against their issuing body, 2026-07-12) and refreshed to the in-force version — confirm each topic→source fit on review. Blank-note gaps are filled and misfit template topics flagged. Job description and proficiency levels are unchanged from v0.3 for this role.*

Job description (v0.3 wording retained)

- Responsible for the overall development and coordination of the specific PV program.
- Ensure the involvement of all the professional environments important for the program in the continued development of the education.
- Act as a head of studies for the academic program and request - in accordance with the curriculum, teaching at the departments and outside of the faculty and possibly outside of the University.
- Responsible for academic guidance of the students and internal information about educational possibilities.
- Ensure continuous improvement of resources and materials provided.
- Engage in continuous improvement of relevant processes.

Competency claims with verified sources

General Knowledge

Competency claim (knowledge topic)	Level	Verified source
Pharmacovigilance principles and Good Pharmacovigilance Practices (GVP) overview	**Expert**	EMA GVP Module I (2012); Dir 2001/83/EC (as amended by Dir 2010/84/EU); Reg (EC) 726/2004 (as amended by Reg (EU) 1235/2010)
The pharmacovigilance system and Pharmacovigilance System Master File (PSMF)	**Expert**	EMA GVP Module II (Rev 2, 2017); Comm. Impl. Reg (EU) 520/2012, as amended
Individual case safety report (ICSR) management and regulatory reporting timelines	**Expert**	EMA GVP Module VI (Rev 2, 2017); ICH E2D(R1) (in force EU 18 Mar 2026); ICH E2B(R3) (v5.02, 2016)

Role-Specific Knowledge *Includes topics derived from this role's job description.*

Competency claim (knowledge topic)	Level	Verified source
PV curriculum and educational methods **VERIFY FIT**	**Expert**	WHO PV Core Curriculum for University Teaching (van Eekeren et al., Drug Saf 2018)
Pharmacovigilance science and research methodology **NEW CITATION**	**Intermediate**	ENCePP Guide on Methodological Standards (Rev 11, 2023); STROBE Statement (von Elm et al., 2007)
Regulatory framework and GVP overview	**Intermediate**	EMA GVP Module I (2012)
Scientific writing and publication **NEW CITATION**	**Intermediate**	ICMJE Recommendations (Jan 2026)
Training, education and capacity building	**Intermediate**	WHO PV Core Curriculum for University Teaching (van Eekeren et al., Drug Saf 2018)
Budgeting, resourcing and business continuity **MANAGEMENT COMPETENCY (NO EXTERNAL REGULATORY SOURCE)**	**Expert**	—

Managerial

Roles that manage PV functions, teams, projects and vendor relationships.

15 roles

9. Head of PV Operations

Code **M.I.HPVO** *Managerial · Industry · PV Operations* **DRAFT** competency standard

Also known as: Global PV Operations Manager; Director of PV Management and Operations

v2: Job description made active-voice and aligned to GVP audit/inspection terminology; knowledge citations verified, ICSR-timeline claim refreshed to ICH E2D(R1).

Job description — v2 (revised wording)

- Provide guidance, advice and direction to ensure pharmacovigilance compliance at regional and country level.
- Interact with Country Medical Directors, General Managers and Commercial as needed to ensure strong PV connectivity and to proactively identify new programmes, initiatives, strategies or risks that may impact the PV system.
- Interact with local safety contacts to ensure pharmacovigilance compliance across the regions and countries.
- Partner with senior local, regional and global roles and participate in regional lead-team forums and governance boards to develop strategies that reduce risk to the PV system.
- Escalate non-compliance in the region as appropriate.
- Be accountable for implementing new regulations in the region by liaising with central/regional teams and third parties.
- Participate in inspection- and audit-readiness activities and support internal and external pharmacovigilance audits.
- Provide adequate support, motivation, encouragement and effective management for all relevant staff.

Competency claims with verified sources

General Knowledge

Competency claim (knowledge topic)	Level	Verified source
GVP and PV compliance obligations	**Expert**	EMA, GVP; EMA GVP Module I (2012)
ICSR management and reporting timelines **CURRENCY**	**Expert**	EMA GVP Module VI (Rev 2, 2017); ICH E2D(R1); ICH E2B(R3)
PV system and quality management	**Intermediate**	EMA GVP Module I (2012); Reg (EU) 520/2012, as amended

Role-Specific Knowledge

Competency claim (knowledge topic)	Level	Verified source
Regional/local PV regulatory requirements	**Expert**	Dir 2001/83/EC (as amended); national PV frameworks
Compliance metrics and non-compliance escalation	**Expert**	EMA GVP Module I (2012), quality-system performance indicators
Audit and inspection readiness	**Intermediate**	EMA GVP Module IV (Rev 1, 2015); Module III (Rev 1, 2014)
Vendor and affiliate oversight	**Intermediate**	EMA GVP Module I (2012); Module VI (Rev 2, 2017)

10. Head of Quality Assurance PV

Code **M.I.HQA** *Managerial · Industry · Quality Assurance* **DRAFT** competency standard

Also known as: Director of Quality Management; Director of Quality Assurance; Director of PV Quality

> *v2: Proposed citation mapping: each topic is paired with a source drawn from the verified base (all sources checked against their issuing body, 2026-07-12) and refreshed to the in-force version — confirm each topic→source fit on review. Blank-note gaps are filled and misfit template topics flagged. Job description and proficiency levels are unchanged from v0.3 for this role.*

Job description (v0.3 wording retained)

- Enhance Quality culture and promote a Quality mindset into the country governance, working principles and ways of operating.
- Person in charge of internal and external audits.
- Lead and coordinate a network of professionals designated in each country function involved in GxP and health-regulated activities and embark them to address all matters related to Quality, including the support to business and digital initiatives.
- Assure that a process for management of GxP documents and records is in place in all GxP and health regulated areas, considering data integrity principles.
- Organize consistent management of Country Quality documents related to GxP and health regulated activities through an appropriate system.
- Implement a screening process for released global quality documents and local regulations to capture the requirements that must be transcribed into Country Quality documents
- Guide country functions that need to develop or update Country Quality documents and related training modules in their respective domains.
- Ensure that required quality documents are in place, in use and up to date at the country level, providing oversight of GxP areas.
- Manage product complaints received from the market in connection with the concerned Global Quality functions.
- Conduct product complaints' trend analysis and signal detection, as appropriate.
- Escalate quality events as necessary occurring at the country level according to defined processes and standards and manage subsequent quality and product alerts.
- Lead and coordinate product recall.
- Provide support on Quality matters to the appropriate functions at a country level and according to the defined responsibilities.
- Participate in inspection/audit related readiness activities and provide support for internal and external PV audits.
- Engage in continuous improvement of relevant processes.
- Provide adequate support, motivation, encouragement, and effective management for all relevant staff.
- Develop and implement relevant training.

Competency claims with verified sources

General Knowledge

Competency claim (knowledge topic)	Level	Verified source
Pharmacovigilance principles and Good Pharmacovigilance Practices (GVP) overview	**Expert**	EMA GVP Module I (2012); Dir 2001/83/EC (as amended by Dir 2010/84/EU); Reg (EC) 726/2004 (as amended by Reg (EU) 1235/2010)
The pharmacovigilance system	**Expert**	EMA GVP Module II (Rev 2, 2017);

Competency claim (knowledge topic)	Level	Verified source
and Pharmacovigilance System Master File (PSMF)		Comm. Impl. Reg (EU) 520/2012, as amended
Individual case safety report (ICSR) management and regulatory reporting timelines	Expert	EMA GVP Module VI (Rev 2, 2017); ICH E2D(R1) (in force EU 18 Mar 2026); ICH E2B(R3) (v5.02, 2016)

Role-Specific Knowledge *Includes topics derived from this role's job description.*

Competency claim (knowledge topic)	Level	Verified source
PV quality management system (GVP Module I)	Expert	EMA GVP Module I (2012); Comm. Impl. Reg (EU) 520/2012, as amended
Audits and regulatory inspections	Expert	EMA GVP Module IV (Rev 1, 2015); EMA GVP Module III (Rev 1, 2014)
CAPA (corrective and preventive action) management	Intermediate	EMA GVP Module IV (Rev 1, 2015)
Deviation and non-compliance handling	Intermediate	EMA GVP Module I (2012)
Signal management process (GVP Module IX)	Expert	EMA GVP Module IX (Rev 1, 2017)
Training, education and capacity building	Intermediate	WHO PV Core Curriculum for University Teaching (van Eekeren et al., Drug Saf 2018)
Data integrity principles (ALCOA+) NEW CITATION	Intermediate	MHRA 'GXP' Data Integrity (2018); FDA Data Integrity (2018) — ALCOA+; EU GMP Annex 11 — Computerised Systems (EudraLex Vol. 4, 2011)

11. Head of Medical PV

Code **M.I.HMPV** *Managerial · Industry · Medical PV* **DRAFT** competency standard

Also known as: Medical Director PV; Director Medical Writing

> *v2: Proposed citation mapping: each topic is paired with a source drawn from the verified base (all sources checked against their issuing body, 2026-07-12) and refreshed to the in-force version — confirm each topic→source fit on review. Blank-note gaps are filled and misfit template topics flagged. Job description and proficiency levels are unchanged from v0.3 for this role.*

Job description (v0.3 wording retained)

- Manage and support medical and safety oversight.
- Direct the Safety Management Team for the assigned project(s) or product(s) ensuring a safety and risk/benefit driven agenda from inception to closure.
- Represent Global DS at internal strategic and/or advisory/governance committees.
- May represent or act as an external technical resource at DSMB or Regulatory Authority meetings.
- Represent as a subject matter expert.
- Detect, validate, and manage pre-and/or post-approval safety signals through to resolution.
- Conduct a medical review of ICSR and analysis of AOSE as necessary, including the assessment of quality within the ICSR process; identify process improvement opportunities and drive changes in the process.
- Evaluate aggregate safety data and provide contributions to core regulatory documents i.e., PSUR, DSUR, RMPs, and other routine and non-routine safety and risk/benefit evaluations for internal or regulatory purposes as required.
- Identify, initiate, and manage to completion, necessary updates to the IB, CCSI and/or local product information, Medication Guide, Patient Leaflet, and other labelling documentation as necessary.
- Responsible for overseeing safety sections of documents and safety interactions with Regulatory authorities. This may include authorship of safety summaries to support changes to the PI/SmPC, significant contribution to MAAs and NDAs.
- Development of annual Medical Affairs strategy and plan in coordination with the departments.
- Management and continuous development of the Medical Affairs team.
- Planning, execution, supervision of medical projects.
- Coordination and medical responsibility for studies on a national level.
- Participate in inspection/audit related readiness activities and provide support for internal and external PV audits.
- Engage in continuous improvement of relevant processes.
- Provide adequate support, motivation, encouragement, and effective management for all relevant staff.
- Develop and implement relevant training.

Competency claims with verified sources

General Knowledge

Competency claim (knowledge topic)	Level	Verified source
Pharmacovigilance principles and Good Pharmacovigilance Practices (GVP) overview	**Expert**	EMA GVP Module I (2012); Dir 2001/83/EC (as amended by Dir 2010/84/EU); Reg (EC) 726/2004 (as amended by Reg (EU) 1235/2010)

Competency claim (knowledge topic)	Level	Verified source
The pharmacovigilance system and Pharmacovigilance System Master File (PSMF)	**Expert**	EMA GVP Module II (Rev 2, 2017); Comm. Impl. Reg (EU) 520/2012, as amended
Individual case safety report (ICSR) management and regulatory reporting timelines	**Expert**	EMA GVP Module VI (Rev 2, 2017); ICH E2D(R1) (in force EU 18 Mar 2026); ICH E2B(R3) (v5.02, 2016)

Role-Specific Knowledge

Includes topics derived from this role's job description.

Competency claim (knowledge topic)	Level	Verified source
Medical review of ICSRs: seriousness, expectedness, causality	**Expert**	EMA GVP Module VI (Rev 2, 2017); ICH E2A (1994)
Benefit–risk assessment and safety science	**Intermediate**	ICH E2C(R2) (PBRER)
Aggregate report medical content and labelling	**Intermediate**	EMA GVP Module VII (Rev 1, 2013)
Clinical pharmacology and disease context **VERIFY FIT**	**Intermediate**	clinical foundation — no single PV regulatory source
Signal management process (GVP Module IX)	**Expert**	EMA GVP Module IX (Rev 1, 2017)
Aggregate safety reports (PBRER/PSUR, DSUR)	**Expert**	EMA GVP Module VII (Rev 1, 2013); ICH E2C(R2) (PBRER); ICH E2F (DSUR, Step 4 2010)
Audits and regulatory inspections	**Expert**	EMA GVP Module IV (Rev 1, 2015); EMA GVP Module III (Rev 1, 2014)
ICSR lifecycle: receipt, triage, data entry, quality control	**Expert**	EMA GVP Module VI (Rev 2, 2017)
Training, education and capacity building	**Intermediate**	WHO PV Core Curriculum for University Teaching (van Eekeren et al., Drug Saf 2018)
Budgeting, resourcing and business continuity **MANAGEMENT COMPETENCY (NO EXTERNAL REGULATORY SOURCE)**	**Expert**	—
Benefit–risk assessment methodology	**Expert**	ICH E2C(R2) (PBRER)

12. Head of PV Data Science

Code **M.I.HPVDS** *Managerial · Industry · Data Science* **DRAFT** competency standard

Also known as: PV Data Science Leader

> *v2: Proposed citation mapping: each topic is paired with a source drawn from the verified base (all sources checked against their issuing body, 2026-07-12) and refreshed to the in-force version — confirm each topic→source fit on review. Blank-note gaps are filled and misfit template topics flagged. Job description and proficiency levels are unchanged from v0.3 for this role.*

Job description (v0.3 wording retained)

- Define and develop overall analytics solutions and data services vision. Identify opportunities for unlocking value from data assets to improve performance through evidence-based decision making. Solicit and anticipate future needs, ensure PV and Medical Safety database outputs evolve to meet current and future business and regulatory needs.
- Promote a data-driven culture by providing data-driven insightful solutions to complex business and performance problems and develop inspiring actions that shape and inform key business decisions. Manage vendors providing data services to ensure high quality, optimize the value and cost of their activities.
- Collaborate with partners in IT to improve the availability of data and data quality as required for high quality, innovative, analytics solutions.
- Bring in efficiency with innovative solutions; effective usage of new technologies and concepts; developing new analysis opportunities by integrating existing and new data sources.
- Direct an expert team to implement an advanced system for the management of data retrievals and self-service tabulations, listings, and statistical analysis.
- Lead automation of aggregate analysis and reports including PSUR, DSUR, PQR, APR and audit/inspection related outputs. Manage timely delivery of high-quality PV safety listing, analysis and data and ensure compliance with health authority regulations.
- Lead the design and oversee the development of predictive and data-driven solutions and services to ensure drug, device, trial, and patient-level benefit/risk information is available proactively for safety analysis, signal detection and risk management.
- A key contributor to the business team managing PV inspections and addressing all questions related to Data Science.
- Manage global team; Build a deep talent bench by driving top-level talent acquisition, succession planning and development of associates across who are working to their full potential and to build a strong talent pipeline.
- Lead a team of data scientists to advance the science of PV and support safety officers with data extractions and insights.
- Participate in inspection/audit related readiness activities and provide support for internal and external PV audits.
- Engage in continuous improvement of relevant processes.
- Provide adequate support, motivation, encouragement, and effective management for all relevant staff.
- Develop and implement relevant training.

Competency claims with verified sources

General Knowledge

Competency claim (knowledge topic)	Level	Verified source
Pharmacovigilance principles	**Expert**	EMA GVP Module I (2012); Dir

Competency claim (knowledge topic)	Level	Verified source
and Good Pharmacovigilance Practices (GVP) overview		2001/83/EC (as amended by Dir 2010/84/EU); Reg (EC) 726/2004 (as amended by Reg (EU) 1235/2010)
The pharmacovigilance system and Pharmacovigilance System Master File (PSMF)	Expert	EMA GVP Module II (Rev 2, 2017); Comm. Impl. Reg (EU) 520/2012, as amended
Individual case safety report (ICSR) management and regulatory reporting timelines	Expert	EMA GVP Module VI (Rev 2, 2017); ICH E2D(R1) (in force EU 18 Mar 2026); ICH E2B(R3) (v5.02, 2016)

Role-Specific Knowledge *Includes topics derived from this role's job description.*

Competency claim (knowledge topic)	Level	Verified source
PV data ecosystem and FAIR data principles	Expert	FAIR Principles (Wilkinson et al., Sci Data 2016)
Statistical, machine-learning and NLP methods for safety data NEW CITATION / · VERIFY FIT (NO SINGLE ML/NLP PV STANDARD)	Expert	CIOMS Working Group VIII (2010); Evans et al. PRR (Pharmacoepidemiol Drug Saf 2001)
Signal detection analytics and dashboards NEW CITATION	Intermediate	EMA GVP Module IX (Rev 1, 2017) Addendum I; CIOMS Working Group VIII (2010)
Data privacy and ethical use of data	Intermediate	EU GDPR — Reg (EU) 2016/679
Signal management process (GVP Module IX)	Expert	EMA GVP Module IX (Rev 1, 2017)
Risk management planning (GVP Module V): RMP structure and lifecycle	Expert	EMA GVP Module V (Rev 2, 2017)
Aggregate safety reports (PBRER/PSUR, DSUR)	Expert	EMA GVP Module VII (Rev 1, 2013); ICH E2C(R2) (PBRER); ICH E2F (DSUR, Step 4 2010)
Audits and regulatory inspections	Expert	EMA GVP Module IV (Rev 1, 2015); EMA GVP Module III (Rev 1, 2014)
Safety database administration and configuration	Expert	ICH E2B(R3) (v5.02, 2016); EMA EudraVigilance
Training, education and capacity building	Intermediate	WHO PV Core Curriculum for University Teaching (van Eekeren et al., Drug Saf 2018)
Vendor governance and outsourcing oversight	Expert	EMA GVP Module I (2012) (outsourced activities)
Benefit–risk assessment methodology	Expert	ICH E2C(R2) (PBRER)
Biostatistics and quantitative safety analysis NEW CITATION	Expert	ICH E9 (1998) / E9(R1) estimands (2019); CIOMS Working Group VIII (2010)

13. Head of PV Pharmacoepidemiology

Code **M.I.HPVPE** *Managerial · Industry · Pharmacoepidemiology* **DRAFT** competency standard

> *v2: Proposed citation mapping: each topic is paired with a source drawn from the verified base (all sources checked against their issuing body, 2026-07-12) and refreshed to the in-force version — confirm each topic→source fit on review. Blank-note gaps are filled and misfit template topics flagged. Job description and proficiency levels are unchanged from v0.3 for this role.*

Job description (v0.3 wording retained)

- Contribute to the vision and operationalization of the pharmacoepidemiology group.
- Serve as the strategic lead for epidemiologic support of drugs, approved and in development, including conducting reviews of the epidemiology of indications and adverse events, analyse of datasets, and designing and executing new studies.
- Prioritize activities across multiple projects and effectively negotiate plans with colleagues and customers.
- Take on the responsibility for professional development of self and share accountability for the achievement of department-wide goals and objectives.
- Participate in inspection/audit related readiness activities and provide support for internal and external PV audits.
- Engage in continuous improvement of relevant processes.
- Provide adequate support, motivation, encouragement, and effective management for all relevant staff.
- Develop and implement relevant training.

Competency claims with verified sources

General Knowledge

Competency claim (knowledge topic)	Level	Verified source
Pharmacovigilance principles and Good Pharmacovigilance Practices (GVP) overview	**Expert**	EMA GVP Module I (2012); Dir 2001/83/EC (as amended by Dir 2010/84/EU); Reg (EC) 726/2004 (as amended by Reg (EU) 1235/2010)
The pharmacovigilance system and Pharmacovigilance System Master File (PSMF)	**Expert**	EMA GVP Module II (Rev 2, 2017); Comm. Impl. Reg (EU) 520/2012, as amended
Individual case safety report (ICSR) management and regulatory reporting timelines	**Expert**	EMA GVP Module VI (Rev 2, 2017); ICH E2D(R1) (in force EU 18 Mar 2026); ICH E2B(R3) (v5.02, 2016)

Role-Specific Knowledge

Includes topics derived from this role's job description.

Competency claim (knowledge topic)	Level	Verified source
Pharmacoepidemiology study design (PASS/PAES)	**Expert**	EMA GVP Module VIII (Rev 3, 2017); ENCePP Guide on Methodological Standards (Rev 11, 2023); STROBE Statement (von Elm et al., 2007)
Real-world evidence (RWE) and data sources	**Intermediate**	ENCePP Guide on Methodological Standards (Rev 11, 2023)
Biostatistics and study analysis **NEW CITATION**	**Intermediate**	ICH E9 (1998) / E9(R1) estimands (2019)
GVP Module VIII (post-authorisation safety studies)	**Intermediate**	EMA GVP Module VIII (Rev 3, 2017)
Audits and regulatory	**Expert**	EMA GVP Module IV (Rev 1, 2015); EMA GVP Module III (Rev 1, 2014)

Competency claim (knowledge topic)	Level	Verified source
inspections		
Training, education and capacity building	**Intermediate**	WHO PV Core Curriculum for University Teaching (van Eekeren et al., Drug Saf 2018)
Post-authorisation safety studies (PASS/PAES)	**Expert**	EMA GVP Module VIII (Rev 3, 2017)

14. PV Project Manager

Code **M.I.PVPM** *Managerial · Industry · Project Management* **DRAFT** competency standard

Also known as: PV Project Director; Head of Project Management

> *v2: Proposed citation mapping: each topic is paired with a source drawn from the verified base (all sources checked against their issuing body, 2026-07-12) and refreshed to the in-force version — confirm each topic→source fit on review. Blank-note gaps are filled and misfit template topics flagged. Job description and proficiency levels are unchanged from v0.3 for this role.*

Job description (v0.3 wording retained)

- Oversee and coordinate work and collaboration on PV projects.
- Prepare project scope and objectives.
- Act as the primary contact point for project-related matters.
- Maintain the project-specific responsibility assignment matrix.
- Assure that all PV staff is familiar with all involved parties and the project scope.
- Have an overview of all tasks to be delivered, including deadlines and interim milestones.
- Ensure that all the outputs are delivered in high quality and before the final deadline.
- Prepare reports and invoices, if delegated.
- Keep an oversight on all communication.
- Make sure that quality standards are met.
- Have oversight of all relevant SOPs.
- Monitor compliance results and propose corrective and preventive actions, where necessary. Prepare Deviation reports.
- Responsible for drafting procedures, manuals, work guides related to the PV project.
- Participate in inspection/audit related readiness activities and provide support for internal and external PV audits.
- Has shared responsibility with corresponding leadership in the improvement of relevant processes.
- Provide adequate support, motivation, encouragement, and effective management for all relevant staff.
- Develop and implement relevant training.

Competency claims with verified sources

General Knowledge

Competency claim (knowledge topic)	Level	Verified source
Pharmacovigilance principles and Good Pharmacovigilance Practices (GVP) overview	**Expert**	EMA GVP Module I (2012); Dir 2001/83/EC (as amended by Dir 2010/84/EU); Reg (EC) 726/2004 (as amended by Reg (EU) 1235/2010)
The pharmacovigilance system and Pharmacovigilance System Master File (PSMF)	**Expert**	EMA GVP Module II (Rev 2, 2017); Comm. Impl. Reg (EU) 520/2012, as amended
Individual case safety report (ICSR) management and regulatory reporting timelines	**Expert**	EMA GVP Module VI (Rev 2, 2017); ICH E2D(R1) (in force EU 18 Mar 2026); ICH E2B(R3) (v5.02, 2016)

Role-Specific Knowledge

Includes topics derived from this role's job description.

Competency claim (knowledge topic)	Level	Verified source
PV project and vendor management	**Expert**	EMA GVP Module I (2012) (outsourced activities)
Outsourcing models and SDEA/PV agreements	**Intermediate**	EMA GVP Module I (2012); EMA GVP Module II (Rev 2, 2017)
Quality and compliance metrics (KPIs/KRIs)	**Intermediate**	EMA GVP Module I (2012) (quality-system performance indicators)
PV process and SOP landscape	**Intermediate**	EMA GVP Module I (2012)
Audits and regulatory inspections	**Expert**	EMA GVP Module IV (Rev 1, 2015); EMA GVP Module III (Rev 1, 2014)
CAPA (corrective and preventive action) management	**Expert**	EMA GVP Module IV (Rev 1, 2015)
Training, education and capacity building	**Intermediate**	WHO PV Core Curriculum for University Teaching (van Eekeren et al., Drug Saf 2018)

15. PV Vendor Manager

Code **M.I.PVVM** *Managerial · Industry · Vendor Management* **DRAFT** competency standard

> *v2: Proposed citation mapping: each topic is paired with a source drawn from the verified base (all sources checked against their issuing body, 2026-07-12) and refreshed to the in-force version — confirm each topic→source fit on review. Blank-note gaps are filled and misfit template topics flagged. Job description and proficiency levels are unchanged from v0.3 for this role.*

Job description (v0.3 wording retained)

- Determine outsourcing tasks.
- Oversee tasks outsourced to service providers.
- Provide clear direction to the vendor for expected deliverables and timelines for completion.
- Provide background information and necessary interval and cumulative data for safety analysis(es) including (but not limited to) most current company core labelling and PBRER, signal source, and safety database and literature outputs.
- Resolve vendor questions and escalate issues to relevant in-house PV staff as appropriate.
- Provide regular vendor feedback to in-house PV Science Manager for inclusion into the Vendor Operational Governance Meetings.
- Review and approve vendor invoices related to outsourced PV tasks to ensure accuracy of unit charges.
- Ensure all globally sourced activities, across all geographical regions, are managed and governed in a tightly controlled and transparent manner.
- Actively participate in business initiatives related to the overall outsourcing strategy, with the responsibility to drive alignment with key transversal partners (i.e. Procurement, Legal, other Stakeholders as needed).
- Maintain a high level of strategic decision-making authority with a high financial impact.
- Support a finance division in developing sound and defensible budgets for PV.
- Participate in inspection/audit related readiness activities and provide support for internal and external PV audits.
- Propose process improvements.
- Provide adequate support, motivation, encouragement, and effective management for all relevant staff.
- Develop and implement relevant training.

Competency claims with verified sources

General Knowledge

Competency claim (knowledge topic)	Level	Verified source
Pharmacovigilance principles and Good Pharmacovigilance Practices (GVP) overview	**Expert**	EMA GVP Module I (2012); Dir 2001/83/EC (as amended by Dir 2010/84/EU); Reg (EC) 726/2004 (as amended by Reg (EU) 1235/2010)
The pharmacovigilance system and Pharmacovigilance System Master File (PSMF)	**Expert**	EMA GVP Module II (Rev 2, 2017); Comm. Impl. Reg (EU) 520/2012, as amended
Individual case safety report (ICSR) management and regulatory reporting timelines	**Expert**	EMA GVP Module VI (Rev 2, 2017); ICH E2D(R1) (in force EU 18 Mar 2026); ICH E2B(R3) (v5.02, 2016)

Role-Specific Knowledge *Includes topics derived from this role's job description.*

Competency claim (knowledge topic)	Level	Verified source
PV project and vendor management	**Expert**	EMA GVP Module I (2012) (outsourced activities)
Outsourcing models and SDEA/PV agreements	**Intermediate**	EMA GVP Module I (2012); EMA GVP Module II (Rev 2, 2017)
Quality and compliance metrics (KPIs/KRIs)	**Intermediate**	EMA GVP Module I (2012) (quality-system performance indicators)
PV process and SOP landscape	**Intermediate**	EMA GVP Module I (2012)
Signal management process (GVP Module IX)	**Expert**	EMA GVP Module IX (Rev 1, 2017)
Aggregate safety reports (PBRER/PSUR, DSUR)	**Expert**	EMA GVP Module VII (Rev 1, 2013); ICH E2C(R2) (PBRER); ICH E2F (DSUR, Step 4 2010)
Audits and regulatory inspections	**Expert**	EMA GVP Module IV (Rev 1, 2015); EMA GVP Module III (Rev 1, 2014)
Safety database administration and configuration	**Expert**	ICH E2B(R3) (v5.02, 2016); EMA EudraVigilance
Literature monitoring and review	**Intermediate**	EMA GVP Module VI (Rev 2, 2017) — literature monitoring
Training, education and capacity building	**Intermediate**	WHO PV Core Curriculum for University Teaching (van Eekeren et al., Drug Saf 2018)
Budgeting, resourcing and business continuity **MANAGEMENT COMPETENCY (NO EXTERNAL REGULATORY SOURCE)**	**Expert**	—
Vendor governance and outsourcing oversight	**Expert**	EMA GVP Module I (2012) (outsourced activities)

16. Head of Signal Management

Code **M.RA.HSM** *Managerial · Regulatory Authority · Signal Management* **DRAFT** competency standard

Also known as: Head of Signal Detection; Signal Management Lead

> *v2: Proposed citation mapping: each topic is paired with a source drawn from the verified base (all sources checked against their issuing body, 2026-07-12) and refreshed to the in-force version — confirm each topic→source fit on review. Blank-note gaps are filled and misfit template topics flagged. Job description and proficiency levels are unchanged from v0.3 for this role.*

Job description (v0.3 wording retained)

- Identify and validate new safety signals and trends by conducting systematic reviews of aggregate data with a focus on spontaneous adverse event reports.
- Prepare reviews of topics and summary analysis reports of safety data, with minimal guidance.
- Provide recommendations for further signal evaluation.
- Participate as a member of the matrix teams to address product-specific safety issues, assist in the development of signal evaluation strategies, and participate in signal evaluation.
- Communicate findings from routine and ad hoc signal detection and assessment activities.
- Assist in the development and implementation of surveillance of adverse event reports for potential safety and product quality issues.
- Assist in the evaluation of novel, computer-assisted tools, and methodologies for the analysis of safety data, including piloting new data sources and methodologies.
- Contribute to transparency and communication initiatives through the provision of scientifically rigorous and consistent information to promote the safe and effective use of medicines.
- Liaise with and provide technical information, advice, and guidance on relevant PV matters to other regulatory colleagues, pharmaceutical companies, relevant national and international bodies, healthcare professionals and members of the public.
- Support external compliance monitoring with PV obligations.
- Participate at all levels (internally and externally) in the formulation and preparation of regulatory policies, guidelines, legislation, and opinions.
- Propose process improvements.
- Provide adequate support, motivation, encouragement, and effective management for all relevant staff.
- Develop and implement relevant training.

Competency claims with verified sources

General Knowledge

Competency claim (knowledge topic)	Level	Verified source
Pharmacovigilance principles and Good Pharmacovigilance Practices (GVP) overview	**Expert**	EMA GVP Module I (2012); Dir 2001/83/EC (as amended by Dir 2010/84/EU); Reg (EC) 726/2004 (as amended by Reg (EU) 1235/2010)
The pharmacovigilance system and Pharmacovigilance System Master File (PSMF)	**Expert**	EMA GVP Module II (Rev 2, 2017); Comm. Impl. Reg (EU) 520/2012, as amended
Individual case safety report (ICSR) management and regulatory reporting timelines	**Expert**	EMA GVP Module VI (Rev 2, 2017); ICH E2D(R1) (in force EU 18 Mar 2026); ICH E2B(R3) (v5.02, 2016)

Role-Specific Knowledge *Includes topics derived from this role's job description.*

Competency claim (knowledge topic)	Level	Verified source
Signal management process (GVP Module IX)	**Expert**	EMA GVP Module IX (Rev 1, 2017)
Signal detection methodologies and disproportionality analysis **NEW CITATION**	**Expert**	EMA GVP Module IX (Rev 1, 2017) Addendum I; CIOMS Working Group VIII (2010); Evans et al. PRR (Pharmacoepidemiol Drug Saf 2001)
Signal validation, assessment and prioritisation	**Intermediate**	EMA GVP Module IX (Rev 1, 2017)
Aggregate safety data sources and their limitations	**Intermediate**	CIOMS Working Group VIII (2010)
Training, education and capacity building	**Intermediate**	WHO PV Core Curriculum for University Teaching (van Eekeren et al., Drug Saf 2018)
PV policy, legislation and guideline development	**Expert**	Dir 2001/83/EC (as amended by Dir 2010/84/EU); Reg (EC) 726/2004 (as amended by Reg (EU) 1235/2010)

17. Head of PV Medical Assessment

Code **M.RA.HPVMA** *Managerial · Regulatory Authority · Medical Assessment* **DRAFT** competency standard

Also known as: Medical Director; Medical Lead

v2: Proposed citation mapping: each topic is paired with a source drawn from the verified base (all sources checked against their issuing body, 2026-07-12) and refreshed to the in-force version — confirm each topic→source fit on review. Blank-note gaps are filled and misfit template topics flagged. Job description and proficiency levels are unchanged from v0.3 for this role.

Job description (v0.3 wording retained)

- Contribute to the development of organisational strategy and identify and agree on strategic objectives in regards to PV medical assessment.
- Respond to changes in the internal and external environment and adapt strategic objectives to ensure delivery of the Authority's public health protection remit, and its contributions at both national and international levels.
- Lead and coordinate the process of translating high-level objectives into specific plans applicable for the department of the PV medical assessment.
- Develop the knowledge network concept to ensure access to specialist skill sets as required.
- Ensure appropriate development and maintenance of scientific and technical expertise and skills of the department staff to meet future assessment and evaluation needs in line with progress and innovation.
- Provision of input to the review and approval process for products where appropriate.
- Propose process improvements.
- Provide adequate support, motivation, encouragement, and effective management for all relevant staff.
- Develop and implement relevant training.

Competency claims with verified sources

General Knowledge

Competency claim (knowledge topic)	Level	Verified source
Pharmacovigilance principles and Good Pharmacovigilance Practices (GVP) overview	**Expert**	EMA GVP Module I (2012); Dir 2001/83/EC (as amended by Dir 2010/84/EU); Reg (EC) 726/2004 (as amended by Reg (EU) 1235/2010)
The pharmacovigilance system and Pharmacovigilance System Master File (PSMF)	**Expert**	EMA GVP Module II (Rev 2, 2017); Comm. Impl. Reg (EU) 520/2012, as amended
Individual case safety report (ICSR) management and regulatory reporting timelines	**Expert**	EMA GVP Module VI (Rev 2, 2017); ICH E2D(R1) (in force EU 18 Mar 2026); ICH E2B(R3) (v5.02, 2016)

Role-Specific Knowledge *Includes topics derived from this role's job description.*

Competency claim (knowledge topic)	Level	Verified source
Medical review of ICSRs: seriousness, expectedness, causality	**Expert**	EMA GVP Module VI (Rev 2, 2017); ICH E2A (1994)
Benefit–risk assessment and safety science	**Intermediate**	ICH E2C(R2) (PBRER)
Aggregate report medical content and labelling	**Intermediate**	EMA GVP Module VII (Rev 1, 2013)

Competency claim (knowledge topic)	Level	Verified source
Clinical pharmacology and disease context **VERIFY FIT**	**Intermediate**	clinical foundation — no single PV regulatory source
Training, education and capacity building	**Intermediate**	WHO PV Core Curriculum for University Teaching (van Eekeren et al., Drug Saf 2018)

18. Head of Data Management

Code **M.RA.HDM** *Managerial · Regulatory Authority · Data Management* **DRAFT** competency standard

Also known as: Head of Statistics; Head of Data Science

v2: Proposed citation mapping: each topic is paired with a source drawn from the verified base (all sources checked against their issuing body, 2026-07-12) and refreshed to the in-force version — confirm each topic→source fit on review. Blank-note gaps are filled and misfit template topics flagged. Job description and proficiency levels are unchanged from v0.3 for this role.

Job description (v0.3 wording retained)

- Formulate short-term and long-term strategies to improve regional data management efficiencies, through collaboration with senior management.
- Identify and implement solutions to regional data management issues and concerns, including proactive prevention strategies based on metrics and forecasts.
- Collaborate with peers to establish global data management competency models and assist with the development of training programs and ensure staff achievement of position competencies.
- Responsible for the global standardization of data management processes and process improvement and efficiency, ensuring that standards are applied.
- Develop global, harmonized SOPs and specific quality processes and procedures for data management activities.
- Identify and implement process improvement solutions.
- Contribute to transparency and communication initiatives through the provision of scientifically rigorous and consistent information to promote the safe and effective use of medicines.
- Liaise with and provide technical information, advice, and guidance on relevant PV matters to other regulatory colleagues, pharmaceutical companies, relevant national and international bodies, healthcare professionals and members of the public.
- Support external compliance monitoring with PV obligations.
- Participate at all levels (internally and externally) in the formulation and preparation of regulatory policies, guidelines, legislation, and opinions.
- Review and research technologies/procedures.
- Provide adequate support, motivation, encouragement, and effective management for all relevant staff.
- Develop and implement relevant training.

Competency claims with verified sources

General Knowledge

Competency claim (knowledge topic)	Level	Verified source
Pharmacovigilance principles and Good Pharmacovigilance Practices (GVP) overview	**Expert**	EMA GVP Module I (2012); Dir 2001/83/EC (as amended by Dir 2010/84/EU); Reg (EC) 726/2004 (as amended by Reg (EU) 1235/2010)
The pharmacovigilance system and Pharmacovigilance System Master File (PSMF)	**Expert**	EMA GVP Module II (Rev 2, 2017); Comm. Impl. Reg (EU) 520/2012, as amended
Individual case safety report (ICSR) management and regulatory reporting timelines	**Expert**	EMA GVP Module VI (Rev 2, 2017); ICH E2D(R1) (in force EU 18 Mar 2026); ICH E2B(R3) (v5.02, 2016)

Role-Specific Knowledge

Includes topics derived from this role's job description.

Competency claim (knowledge topic)	Level	Verified source
ICSR lifecycle: receipt, triage, data entry, quality control	**Expert**	EMA GVP Module VI (Rev 2, 2017)
ICH E2A / E2B(R3) data elements and expedited reporting	**Expert**	ICH E2A (1994); ICH E2B(R3) (v5.02, 2016)
MedDRA and WHODrug coding conventions	**Intermediate**	MedDRA (ICH/MSSO; v29.0, Mar 2026); WHODrug Global (WHO-UMC)
Data integrity principles (ALCOA+) **NEW CITATION**	**Intermediate**	MHRA 'GXP' Data Integrity (2018); FDA Data Integrity (2018) — ALCOA+; EU GMP Annex 11 — Computerised Systems (EudraLex Vol. 4, 2011)
Training, education and capacity building	**Intermediate**	WHO PV Core Curriculum for University Teaching (van Eekeren et al., Drug Saf 2018)
PV policy, legislation and guideline development	**Expert**	Dir 2001/83/EC (as amended by Dir 2010/84/EU); Reg (EC) 726/2004 (as amended by Reg (EU) 1235/2010)

19. Head of Risk Management

Code **M.RA.HRM** *Managerial · Regulatory Authority · Risk Management* **DRAFT** competency standard

Also known as: Safety Risk Lead; Director of Risk Operations; Head of Risk And Compliance

v2: Proposed citation mapping: each topic is paired with a source drawn from the verified base (all sources checked against their issuing body, 2026-07-12) and refreshed to the in-force version — confirm each topic→source fit on review. Blank-note gaps are filled and misfit template topics flagged. Job description and proficiency levels are unchanged from v0.3 for this role.

Job description (v0.3 wording retained)

- Provide strategic guidance to product teams during the development of risk management planning documents, provide recommendations for risk management activities including country-specific PV and risk minimization activities, as needed.
- Attend relevant safety risk management meetings.
- Perform strategic, targeted review of risk management planning documents for appropriateness of the content, compliance with the applicable template(s), and consistency with related documents.
- Maintain and share knowledge of evolving global regulatory risk management requirements.
- As appropriate, lead or participate in the provision of feedback regarding draft guidance and other regulatory initiatives to health authorities.
- Partner with other functional areas to support safety risk management initiatives.
- Identify, explore, and pursue innovative risk management opportunities through internal and external partnerships.
- Proactively identify and resolve issues related to safety risk management.
- Contribute to transparency and communication initiatives through the provision of scientifically rigorous and consistent information to promote the safe and effective use of medicines.
- Liaise with and provide technical information, advice and guidance on relevant PV matters to other regulatory colleagues, pharmaceutical companies, relevant national and international bodies, healthcare professionals and members of the public.
- Support external compliance monitoring with PV obligations.
- Participate at all levels (internally and externally) in the formulation and preparation of regulatory policies, guidelines, legislation, and opinions.
- Develop and promote best practices, processes, tools, and policies to ensure consistent safety risk management excellence across the organization.
- Provide leadership, motivation, encouragement, and effective management for all relevant staff.
- Develop and implement relevant training.

Competency claims with verified sources

General Knowledge

Competency claim (knowledge topic)	Level	Verified source
Pharmacovigilance principles and Good Pharmacovigilance Practices (GVP) overview	**Expert**	EMA GVP Module I (2012); Dir 2001/83/EC (as amended by Dir 2010/84/EU); Reg (EC) 726/2004 (as amended by Reg (EU) 1235/2010)
The pharmacovigilance system and Pharmacovigilance System Master File (PSMF)	**Expert**	EMA GVP Module II (Rev 2, 2017); Comm. Impl. Reg (EU) 520/2012, as amended

Competency claim (knowledge topic)	Level	Verified source
Individual case safety report (ICSR) management and regulatory reporting timelines	**Expert**	EMA GVP Module VI (Rev 2, 2017); ICH E2D(R1) (in force EU 18 Mar 2026); ICH E2B(R3) (v5.02, 2016)

Role-Specific Knowledge

Includes topics derived from this role's job description.

Competency claim (knowledge topic)	Level	Verified source
Risk management planning (GVP Module V): RMP structure and lifecycle	**Expert**	EMA GVP Module V (Rev 2, 2017)
Risk minimisation measures and REMS CURRENCY	**Expert**	EMA GVP Module XVI (Rev 3, 2024); FDA REMS — FDAAA 2007, FD&C Act §505-1
Benefit–risk assessment methodology	**Intermediate**	ICH E2C(R2) (PBRER)
Post-authorisation safety studies (PASS/PAES)	**Intermediate**	EMA GVP Module VIII (Rev 3, 2017)
Training, education and capacity building	**Intermediate**	WHO PV Core Curriculum for University Teaching (van Eekeren et al., Drug Saf 2018)
PV policy, legislation and guideline development	**Expert**	Dir 2001/83/EC (as amended by Dir 2010/84/EU); Reg (EC) 726/2004 (as amended by Reg (EU) 1235/2010)

20. Head of PV Inspectorate

Code **M.RA.HPVI** *Managerial · Regulatory Authority · Inspectorate* **DRAFT** competency standard

Also known as: Head of PV Audits & Inspections

> *v2: Proposed citation mapping: each topic is paired with a source drawn from the verified base (all sources checked against their issuing body, 2026-07-12) and refreshed to the in-force version — confirm each topic→source fit on review. Blank-note gaps are filled and misfit template topics flagged. Job description and proficiency levels are unchanged from v0.3 for this role.*

Job description (v0.3 wording retained)

- Ensure appropriate objectives, analytics, and targets are in use to drive performance and that these are incorporated into the management plans of the individual teams within the department.
- Ensure that the department has the required technical, managerial, investigative, and operational skills; and that the department's processes and practices are supported by appropriate standards, policies, and guidelines.
- Lead quality improvement in terms of reviewing processes and making these more efficient, smarter, and informed by experience.
- Lead the department's participation in the identification and implementation of change initiatives required to enhance the organisation's approach to risk management and inspections, authorisations, and investigations.
- Responsible for representing the regulatory authority on relevant regulatory activities within the department's remit.
- Represent the regulatory authority at the country and international level as required.
- Contribute to transparency and communication initiatives through the provision of scientifically rigorous and consistent information to promote the safe and effective use of medicines.
- Liaise with and provide technical information, advice, and guidance on relevant PV matters to other regulatory colleagues, pharmaceutical companies, relevant national and international bodies, healthcare professionals and members of the public.
- Support external compliance monitoring with PV obligations.
- Participate at all levels (internally and externally) in the formulation and preparation of regulatory policies, guidelines, legislation, and opinions.
- Propose process improvements.
- Provide adequate support, motivation, encouragement, and effective management for all relevant staff.
- Develop and implement relevant training.

Competency claims with verified sources

General Knowledge

Competency claim (knowledge topic)	Level	Verified source
Pharmacovigilance principles and Good Pharmacovigilance Practices (GVP) overview	**Expert**	EMA GVP Module I (2012); Dir 2001/83/EC (as amended by Dir 2010/84/EU); Reg (EC) 726/2004 (as amended by Reg (EU) 1235/2010)
The pharmacovigilance system and Pharmacovigilance System Master File (PSMF)	**Expert**	EMA GVP Module II (Rev 2, 2017); Comm. Impl. Reg (EU) 520/2012, as amended
Individual case safety report (ICSR) management and regulatory reporting timelines	**Expert**	EMA GVP Module VI (Rev 2, 2017); ICH E2D(R1) (in force EU 18 Mar 2026); ICH E2B(R3) (v5.02, 2016)

Role-Specific Knowledge *Includes topics derived from this role's job description.*

Competency claim (knowledge topic)	Level	Verified source
PV inspection methodology and planning	**Expert**	EMA GVP Module III (Rev 1, 2014)
GVP compliance requirements and legislation	**Expert**	EMA GVP Module I (2012); Dir 2001/83/EC (as amended by Dir 2010/84/EU); Reg (EC) 726/2004 (as amended by Reg (EU) 1235/2010)
Risk-based inspection and CAPA evaluation	**Intermediate**	EMA GVP Module III (Rev 1, 2014); EMA GVP Module IV (Rev 1, 2015)
Inspection reporting and evidence standards	**Intermediate**	EMA GVP Module III (Rev 1, 2014)
Risk management planning (GVP Module V): RMP structure and lifecycle	**Expert**	EMA GVP Module V (Rev 2, 2017)
Audits and regulatory inspections	**Expert**	EMA GVP Module IV (Rev 1, 2015); EMA GVP Module III (Rev 1, 2014)
Training, education and capacity building	**Intermediate**	WHO PV Core Curriculum for University Teaching (van Eekeren et al., Drug Saf 2018)
PV policy, legislation and guideline development	**Expert**	Dir 2001/83/EC (as amended by Dir 2010/84/EU); Reg (EC) 726/2004 (as amended by Reg (EU) 1235/2010)
Statistical, machine-learning and NLP methods for safety data **NEW CITATION / · VERIFY FIT (NO SINGLE ML/NLP PV STANDARD)**	**Expert**	CIOMS Working Group VIII (2010); Evans et al. PRR (Pharmacoepidemiol Drug Saf 2001)

21. Team Leader in PV

Code **M.RA.TLPV** *Managerial · Regulatory Authority* **DRAFT** competency standard

Also known as: PV Systems Team Leader

v2: Proposed citation mapping: each topic is paired with a source drawn from the verified base (all sources checked against their issuing body, 2026-07-12) and refreshed to the in-force version — confirm each topic→source fit on review. Blank-note gaps are filled and misfit template topics flagged. Job description and proficiency levels are unchanged from v0.3 for this role.

Job description (v0.3 wording retained)

- Provide leadership, management, general oversight, and direction for all PV projects.
- Ensure project team management and communication, quality, adequate resource planning and allocation, and financial performance.
- Serve as the primary point of contact and communication.
- Contribute to transparency and communication initiatives through the provision of scientifically rigorous and consistent information to promote the safe and effective use of medicines.
- Liaise with and provide technical information, advice, and guidance on relevant PV matters to other regulatory colleagues, pharmaceutical companies, relevant national and international bodies, healthcare professionals and members of the public.
- Support external compliance monitoring with PV obligations.
- Participate at all levels (internally and externally) in the formulation and preparation of regulatory policies, guidelines, legislation, and opinions.
- Propose process improvements.
- Provide adequate support, motivation, encouragement, and effective management for all relevant staff.
- Develop and implement relevant training.

Competency claims with verified sources

General Knowledge

Competency claim (knowledge topic)	Level	Verified source
Pharmacovigilance principles and Good Pharmacovigilance Practices (GVP) overview	**Expert**	EMA GVP Module I (2012); Dir 2001/83/EC (as amended by Dir 2010/84/EU); Reg (EC) 726/2004 (as amended by Reg (EU) 1235/2010)
The pharmacovigilance system and Pharmacovigilance System Master File (PSMF)	**Expert**	EMA GVP Module II (Rev 2, 2017); Comm. Impl. Reg (EU) 520/2012, as amended
Individual case safety report (ICSR) management and regulatory reporting timelines	**Expert**	EMA GVP Module VI (Rev 2, 2017); ICH E2D(R1) (in force EU 18 Mar 2026); ICH E2B(R3) (v5.02, 2016)

Role-Specific Knowledge *Includes topics derived from this role's job description.*

Competency claim (knowledge topic)	Level	Verified source
PV governance, strategy and the PV system	**Expert**	EMA GVP Module I (2012)
PV legislation and GVP across regions	**Expert**	Dir 2001/83/EC (as amended by Dir 2010/84/EU); Reg (EC) 726/2004 (as amended by Reg (EU) 1235/2010)
Risk management and aggregate reporting oversight	**Expert**	EMA GVP Module V (Rev 2, 2017); EMA GVP Module VII (Rev 1, 2013)

Competency claim (knowledge topic)	Level	Verified source
Audit, inspection readiness and CAPA	**Intermediate**	EMA GVP Module IV (Rev 1, 2015); EMA GVP Module III (Rev 1, 2014)
Budgeting, resourcing and business continuity **MANAGEMENT COMPETENCY (NO EXTERNAL REGULATORY SOURCE)**	**Intermediate**	—
Training, education and capacity building	**Intermediate**	WHO PV Core Curriculum for University Teaching (van Eekeren et al., Drug Saf 2018)
PV policy, legislation and guideline development	**Expert**	Dir 2001/83/EC (as amended by Dir 2010/84/EU); Reg (EC) 726/2004 (as amended by Reg (EU) 1235/2010)

22. PV Academic Program Manager

Code **M.A.PVPM** *Managerial · Academia* **DRAFT** competency standard

> *v2: Proposed citation mapping: each topic is paired with a source drawn from the verified base (all sources checked against their issuing body, 2026-07-12) and refreshed to the in-force version — confirm each topic→source fit on review. Blank-note gaps are filled and misfit template topics flagged. Job description and proficiency levels are unchanged from v0.3 for this role.*

Job description (v0.3 wording retained)

- Oversee the development of a detailed PV program. Serve as the primary reviewer/approver.
- Develop and manage integrated PV program delivery timelines and risk assessments to report the progress.
- Train PV program team members on program-specific tasks and provide a working knowledge of the program assigned.
- Work with relevant departments to verify adequate program resourcing.
- When applicable guide PV best practices, regulatory recommendations, and operational processes.
- Provide oversight and direction of PV deliverables as a PV subject matter expert, encompassing all activities throughout the duration of a project/program.
- Provide oversight and direction of PV deliverables as a PV subject matter expert, encompassing all activities throughout the duration of PV program(s).
- Responsibilities are shared with the head of the PV Academic Program in the improvement of relevant processes.
- Provide adequate support, motivation, encouragement, and effective management for all relevant staff.
- Develop and implement relevant training.

Competency claims with verified sources

General Knowledge

Competency claim (knowledge topic)	Level	Verified source
Pharmacovigilance principles and Good Pharmacovigilance Practices (GVP) overview	**Expert**	EMA GVP Module I (2012); Dir 2001/83/EC (as amended by Dir 2010/84/EU); Reg (EC) 726/2004 (as amended by Reg (EU) 1235/2010)
The pharmacovigilance system and Pharmacovigilance System Master File (PSMF)	**Expert**	EMA GVP Module II (Rev 2, 2017); Comm. Impl. Reg (EU) 520/2012, as amended
Individual case safety report (ICSR) management and regulatory reporting timelines	**Expert**	EMA GVP Module VI (Rev 2, 2017); ICH E2D(R1) (in force EU 18 Mar 2026); ICH E2B(R3) (v5.02, 2016)

Role-Specific Knowledge *Includes topics derived from this role's job description.*

Competency claim (knowledge topic)	Level	Verified source
PV curriculum and educational methods **VERIFY FIT**	**Expert**	WHO PV Core Curriculum for University Teaching (van Eekeren et al., Drug Saf 2018)
Pharmacovigilance science and research methodology **NEW CITATION**	**Intermediate**	ENCePP Guide on Methodological Standards (Rev 11, 2023); STROBE Statement (von Elm et al., 2007)
Regulatory framework and GVP	**Intermediate**	EMA GVP Module I (2012)

Competency claim (knowledge topic)	Level	Verified source
overview		
Scientific writing and publication **NEW CITATION**	**Intermediate**	ICMJE Recommendations (Jan 2026)
Training, education and capacity building	**Intermediate**	WHO PV Core Curriculum for University Teaching (van Eekeren et al., Drug Saf 2018)
Budgeting, resourcing and business continuity **MANAGEMENT COMPETENCY (NO EXTERNAL REGULATORY SOURCE)**	**Expert**	—

23. PV Academic Project Manager

Code **M.A.PVPM2** *Managerial · Academia* **DRAFT** competency standard

Also known as: Project Coordinator

v2: Proposed citation mapping: each topic is paired with a source drawn from the verified base (all sources checked against their issuing body, 2026-07-12) and refreshed to the in-force version — confirm each topic→source fit on review. Blank-note gaps are filled and misfit template topics flagged. Job description and proficiency levels are unchanged from v0.3 for this role.

Job description (v0.3 wording retained)

- Oversee and coordinate work and collaboration on PV projects.
- Prepare project scope and objectives.
- Act as the primary contact point for project-related matters.
- Identify development prospects and conduct preliminary feasibility assessments.
- Attend community meetings and engage with industry, state and local officials, and other stakeholders.
- Conduct project assessments.
- Collaborate to provide project support for development and project plan.
- Track project development efforts by creating timelines and project schedules.
- Foster effective and positive business relationships with all parties throughout project phases.
- Shared responsibility with the Head of PV Academic Program and/or PV Academic Program Manager, in the improvement of relevant processes.
- Provide adequate support, motivation, encouragement, and effective management for all relevant staff.
- Develop and implement relevant training.

Competency claims with verified sources

General Knowledge

Competency claim (knowledge topic)	Level	Verified source
Pharmacovigilance principles and Good Pharmacovigilance Practices (GVP) overview	**Expert**	EMA GVP Module I (2012); Dir 2001/83/EC (as amended by Dir 2010/84/EU); Reg (EC) 726/2004 (as amended by Reg (EU) 1235/2010)
The pharmacovigilance system and Pharmacovigilance System Master File (PSMF)	**Expert**	EMA GVP Module II (Rev 2, 2017); Comm. Impl. Reg (EU) 520/2012, as amended
Individual case safety report (ICSR) management and regulatory reporting timelines	**Expert**	EMA GVP Module VI (Rev 2, 2017); ICH E2D(R1) (in force EU 18 Mar 2026); ICH E2B(R3) (v5.02, 2016)

Role-Specific Knowledge

Includes topics derived from this role's job description.

Competency claim (knowledge topic)	Level	Verified source
PV curriculum and educational methods **VERIFY FIT**	**Expert**	WHO PV Core Curriculum for University Teaching (van Eekeren et al., Drug Saf 2018)
Pharmacovigilance science and research methodology **NEW CITATION**	**Intermediate**	ENCePP Guide on Methodological Standards (Rev 11, 2023); STROBE Statement (von Elm et al., 2007)
Regulatory framework and GVP overview	**Intermediate**	EMA GVP Module I (2012)

Competency claim (knowledge topic)	Level	Verified source
Scientific writing and publication **NEW CITATION**	**Intermediate**	ICMJE Recommendations (Jan 2026)
Training, education and capacity building	**Intermediate**	WHO PV Core Curriculum for University Teaching (van Eekeren et al., Drug Saf 2018)

Scientific

Roles that perform the scientific work of pharmacovigilance — case assessment, signal, risk, data science and writing.

25 roles

24. Pharmacovigilance Awareness for Healthcare Professionals

Scientific · Healthcare · Awareness **PUBLISHED** competency standard

Job description (v0.3 wording retained)

- Recognise adverse drug reactions (ADRs) in day-to-day clinical practice and understand their impact on individual patients.
- Apply safe prescribing and dispensing practices informed by product safety information.
- Report suspected adverse reactions completely and promptly to the relevant pharmacovigilance system.
- Communicate the benefits and risks of medicines to patients and colleagues.

Knowledge

General Knowledge

Knowledge topic	Level
Pharmacovigilance definition, aim, and objectives	**Basic**
Pharmacovigilance history	**Basic**
Stakeholders in pharmacovigilance	**Basic**
WHO UMC: Safety monitoring of medicinal products — Guidelines for setting up and running a Pharmacovigilance centre	**Basic**

Regional Regulatory Specific Knowledge *Optional — mandatory only for local certificate variants.*

Knowledge topic	Level
Local regulatory authority guidance for HCPs (if applicable)	**Basic**

Role Specific Knowledge

Knowledge topic	Level
WHO UMC: The Safety of Medicines in Public Health Programmes — Pharmacovigilance, an essential tool	**Basic**
WHO UMC: Collecting high quality ADR reports (course available for HCPs)	**Basic**
WHO UMC: Essentials of pharmacovigilance communications (course available for HCPs)	**Basic**

25. Medical Reviewer

Code **S.I.DM.MR** *Scientific · Industry · Data Management* **DRAFT** competency standard

Also known as: Medical Record Reviewer; Medical Document Reviewer; Clinical Reviewer

v2: Proposed citation mapping: each topic is paired with a source drawn from the verified base (all sources checked against their issuing body, 2026-07-12) and refreshed to the in-force version — confirm each topic→source fit on review. Blank-note gaps are filled and misfit template topics flagged. Job description and proficiency levels are unchanged from v0.3 for this role.

Job description (v0.3 wording retained)

- Lead the medical review — including seriousness, expectedness/listedness, causality, coding, and narratives — of individual case safety reports for medical completeness, accuracy, and overall medical content, for assigned investigational and marketed products.
- Direct medical oversight including literature review for individual case safety reports.
- Lead and direct the preparation, authoring, and approval of analysis of similar events for expedited case reports.
- Manage the review of cases according to internal timelines.
- Contribute to solving reconciliation medical coding issues/discrepancies.
- Review and update generated follow-up letters for the reporters and investigators as appropriate.
- Identify, communicate, and effectively manage potential safety issues.
- Review the Line Listings, evaluate the coding and labelling, and confirm the events are evaluated correctly.
- Lead and direct medical oversight and guidance to vendors performing case processing, including required training.

Competency claims with verified sources

General Knowledge

Competency claim (knowledge topic)	Level	Verified source
Pharmacovigilance principles and GVP overview **NEW CITATION**	**Intermediate**	EMA GVP Module I (2012); Dir 2001/83/EC (as amended by Dir 2010/84/EU); Reg (EC) 726/2004 (as amended by Reg (EU) 1235/2010)
ICH E2A/E2B — expedited reporting and data elements **NEW CITATION**	**Expert**	ICH E2A (1994); ICH E2B(R3) (v5.02, 2016)
ICSR lifecycle and case processing **NEW CITATION**	**Expert**	EMA GVP Module VI (Rev 2, 2017)

Role-Specific Knowledge

Competency claim (knowledge topic)	Level	Verified source
Seriousness, expectedness and causality assessment **NEW CITATION**	**Expert**	EMA GVP Module VI (Rev 2, 2017); ICH E2A (1994); ICH E2D(R1) (in force EU 18 Mar 2026)
MedDRA coding and medical coding reconciliation **NEW CITATION**	**Expert**	MedDRA (ICH/MSSO; v29.0, Mar 2026)
Case narratives and follow-up correspondence **NEW CITATION**	**Intermediate**	EMA GVP Module VI (Rev 2, 2017)
Analysis of similar events (AOSE) **NEW CITATION / · VERIFY FIT**	**Intermediate**	EMA GVP Module VI (Rev 2, 2017); EMA GVP Module IX (Rev 1, 2017)

Competency claim (knowledge topic)	Level	Verified source
Reference safety information and labelling assessment NEW CITATION	**Intermediate**	EMA GVP Module VII (Rev 1, 2013); Dir 2001/83/EC (SmPC)

26. Signal Evaluator

Code **S.I.SM.SE** *Scientific · Industry · Signal Management* **DRAFT** competency standard

Also known as: Signal Scientist; Safety Signal Assessor

v2: Job description tightened and "validate" added (a distinct GVP Module IX step); disproportionality claim now anchored to Module IX Addendum I, CIOMS WG VIII and the Evans PRR paper.

Job description — v2 (revised wording)

- Educate stakeholders on state-of-the-art signal-detection methodologies, signal-management processes and tools.
- Provide strategic support, training and expertise for the development and maintenance of excellence in signal management, working in close collaboration with other functions.
- Develop and conduct signal-detection activities and adverse-event trending analyses, and prepare signal-detection and trending reports.
- Perform and oversee routine signal detection (literature review, individual-case review and aggregate-data review) to identify, validate, assess and escalate signals appropriately.
- Author and contribute to relevant regulatory documents (e.g., PSURs/PBRERs, renewal documents, RMPs, submission documents) according to agreed timelines and processes.
- Develop and deliver relevant training.

Competency claims with verified sources

General Knowledge

Competency claim (knowledge topic)	Level	Verified source
Pharmacovigilance principles and signal management	**Expert**	EMA GVP Module IX (Rev 1, 2017)
Sources of safety data (spontaneous, literature, aggregate)	**Expert**	EMA GVP Module VI (Rev 2, 2017); Module IX (Rev 1)
Benefit–risk concepts	**Intermediate**	ICH E2C(R2) (PBRER)

Role-Specific Knowledge

Competency claim (knowledge topic)	Level	Verified source
Signal-detection methodologies and disproportionality analysis **NEW CITATIONS**	**Expert**	EMA GVP Module IX Addendum I; CIOMS WG VIII (2010); Evans et al. PRR, Pharmacoepidemiol Drug Saf 2001
Signal validation, assessment and escalation	**Expert**	EMA GVP Module IX (Rev 1, 2017)
Adverse-event trending and reporting	**Intermediate**	EMA GVP Module IX (Rev 1, 2017)
Aggregate reports (PSUR/PBRER) and RMP contributions	**Intermediate**	EMA GVP Module VII (Rev 1, 2013); ICH E2C(R2); Module V (Rev 2, 2017)

27. PV Data Supervisor

Code **S.I.DM.DS** *Scientific · Industry · Data Management* **DRAFT** competency standard

Also known as: Data Entry Supervisor

v2: Proposed citation mapping: each topic is paired with a source drawn from the verified base (all sources checked against their issuing body, 2026-07-12) and refreshed to the in-force version — confirm each topic→source fit on review. Blank-note gaps are filled and misfit template topics flagged. Job description and proficiency levels are unchanged from v0.3 for this role.

Job description (v0.3 wording retained)

- Ensure that data entry services are completed in an accurate, efficient, and timely manner.
- Ensure confidentiality and security of sensitive data and reports including personnel data, subscriber personal data, and financial data.
- Serve as a liaison between data entry and other divisions, assessing current and future data entry needs and ensuring proper staffing to address those needs.
- Identify needed equipment and software upgrades, requests procurement.
- Assist with planning and implementation of departmental budget.
- Oversee the daily workflow of the department.
- Formulate techniques for quality data collection to ensure adequacy, accuracy, and legitimacy of data.
- Recommend and implement new methods, procedures, policies, and services.
- Participate in inspection/audit related readiness activities and provide support for internal and external PV audits.
- Develop and deliver relevant training.

Competency claims with verified sources

General Knowledge

Competency claim (knowledge topic)	Level	Verified source
Pharmacovigilance principles and Good Pharmacovigilance Practices (GVP) overview	**Intermediate**	EMA GVP Module I (2012); Dir 2001/83/EC (as amended by Dir 2010/84/EU); Reg (EC) 726/2004 (as amended by Reg (EU) 1235/2010)
The pharmacovigilance system and Pharmacovigilance System Master File (PSMF)	**Intermediate**	EMA GVP Module II (Rev 2, 2017); Comm. Impl. Reg (EU) 520/2012, as amended
Individual case safety report (ICSR) management and regulatory reporting timelines	**Intermediate**	EMA GVP Module VI (Rev 2, 2017); ICH E2D(R1) (in force EU 18 Mar 2026); ICH E2B(R3) (v5.02, 2016)

Role-Specific Knowledge *Includes topics derived from this role's job description.*

Competency claim (knowledge topic)	Level	Verified source
ICSR lifecycle: receipt, triage, data entry, quality control	**Expert**	EMA GVP Module VI (Rev 2, 2017)
ICH E2A / E2B(R3) data elements and expedited reporting	**Expert**	ICH E2A (1994); ICH E2B(R3) (v5.02, 2016)
MedDRA and WHODrug coding conventions	**Intermediate**	MedDRA (ICH/MSSO; v29.0, Mar 2026); WHODrug Global (WHO-UMC)
Data integrity principles	**Intermediate**	MHRA 'GXP' Data Integrity (2018);

Competency claim (knowledge topic)	Level	Verified source
(ALCOA+) **NEW CITATION**		FDA Data Integrity (2018) — ALCOA+; EU GMP Annex 11 — Computerised Systems (EudraLex Vol. 4, 2011)
Audits and regulatory inspections	**Intermediate**	EMA GVP Module IV (Rev 1, 2015); EMA GVP Module III (Rev 1, 2014)
Training, education and capacity building	**Basic**	WHO PV Core Curriculum for University Teaching (van Eekeren et al., Drug Saf 2018)
Budgeting, resourcing and business continuity **MANAGEMENT COMPETENCY (NO EXTERNAL REGULATORY SOURCE)**	**Intermediate**	—

28. PV Data Scientist

Code **S.I.DM.DSC** *Scientific · Industry · Data Management* **DRAFT** competency standard

Also known as: Process Data Scientist

v2: Proposed citation mapping: each topic is paired with a source drawn from the verified base (all sources checked against their issuing body, 2026-07-12) and refreshed to the in-force version — confirm each topic→source fit on review. Blank-note gaps are filled and misfit template topics flagged. Job description and proficiency levels are unchanged from v0.3 for this role.

Job description (v0.3 wording retained)

- Provide expert knowledge to analytical projects, generate hypotheses and scoping in PV and drive the definition, design, implementation and validation of advanced analytic algorithms and models.
- Transform data science prototypes to validated end to end solutions as well as perform complex simulations, modelling and machine learning algorithms and integrate multi-layered data models.
- Analyse diverse internal and external sources for value-adding benefit/risk information concerning medical products by leveraging complex statistical and predictive models.
- Develop digital strategies to extract benefit/risk information from unstructured information, including literature, social media, and adverse events source documents.
- Ensure FAIR (Findable, Accessible, Interoperable and Re-usable) data principles before including data sources in the PV data ecosystem.
- Develop dashboards for real-time monitoring and trending of potential safety signals in external data sources.
- Design and implement novel methods for PV.
- Participate in inspection/audit related readiness activities and provide support for internal and external PV audits.
- Develop and deliver relevant training.

Competency claims with verified sources

General Knowledge

Competency claim (knowledge topic)	Level	Verified source
Pharmacovigilance principles and Good Pharmacovigilance Practices (GVP) overview	**Intermediate**	EMA GVP Module I (2012); Dir 2001/83/EC (as amended by Dir 2010/84/EU); Reg (EC) 726/2004 (as amended by Reg (EU) 1235/2010)
The pharmacovigilance system and Pharmacovigilance System Master File (PSMF)	**Intermediate**	EMA GVP Module II (Rev 2, 2017); Comm. Impl. Reg (EU) 520/2012, as amended
Individual case safety report (ICSR) management and regulatory reporting timelines	**Intermediate**	EMA GVP Module VI (Rev 2, 2017); ICH E2D(R1) (in force EU 18 Mar 2026); ICH E2B(R3) (v5.02, 2016)

Role-Specific Knowledge *Includes topics derived from this role's job description.*

Competency claim (knowledge topic)	Level	Verified source
ICSR lifecycle: receipt, triage, data entry, quality control	**Expert**	EMA GVP Module VI (Rev 2, 2017)
ICH E2A / E2B(R3) data elements and expedited reporting	**Expert**	ICH E2A (1994); ICH E2B(R3) (v5.02, 2016)
MedDRA and WHODrug coding	**Intermediate**	MedDRA (ICH/MSSO; v29.0, Mar

Competency claim (knowledge topic)	Level	Verified source
conventions		2026); WHODrug Global (WHO-UMC)
Data integrity principles (ALCOA+) NEW CITATION	**Intermediate**	MHRA 'GXP' Data Integrity (2018); FDA Data Integrity (2018) — ALCOA+; EU GMP Annex 11 — Computerised Systems (EudraLex Vol. 4, 2011)
Signal management process (GVP Module IX)	**Intermediate**	EMA GVP Module IX (Rev 1, 2017)
Audits and regulatory inspections	**Intermediate**	EMA GVP Module IV (Rev 1, 2015); EMA GVP Module III (Rev 1, 2014)
Safety database administration and configuration	**Intermediate**	ICH E2B(R3) (v5.02, 2016); EMA EudraVigilance
Literature monitoring and review	**Basic**	EMA GVP Module VI (Rev 2, 2017) — literature monitoring
Training, education and capacity building	**Basic**	WHO PV Core Curriculum for University Teaching (van Eekeren et al., Drug Saf 2018)
Benefit–risk assessment methodology	**Intermediate**	ICH E2C(R2) (PBRER)
Biostatistics and quantitative safety analysis NEW CITATION	**Intermediate**	ICH E9 (1998) / E9(R1) estimands (2019); CIOMS Working Group VIII (2010)
Statistical, machine-learning and NLP methods for safety data NEW CITATION / · VERIFY FIT (NO SINGLE ML/NLP PV STANDARD)	**Intermediate**	CIOMS Working Group VIII (2010); Evans et al. PRR (Pharmacoepidemiol Drug Saf 2001)

29. Medical Evaluator

Code **S.I.SM.ME** *Scientific · Industry · Signal Management* **DRAFT** competency standard

Also known as: Medical Review Evaluator; Clinical Evaluator; Medical Care Evaluator; Medical Liaison

v2: Proposed citation mapping: each topic is paired with a source drawn from the verified base (all sources checked against their issuing body, 2026-07-12) and refreshed to the in-force version — confirm each topic→source fit on review. Blank-note gaps are filled and misfit template topics flagged. Job description and proficiency levels are unchanged from v0.3 for this role.

Job description (v0.3 wording retained)

- Implement risk mitigation activities, prepare benefit/risk sections of aggregate reports and safety summaries in accordance with regulatory requirements for assigned compounds.
- Participate as a member of the matrix teams to address product-specific safety issues, assist in the development of signal evaluation strategies, and participate in signal evaluation.
- Lead the medical review, including seriousness, expectedness/listedness, causality, coding, and narratives of aggregated safety reports for medical completeness, accuracy, and overall medical content, for the assigned investigational and marketed products.
- Direct medical oversight including literature review for aggregated safety reports.
- Manage the review of cases according to internal timelines.
- Contribute to solving reconciliation medical coding issues/discrepancies.
- Review and update generated follow-up letters for the reporters and investigators as appropriate.
- Identify, communicate, and effectively manage potential safety issues.
- Review the Line Listings and evaluate the coding and labelling, confirming that the events are evaluated correctly.
- Lead and direct the medical input and guidance for ad-hoc queries for aggregated cases.
- Lead and direct medical oversight and guidance to vendors performing case processing.
- Lead and implement with alliance partners harmonization and industry-standard medical review and case assessment standards.
- Participate in inspection/audit related readiness activities and provide support for internal and external PV audits.
- Develop and deliver relevant training.

Competency claims with verified sources

General Knowledge

Competency claim (knowledge topic)	Level	Verified source
Pharmacovigilance principles and Good Pharmacovigilance Practices (GVP) overview	**Intermediate**	EMA GVP Module I (2012); Dir 2001/83/EC (as amended by Dir 2010/84/EU); Reg (EC) 726/2004 (as amended by Reg (EU) 1235/2010)
The pharmacovigilance system and Pharmacovigilance System Master File (PSMF)	**Intermediate**	EMA GVP Module II (Rev 2, 2017); Comm. Impl. Reg (EU) 520/2012, as amended
Individual case safety report (ICSR) management and regulatory reporting timelines	**Intermediate**	EMA GVP Module VI (Rev 2, 2017); ICH E2D(R1) (in force EU 18 Mar 2026); ICH E2B(R3) (v5.02, 2016)

Role-Specific Knowledge *Includes topics derived from this role's job description.*

Competency claim (knowledge topic)	Level	Verified source
Signal management process (GVP Module IX)	**Expert**	EMA GVP Module IX (Rev 1, 2017)
Signal detection methodologies and disproportionality analysis NEW CITATION	**Expert**	EMA GVP Module IX (Rev 1, 2017) Addendum I; CIOMS Working Group VIII (2010); Evans et al. PRR (Pharmacoepidemiol Drug Saf 2001)
Signal validation, assessment and prioritisation	**Intermediate**	EMA GVP Module IX (Rev 1, 2017)
Aggregate safety data sources and their limitations	**Intermediate**	CIOMS Working Group VIII (2010)
Aggregate safety reports (PBRER/PSUR, DSUR)	**Intermediate**	EMA GVP Module VII (Rev 1, 2013); ICH E2C(R2) (PBRER); ICH E2F (DSUR, Step 4 2010)
Audits and regulatory inspections	**Intermediate**	EMA GVP Module IV (Rev 1, 2015); EMA GVP Module III (Rev 1, 2014)
MedDRA and WHODrug coding conventions	**Intermediate**	MedDRA (ICH/MSSO; v29.0, Mar 2026); WHODrug Global (WHO-UMC)
ICSR lifecycle: receipt, triage, data entry, quality control	**Intermediate**	EMA GVP Module VI (Rev 2, 2017)
Medical review of ICSRs: seriousness, expectedness, causality	**Intermediate**	EMA GVP Module VI (Rev 2, 2017); ICH E2A (1994)
Literature monitoring and review	**Basic**	EMA GVP Module VI (Rev 2, 2017) — literature monitoring
Training, education and capacity building	**Basic**	WHO PV Core Curriculum for University Teaching (van Eekeren et al., Drug Saf 2018)
Vendor governance and outsourcing oversight	**Intermediate**	EMA GVP Module I (2012) (outsourced activities)
Benefit–risk assessment methodology	**Intermediate**	ICH E2C(R2) (PBRER)

30. Risk Management Scientist

Code **S.I.RM.RMS** *Scientific · Industry · Risk Management* **DRAFT** competency standard

Also known as: PV and Risk Management Scientist

v2: Proposed citation mapping: each topic is paired with a source drawn from the verified base (all sources checked against their issuing body, 2026-07-12) and refreshed to the in-force version — confirm each topic→source fit on review. Blank-note gaps are filled and misfit template topics flagged. Job description and proficiency levels are unchanged from v0.3 for this role.

Job description (v0.3 wording retained)

- Perform and contribute to safety analyses through review of case series, tabulated data and/or adverse event trend information.
- Contribute to document authoring, describing the evaluated safety data and assigned product(s).
- Perform and contribute with more senior scientists and safety physicians to signal detection activities and the signal management process.
- Collaborate with more senior scientists and safety physicians on risk management activities.
- Participate in the development and maintenance of RMPs/REMS.
- Participate in the review of medical/scientific literature to identify the literature relevant for signal detection activities and aggregate reporting.
- Participate in the preparation of aggregate safety reports.
- Contribute to the creation and maintenance of the RSI and company core labelling.
- Contribute, participate, and support Benefit-Risk Team meetings, including materials preparation, meeting minutes, and action item tracking.
- Contribute to a regulatory authority or other safety-related query responses.
- Participate in continuous process improvement projects and proactively identify and resolve issues related to safety risk management.
- Ensure that risk management documents are compliant with relevant regulatory requirements.
- Participate in inspection/audit related readiness activities and provide support for internal and external PV audits.
- Develop and deliver relevant training.

Competency claims with verified sources

General Knowledge

Competency claim (knowledge topic)	Level	Verified source
Pharmacovigilance principles and Good Pharmacovigilance Practices (GVP) overview	**Intermediate**	EMA GVP Module I (2012); Dir 2001/83/EC (as amended by Dir 2010/84/EU); Reg (EC) 726/2004 (as amended by Reg (EU) 1235/2010)
The pharmacovigilance system and Pharmacovigilance System Master File (PSMF)	**Intermediate**	EMA GVP Module II (Rev 2, 2017); Comm. Impl. Reg (EU) 520/2012, as amended
Individual case safety report (ICSR) management and regulatory reporting timelines	**Intermediate**	EMA GVP Module VI (Rev 2, 2017); ICH E2D(R1) (in force EU 18 Mar 2026); ICH E2B(R3) (v5.02, 2016)

Role-Specific Knowledge

Includes topics derived from this role's job description.

Competency claim (knowledge topic)	Level	Verified source
Risk management planning (GVP Module V): RMP structure and lifecycle	**Expert**	EMA GVP Module V (Rev 2, 2017)
Risk minimisation measures and REMS CURRENCY	**Expert**	EMA GVP Module XVI (Rev 3, 2024); FDA REMS — FDAAA 2007, FD&C Act §505-1
Benefit–risk assessment methodology	**Intermediate**	ICH E2C(R2) (PBRER)
Post-authorisation safety studies (PASS/PAES)	**Intermediate**	EMA GVP Module VIII (Rev 3, 2017)
Signal management process (GVP Module IX)	**Intermediate**	EMA GVP Module IX (Rev 1, 2017)
Aggregate safety reports (PBRER/PSUR, DSUR)	**Intermediate**	EMA GVP Module VII (Rev 1, 2013); ICH E2C(R2) (PBRER); ICH E2F (DSUR, Step 4 2010)
Audits and regulatory inspections	**Intermediate**	EMA GVP Module IV (Rev 1, 2015); EMA GVP Module III (Rev 1, 2014)
Literature monitoring and review	**Basic**	EMA GVP Module VI (Rev 2, 2017) — literature monitoring
Training, education and capacity building	**Basic**	WHO PV Core Curriculum for University Teaching (van Eekeren et al., Drug Saf 2018)

31. Quality Assurance Scientist

Code **S.I.QA.QAS** *Scientific · Industry · Quality Assurance* **DRAFT** competency standard

Also known as: QA Assurance Specialist; Quality Control Scientist

v2: Proposed citation mapping: each topic is paired with a source drawn from the verified base (all sources checked against their issuing body, 2026-07-12) and refreshed to the in-force version — confirm each topic→source fit on review. Blank-note gaps are filled and misfit template topics flagged. Job description and proficiency levels are unchanged from v0.3 for this role.

Job description (v0.3 wording retained)

- Ensure that relevant standard procedures, diagnostic tools, and audit plans are fully understood and applied in audit activities and capabilities to support the corrective and preventive action process following the audit as needed.
- Support the management of the documentation system.
- Support identification of gaps, risks, and opportunities for continuous improvement of the QMS and work on their remediation and implementation respectively.
- Lead initiatives and actively participate in key projects across the organization or company.
- Participate in inspection/audit related readiness activities and provide support for internal and external PV audits.
- May participate in regulatory inspections in a leadership role.
- Responsible for identifying training needs and supporting development and training conduct.
- Complete training requirements in a timely manner to ensure inspection readiness at all times.

Competency claims with verified sources

General Knowledge

Competency claim (knowledge topic)	Level	Verified source
Pharmacovigilance principles and Good Pharmacovigilance Practices (GVP) overview	**Intermediate**	EMA GVP Module I (2012); Dir 2001/83/EC (as amended by Dir 2010/84/EU); Reg (EC) 726/2004 (as amended by Reg (EU) 1235/2010)
The pharmacovigilance system and Pharmacovigilance System Master File (PSMF)	**Intermediate**	EMA GVP Module II (Rev 2, 2017); Comm. Impl. Reg (EU) 520/2012, as amended
Individual case safety report (ICSR) management and regulatory reporting timelines	**Intermediate**	EMA GVP Module VI (Rev 2, 2017); ICH E2D(R1) (in force EU 18 Mar 2026); ICH E2B(R3) (v5.02, 2016)

Role-Specific Knowledge *Includes topics derived from this role's job description.*

Competency claim (knowledge topic)	Level	Verified source
PV quality management system (GVP Module I)	**Expert**	EMA GVP Module I (2012); Comm. Impl. Reg (EU) 520/2012, as amended
Audits and regulatory inspections	**Expert**	EMA GVP Module IV (Rev 1, 2015); EMA GVP Module III (Rev 1, 2014)
CAPA (corrective and preventive action) management	**Intermediate**	EMA GVP Module IV (Rev 1, 2015)
Deviation and non-compliance handling	**Intermediate**	EMA GVP Module I (2012)

Competency claim (knowledge topic)	Level	Verified source
Training, education and capacity building	**Basic**	WHO PV Core Curriculum for University Teaching (van Eekeren et al., Drug Saf 2018)

32. PV Systems Architect

Code **S.I.PVS.SA** *Scientific · Industry · PV Systems* **DRAFT** competency standard

Also known as: Clinical System Architect; PV Solution Architect

> *v2: Proposed citation mapping: each topic is paired with a source drawn from the verified base (all sources checked against their issuing body, 2026-07-12) and refreshed to the in-force version — confirm each topic→source fit on review. Blank-note gaps are filled and misfit template topics flagged. Job description and proficiency levels are unchanged from v0.3 for this role.*

Job description (v0.3 wording retained)

- Design and implement long-term strategic goals and short-term tactical plans for managing and maintaining PV systems and software.
- Ensure that proposed and existing systems architectures are aligned with the company's goals and objectives.
- Provide architectural expertise, direction, and assistance to other staff.
- Develop, document, and communicate plans for investing in systems architecture, including analysis of cost reduction opportunities.
- Conduct research on emerging technologies in support of systems development efforts and recommend technologies that will increase cost-effectiveness and systems flexibility.
- Participate in inspection/audit related readiness activities and provide support for internal and external PV audits.
- Develop and deliver relevant training.

Competency claims with verified sources

General Knowledge

Competency claim (knowledge topic)	Level	Verified source
Pharmacovigilance principles and Good Pharmacovigilance Practices (GVP) overview	**Intermediate**	EMA GVP Module I (2012); Dir 2001/83/EC (as amended by Dir 2010/84/EU); Reg (EC) 726/2004 (as amended by Reg (EU) 1235/2010)
The pharmacovigilance system and Pharmacovigilance System Master File (PSMF)	**Intermediate**	EMA GVP Module II (Rev 2, 2017); Comm. Impl. Reg (EU) 520/2012, as amended
Individual case safety report (ICSR) management and regulatory reporting timelines	**Intermediate**	EMA GVP Module VI (Rev 2, 2017); ICH E2D(R1) (in force EU 18 Mar 2026); ICH E2B(R3) (v5.02, 2016)

Role-Specific Knowledge *Includes topics derived from this role's job description.*

Competency claim (knowledge topic)	Level	Verified source
Safety database administration and configuration	**Expert**	ICH E2B(R3) (v5.02, 2016); EMA EudraVigilance
Computer-system validation (CSV) and UAT	**Expert**	EU GMP Annex 11 — Computerised Systems (EudraLex Vol. 4, 2011); ISPE GAMP 5, 2nd Ed. (2022)
PSMF and Safety Data Exchange Agreements (SDEA)	**Intermediate**	EMA GVP Module II (Rev 2, 2017); EMA GVP Module I (2012)
System integrations, gateways and reporting rules	**Intermediate**	ICH E2B(R3) (v5.02, 2016); EMA EudraVigilance
Audits and regulatory inspections	**Intermediate**	EMA GVP Module IV (Rev 1, 2015); EMA GVP Module III (Rev 1, 2014)

Competency claim (knowledge topic)	Level	Verified source
Training, education and capacity building	**Basic**	WHO PV Core Curriculum for University Teaching (van Eekeren et al., Drug Saf 2018)

33. PV Medical Writer

Code **S.I.MW.MW** *Scientific · Industry · PV Medical Writing* **DRAFT** competency standard

> *v2: Proposed citation mapping: each topic is paired with a source drawn from the verified base (all sources checked against their issuing body, 2026-07-12) and refreshed to the in-force version — confirm each topic→source fit on review. Blank-note gaps are filled and misfit template topics flagged. Job description and proficiency levels are unchanged from v0.3 for this role.*

Competency claims with verified sources

General Knowledge

Competency claim (knowledge topic)	Level	Verified source
Pharmacovigilance principles and Good Pharmacovigilance Practices (GVP) overview	**Intermediate**	EMA GVP Module I (2012); Dir 2001/83/EC (as amended by Dir 2010/84/EU); Reg (EC) 726/2004 (as amended by Reg (EU) 1235/2010)
The pharmacovigilance system and Pharmacovigilance System Master File (PSMF)	**Intermediate**	EMA GVP Module II (Rev 2, 2017); Comm. Impl. Reg (EU) 520/2012, as amended
Individual case safety report (ICSR) management and regulatory reporting timelines	**Intermediate**	EMA GVP Module VI (Rev 2, 2017); ICH E2D(R1) (in force EU 18 Mar 2026); ICH E2B(R3) (v5.02, 2016)

Role-Specific Knowledge

Competency claim (knowledge topic)	Level	Verified source
Aggregate safety reports (PBRER/PSUR, DSUR)	**Expert**	EMA GVP Module VII (Rev 1, 2013); ICH E2C(R2) (PBRER); ICH E2F (DSUR, Step 4 2010)
Risk management plan (RMP) / REMS authoring **CURRENCY**	**Intermediate**	EMA GVP Module V (Rev 2, 2017); EMA GVP Module XVI (Rev 3, 2024); FDA REMS — FDAAA 2007, FD&C Act §505-1
Regulatory templates, SOPs and QC checklists	**Expert**	EMA GVP Module I (2012)
Benefit–risk narrative and safety data interpretation	**Intermediate**	ICH E2C(R2) (PBRER)

34. PBRER Writer

Code **S.I.MW.PBRER** *Scientific · Industry · PV Medical Writing* **DRAFT** competency standard

Also known as: PSUR Writer

v2: Proposed citation mapping: each topic is paired with a source drawn from the verified base (all sources checked against their issuing body, 2026-07-12) and refreshed to the in-force version — confirm each topic→source fit on review. Blank-note gaps are filled and misfit template topics flagged. Job description and proficiency levels are unchanged from v0.3 for this role.

Job description (v0.3 wording retained)

- Plan and organize workload for assigned projects and tasks, i.e., identify project needs, track timelines, and implement requests.
- Prepare PBRER and addenda to the safety/regulatory documents following relevant SOPs and templates.
- Perform QC of PBRER and addenda to the safety/regulatory associated documents in accordance with relevant SOPs and QC checklists.
- Function as the medical writing lead on a variety of projects.
- Participate in inspection/audit related readiness activities and provide support for internal and external PV audits.
- Train, support and work closely with other staff and the company’s divisions to develop appropriate project plans.

Competency claims with verified sources

General Knowledge

Competency claim (knowledge topic)	Level	Verified source
Pharmacovigilance principles and Good Pharmacovigilance Practices (GVP) overview	**Intermediate**	EMA GVP Module I (2012); Dir 2001/83/EC (as amended by Dir 2010/84/EU); Reg (EC) 726/2004 (as amended by Reg (EU) 1235/2010)
The pharmacovigilance system and Pharmacovigilance System Master File (PSMF)	**Intermediate**	EMA GVP Module II (Rev 2, 2017); Comm. Impl. Reg (EU) 520/2012, as amended
Individual case safety report (ICSR) management and regulatory reporting timelines	**Intermediate**	EMA GVP Module VI (Rev 2, 2017); ICH E2D(R1) (in force EU 18 Mar 2026); ICH E2B(R3) (v5.02, 2016)

Role-Specific Knowledge *Includes topics derived from this role's job description.*

Competency claim (knowledge topic)	Level	Verified source
Aggregate safety reports (PBRER/PSUR, DSUR)	**Expert**	EMA GVP Module VII (Rev 1, 2013); ICH E2C(R2) (PBRER); ICH E2F (DSUR, Step 4 2010)
Risk management plan (RMP) / REMS authoring **CURRENCY**	**Intermediate**	EMA GVP Module V (Rev 2, 2017); EMA GVP Module XVI (Rev 3, 2024); FDA REMS — FDAAA 2007, FD&C Act §505-1
Regulatory templates, SOPs and QC checklists	**Expert**	EMA GVP Module I (2012)
Benefit–risk narrative and safety data interpretation	**Intermediate**	ICH E2C(R2) (PBRER)
Audits and regulatory inspections	**Intermediate**	EMA GVP Module IV (Rev 1, 2015); EMA GVP Module III (Rev 1, 2014)

35. RMP Writer

Code **S.I.MW.RMP** *Scientific · Industry · PV Medical Writing* **DRAFT** competency standard

> *v2: Proposed citation mapping: each topic is paired with a source drawn from the verified base (all sources checked against their issuing body, 2026-07-12) and refreshed to the in-force version — confirm each topic→source fit on review. Blank-note gaps are filled and misfit template topics flagged. Job description and proficiency levels are unchanged from v0.3 for this role.*

Job description (v0.3 wording retained)

- Plan and organize workload for assigned projects and tasks, i.e., identify project needs, track timelines, and implement requests.
- Prepare RMPs and addenda to the safety/regulatory documents in accordance with relevant SOPs and templates.
- Perform QC RMPs and addenda to the safety/regulatory associated documents in accordance with relevant SOPs and QC checklists.
- Function as the medical writing lead on a variety of projects.
- Participate in inspection/audit related readiness activities and provide support for internal and external PV audits.
- Train, support and work closely with other staff and the company's divisions to develop appropriate project plans.

Competency claims with verified sources

General Knowledge

Competency claim (knowledge topic)	Level	Verified source
Pharmacovigilance principles and Good Pharmacovigilance Practices (GVP) overview	**Intermediate**	EMA GVP Module I (2012); Dir 2001/83/EC (as amended by Dir 2010/84/EU); Reg (EC) 726/2004 (as amended by Reg (EU) 1235/2010)
The pharmacovigilance system and Pharmacovigilance System Master File (PSMF)	**Intermediate**	EMA GVP Module II (Rev 2, 2017); Comm. Impl. Reg (EU) 520/2012, as amended
Individual case safety report (ICSR) management and regulatory reporting timelines	**Intermediate**	EMA GVP Module VI (Rev 2, 2017); ICH E2D(R1) (in force EU 18 Mar 2026); ICH E2B(R3) (v5.02, 2016)

Role-Specific Knowledge

Includes topics derived from this role's job description.

Competency claim (knowledge topic)	Level	Verified source
Aggregate safety reports (PBRER/PSUR, DSUR)	**Expert**	EMA GVP Module VII (Rev 1, 2013); ICH E2C(R2) (PBRER); ICH E2F (DSUR, Step 4 2010)
Risk management plan (RMP) / REMS authoring **CURRENCY**	**Intermediate**	EMA GVP Module V (Rev 2, 2017); EMA GVP Module XVI (Rev 3, 2024); FDA REMS — FDAAA 2007, FD&C Act §505-1
Regulatory templates, SOPs and QC checklists	**Expert**	EMA GVP Module I (2012)
Benefit–risk narrative and safety data interpretation	**Intermediate**	ICH E2C(R2) (PBRER)
Audits and regulatory inspections	**Intermediate**	EMA GVP Module IV (Rev 1, 2015); EMA GVP Module III (Rev 1, 2014)

36. REMS Writer

Code **S.I.MW.REMS** *Scientific · Industry · PV Medical Writing* **DRAFT** competency standard

> *v2: Proposed citation mapping: each topic is paired with a source drawn from the verified base (all sources checked against their issuing body, 2026-07-12) and refreshed to the in-force version — confirm each topic→source fit on review. Blank-note gaps are filled and misfit template topics flagged. Job description and proficiency levels are unchanged from v0.3 for this role.*

Job description (v0.3 wording retained)

- Plan and organize workload for assigned projects and tasks, i.e., identify project needs, track timelines, and implement requests.
- Prepare REMS and addenda to the safety/regulatory documents in accordance with relevant SOPs and templates.
- Perform QC REMS and addenda to the safety/regulatory associated documents in accordance with relevant SOPs and QC checklists.
- Function as the medical writing lead on a variety of projects.
- Participate in inspection/audit related readiness activities and provide support for internal and external PV audits.
- Train, support and work closely with other staff and the company's divisions to develop appropriate project plans.

Competency claims with verified sources

General Knowledge

Competency claim (knowledge topic)	Level	Verified source
Pharmacovigilance principles and Good Pharmacovigilance Practices (GVP) overview	**Intermediate**	EMA GVP Module I (2012); Dir 2001/83/EC (as amended by Dir 2010/84/EU); Reg (EC) 726/2004 (as amended by Reg (EU) 1235/2010)
The pharmacovigilance system and Pharmacovigilance System Master File (PSMF)	**Intermediate**	EMA GVP Module II (Rev 2, 2017); Comm. Impl. Reg (EU) 520/2012, as amended
Individual case safety report (ICSR) management and regulatory reporting timelines	**Intermediate**	EMA GVP Module VI (Rev 2, 2017); ICH E2D(R1) (in force EU 18 Mar 2026); ICH E2B(R3) (v5.02, 2016)

Role-Specific Knowledge *Includes topics derived from this role's job description.*

Competency claim (knowledge topic)	Level	Verified source
Aggregate safety reports (PBRER/PSUR, DSUR)	**Expert**	EMA GVP Module VII (Rev 1, 2013); ICH E2C(R2) (PBRER); ICH E2F (DSUR, Step 4 2010)
Risk management plan (RMP) / REMS authoring **CURRENCY**	**Intermediate**	EMA GVP Module V (Rev 2, 2017); EMA GVP Module XVI (Rev 3, 2024); FDA REMS — FDAAA 2007, FD&C Act §505-1
Regulatory templates, SOPs and QC checklists	**Expert**	EMA GVP Module I (2012)
Benefit–risk narrative and safety data interpretation	**Intermediate**	ICH E2C(R2) (PBRER)
Risk management planning (GVP Module V): RMP structure and lifecycle	**Intermediate**	EMA GVP Module V (Rev 2, 2017)
Audits and regulatory	**Intermediate**	EMA GVP Module IV (Rev 1, 2015);

Competency claim (knowledge topic)	Level	Verified source
inspections		EMA GVP Module III (Rev 1, 2014)

37. DSUR Writer

Code **S.I.MW.DSUR** *Scientific · Industry · PV Medical Writing* **DRAFT** competency standard

> *v2: Proposed citation mapping: each topic is paired with a source drawn from the verified base (all sources checked against their issuing body, 2026-07-12) and refreshed to the in-force version — confirm each topic→source fit on review. Blank-note gaps are filled and misfit template topics flagged. Job description and proficiency levels are unchanged from v0.3 for this role.*

Job description (v0.3 wording retained)

- Plan and organize workload for assigned projects and tasks, i.e., identify project needs, track timelines, and implement requests.
- Prepare DSUR and addenda to the safety/regulatory documents in accordance with relevant SOPs and templates.
- Perform QC DSUR and addenda to the safety/regulatory associated documents in accordance with relevant SOPs and QC checklists.
- Function as the medical writing lead on a variety of projects.
- Participate in inspection/audit related readiness activities and provide support for internal and external PV audits.
- Train, suport, and work closely with other staff and the company's divisions to develop appropriate project plans.

Competency claims with verified sources

General Knowledge

Competency claim (knowledge topic)	Level	Verified source
Pharmacovigilance principles and Good Pharmacovigilance Practices (GVP) overview	**Intermediate**	EMA GVP Module I (2012); Dir 2001/83/EC (as amended by Dir 2010/84/EU); Reg (EC) 726/2004 (as amended by Reg (EU) 1235/2010)
The pharmacovigilance system and Pharmacovigilance System Master File (PSMF)	**Intermediate**	EMA GVP Module II (Rev 2, 2017); Comm. Impl. Reg (EU) 520/2012, as amended
Individual case safety report (ICSR) management and regulatory reporting timelines	**Intermediate**	EMA GVP Module VI (Rev 2, 2017); ICH E2D(R1) (in force EU 18 Mar 2026); ICH E2B(R3) (v5.02, 2016)

Role-Specific Knowledge *Includes topics derived from this role's job description.*

Competency claim (knowledge topic)	Level	Verified source
Aggregate safety reports (PBRER/PSUR, DSUR)	**Expert**	EMA GVP Module VII (Rev 1, 2013); ICH E2C(R2) (PBRER); ICH E2F (DSUR, Step 4 2010)
Risk management plan (RMP) / REMS authoring **CURRENCY**	**Intermediate**	EMA GVP Module V (Rev 2, 2017); EMA GVP Module XVI (Rev 3, 2024); FDA REMS — FDAAA 2007, FD&C Act §505-1
Regulatory templates, SOPs and QC checklists	**Expert**	EMA GVP Module I (2012)
Benefit–risk narrative and safety data interpretation	**Intermediate**	ICH E2C(R2) (PBRER)
Audits and regulatory inspections	**Intermediate**	EMA GVP Module IV (Rev 1, 2015); EMA GVP Module III (Rev 1, 2014)

38. PV Pharmacoepidemiologist

Code **S.I.DCS.PE** *Scientific · Industry · Data Collection Schemes* **DRAFT** competency standard

Also known as: PV Epidemiologist Researcher; PV Research Fellow

v2: Proposed citation mapping: each topic is paired with a source drawn from the verified base (all sources checked against their issuing body, 2026-07-12) and refreshed to the in-force version — confirm each topic→source fit on review. Blank-note gaps are filled and misfit template topics flagged. Job description and proficiency levels are unchanged from v0.3 for this role.

Job description (v0.3 wording retained)

- Responsible for managing pharmacoepidemiologic projects and activities with limited direction in support of marketed products in accordance with global regulations the and company's SOPs and working practices.
- Serve as a subject matter expert on pharmacoepidemiology for assigned marketed/development compound(s) and to other divisions.
- Keep up to date with the latest epidemiologic methods and resources, to be able to be responsive within cross-functional teams and to guide decision making where needed.
- Responsible for implementation of pharmacoepidemiology strategy, generation of RWE, the conduct of regulatory agency required epidemiologic studies for post-marketing commitments (e.g., PASS, PAES, PMR, DUS, the effectiveness of REMS and RMMs).
- Provide a critical review of relevant published literature.
- Build and maintain effective partnerships with Medical Affairs, Clinical Development, and Regulatory Affairs departments.
- Participate in inspection/audit related readiness activities and provide support for internal and external PV audits.
- Develop and deliver relevant training.

Competency claims with verified sources

General Knowledge

Competency claim (knowledge topic)	Level	Verified source
Pharmacovigilance principles and Good Pharmacovigilance Practices (GVP) overview	**Intermediate**	EMA GVP Module I (2012); Dir 2001/83/EC (as amended by Dir 2010/84/EU); Reg (EC) 726/2004 (as amended by Reg (EU) 1235/2010)
The pharmacovigilance system and Pharmacovigilance System Master File (PSMF)	**Intermediate**	EMA GVP Module II (Rev 2, 2017); Comm. Impl. Reg (EU) 520/2012, as amended
Individual case safety report (ICSR) management and regulatory reporting timelines	**Intermediate**	EMA GVP Module VI (Rev 2, 2017); ICH E2D(R1) (in force EU 18 Mar 2026); ICH E2B(R3) (v5.02, 2016)

Role-Specific Knowledge

Includes topics derived from this role's job description.

Competency claim (knowledge topic)	Level	Verified source
Pharmacoepidemiology study design (PASS/PAES)	**Expert**	EMA GVP Module VIII (Rev 3, 2017); ENCePP Guide on Methodological Standards (Rev 11, 2023); STROBE Statement (von Elm et al., 2007)
Real-world evidence (RWE) and data sources	**Intermediate**	ENCePP Guide on Methodological Standards (Rev 11, 2023)
Biostatistics and study analysis **NEW CITATION**	**Intermediate**	ICH E9 (1998) / E9(R1) estimands (2019)

Competency claim (knowledge topic)	Level	Verified source
GVP Module VIII (post-authorisation safety studies)	**Intermediate**	EMA GVP Module VIII (Rev 3, 2017)
Risk management planning (GVP Module V): RMP structure and lifecycle	**Intermediate**	EMA GVP Module V (Rev 2, 2017)
Audits and regulatory inspections	**Intermediate**	EMA GVP Module IV (Rev 1, 2015); EMA GVP Module III (Rev 1, 2014)
Literature monitoring and review	**Basic**	EMA GVP Module VI (Rev 2, 2017) — literature monitoring
Training, education and capacity building	**Basic**	WHO PV Core Curriculum for University Teaching (van Eekeren et al., Drug Saf 2018)
Budgeting, resourcing and business continuity **MANAGEMENT COMPETENCY (NO EXTERNAL REGULATORY SOURCE)**	**Intermediate**	—
Post-authorisation safety studies (PASS/PAES)	**Intermediate**	EMA GVP Module VIII (Rev 3, 2017)

39. PV Biostatistician

Code **S.I.DCS.BS** *Scientific · Industry · Data Collection Schemes* **DRAFT** competency standard

Also known as: Biostatistician

> *v2: Proposed citation mapping: each topic is paired with a source drawn from the verified base (all sources checked against their issuing body, 2026-07-12) and refreshed to the in-force version — confirm each topic→source fit on review. Blank-note gaps are filled and misfit template topics flagged. Job description and proficiency levels are unchanged from v0.3 for this role.*

Job description (v0.3 wording retained)

- Provide oversight of statistical aspects in the design and analysis of studies, including project management, statistical analysis, report preparation, and advising other project statisticians.
- Provide sample size calculations and review protocols for completeness, appropriateness of clinical design, and sound statistical analysis. Contribute to writing appropriate protocol sections.
- Write/review analysis plans and guide others on the team in its implementation.
- Define appropriate methods and procedures for statistical analysis.
- Provide specifications for analysis database, oversee its development, and assure completeness for use in all programming.
- Provide statistical advice and sample size planning. Help with the development and implementation of statistical analysis plans.
- Carry out complex statistical analyses and work with statistical software.
- Prepare and present study results.
- Coordinate with programs and data management personnel as to database maintenance, updating, and documentation.
- Participate in inspection/audit related readiness activities and provide support for internal and external PV audits.
- Develop and deliver relevant training.

Competency claims with verified sources

General Knowledge

Competency claim (knowledge topic)	Level	Verified source
Pharmacovigilance principles and Good Pharmacovigilance Practices (GVP) overview	**Intermediate**	EMA GVP Module I (2012); Dir 2001/83/EC (as amended by Dir 2010/84/EU); Reg (EC) 726/2004 (as amended by Reg (EU) 1235/2010)
The pharmacovigilance system and Pharmacovigilance System Master File (PSMF)	**Intermediate**	EMA GVP Module II (Rev 2, 2017); Comm. Impl. Reg (EU) 520/2012, as amended
Individual case safety report (ICSR) management and regulatory reporting timelines	**Intermediate**	EMA GVP Module VI (Rev 2, 2017); ICH E2D(R1) (in force EU 18 Mar 2026); ICH E2B(R3) (v5.02, 2016)

Role-Specific Knowledge *Includes topics derived from this role's job description.*

Competency claim (knowledge topic)	Level	Verified source
Pharmacoepidemiology study design (PASS/PAES)	**Expert**	EMA GVP Module VIII (Rev 3, 2017); ENCePP Guide on Methodological Standards (Rev 11, 2023); STROBE Statement (von Elm et al., 2007)
Real-world evidence (RWE) and	**Intermediate**	ENCePP Guide on Methodological

Competency claim (knowledge topic)	Level	Verified source
data sources		Standards (Rev 11, 2023)
Biostatistics and study analysis NEW CITATION	**Intermediate**	ICH E9 (1998) / E9(R1) estimands (2019)
GVP Module VIII (post-authorisation safety studies)	**Intermediate**	EMA GVP Module VIII (Rev 3, 2017)
Audits and regulatory inspections	**Intermediate**	EMA GVP Module IV (Rev 1, 2015); EMA GVP Module III (Rev 1, 2014)
Safety database administration and configuration	**Intermediate**	ICH E2B(R3) (v5.02, 2016); EMA EudraVigilance
Training, education and capacity building	**Basic**	WHO PV Core Curriculum for University Teaching (van Eekeren et al., Drug Saf 2018)
Biostatistics and quantitative safety analysis NEW CITATION	**Intermediate**	ICH E9 (1998) / E9(R1) estimands (2019); CIOMS Working Group VIII (2010)

40. PV Medical Assessor

Code **S.RA.MA** *Scientific · Regulatory Authority* **DRAFT** competency standard

Also known as: PV Medical Officer; Pharmaceutical Assessor

v2: Generated DRAFT. Job description tightened; base-law citations updated to "as amended" and ICH E2D refreshed to E2D(R1). The WHO-curriculum citation is flagged for verification.

Job description — v2 (revised wording)

- Provide administrative oversight of medical-review activities.
- Review and evaluate the causality assessment of adverse events in individual case safety reports (ICSRs).
- Author scientific publications on behalf of the regulatory authority.
- Contribute to transparency and communication initiatives by providing scientifically rigorous, consistent information that promotes the safe and effective use of medicines.
- Liaise with, and provide technical advice and guidance on, pharmacovigilance matters to regulatory colleagues, pharmaceutical companies, national and international bodies, healthcare professionals and the public.
- Contribute, internally and externally, to the formulation of regulatory policies, guidelines, legislation and opinions.
- Develop and deliver relevant training.

Competency claims with verified sources

General Knowledge

Competency claim (knowledge topic)	Level	Verified source
Pharmacovigilance principles and GVP overview **CURRENCY**	**Intermediate**	EMA GVP Module I (2012); Reg (EC) 726/2004 & Dir 2001/83/EC, as amended
The pharmacovigilance system and Pharmacovigilance System Master File (PSMF)	**Intermediate**	EMA GVP Module II (Rev 2, 2017)
Individual case safety report (ICSR) management and regulatory reporting timelines **CURRENCY: E2D→E2D(R1)**	**Intermediate**	EMA GVP Module VI (Rev 2, 2017); ICH E2D(R1); ICH E2B(R3)

Role-Specific Knowledge *Includes topics derived from this role's job description.*

Competency claim (knowledge topic)	Level	Verified source
PV legislation and regulatory assessment procedures **CURRENCY**	**Expert**	Regulation (EC) No 726/2004 & Directive 2001/83/EC, as amended by the 2010 PV legislation
Assessment of causality, signals and aggregate data	**Expert**	EMA GVP Module IX (Rev 1, 2017); Module VII (Rev 1, 2013)
Regulatory action and risk communication	**Intermediate**	EMA GVP Module XV — Safety communication (Rev 1, 2017)
Nomenclature and coding standards	**Intermediate**	MedDRA v29.0 (2026), MSSO; ISO IDMP standards
ICSR lifecycle: receipt, triage, data entry, quality control	**Intermediate**	EMA GVP Module VI (Rev 2, 2017)
Medical review of ICSRs: seriousness, expectedness, causality	**Intermediate**	EMA GVP Module VI (Rev 2, 2017); ICH E2A

Competency claim (knowledge topic)	Level	Verified source
Training, education and capacity building VERIFY	**Basic**	WHO PV curriculum — citation imprecise; confirm exact title before use
PV policy, legislation and guideline development CURRENCY	**Intermediate**	Regulation (EC) No 726/2004 & Directive 2001/83/EC, as amended

41. PV Scientific Assessor

Code **S.RA.SA** *Scientific · Regulatory Authority* **DRAFT** competency standard

Also known as: PV Scientific Officer

> *v2: Proposed citation mapping: each topic is paired with a source drawn from the verified base (all sources checked against their issuing body, 2026-07-12) and refreshed to the in-force version — confirm each topic→source fit on review. Blank-note gaps are filled and misfit template topics flagged. Job description and proficiency levels are unchanged from v0.3 for this role.*

Job description (v0.3 wording retained)

- Review and evaluation of adverse reaction data.
- Work with other staff to facilitate changes to safety reporting requirements arising from revisions to clinical trials legislation.
- Liaise with and provide technical information, advice, and guidance on PV matters.
- Support the PV Medical Assessor and other staff.
- Prepare and compile PV data for review and draft of reports.
- Contribute to the review and analysis of adverse reaction reporting trends.
- Contribute to the preparation of PV related publications.
- Assist in the implementation and maintenance of quality management in the PV section, including identifying potential problems and providing solutions in a timely manner.
- Ensure accurate and consistent use of nomenclatures and coding standards/requirements.
- Ensure appropriate maintenance and management of adverse reaction data.
- Assist with the effective implementation of the NRA quality management system within the department.
- Assist the Management team to ensure that PV section procedures remain consistent with relevant developments in national and international regulations, legislation, and guidelines.
- Contribute to transparency and communication initiatives through the provision of scientifically rigorous and consistent information to promote the safe and effective use of medicines.
- Liaise with and provide technical information, advice, and guidance on relevant PV matters to other regulatory colleagues, pharmaceutical companies, relevant national and international bodies, healthcare professionals and members of the public.
- Support external compliance monitoring with PV obligations.
- Participate at all levels (internally and externally) in the formulation and preparation of regulatory policies, guidelines, legislation, and opinions.
- Develop and deliver relevant training.

Competency claims with verified sources

General Knowledge

Competency claim (knowledge topic)	Level	Verified source
Pharmacovigilance principles and Good Pharmacovigilance Practices (GVP) overview	**Intermediate**	EMA GVP Module I (2012); Dir 2001/83/EC (as amended by Dir 2010/84/EU); Reg (EC) 726/2004 (as amended by Reg (EU) 1235/2010)
The pharmacovigilance system and Pharmacovigilance System Master File (PSMF)	**Intermediate**	EMA GVP Module II (Rev 2, 2017); Comm. Impl. Reg (EU) 520/2012, as amended

Competency claim (knowledge topic)	Level	Verified source
Individual case safety report (ICSR) management and regulatory reporting timelines	**Intermediate**	EMA GVP Module VI (Rev 2, 2017); ICH E2D(R1) (in force EU 18 Mar 2026); ICH E2B(R3) (v5.02, 2016)

Role-Specific Knowledge

Includes topics derived from this role's job description.

Competency claim (knowledge topic)	Level	Verified source
PV legislation and regulatory assessment procedures	**Expert**	Dir 2001/83/EC (as amended by Dir 2010/84/EU); Reg (EC) 726/2004 (as amended by Reg (EU) 1235/2010)
Assessment of causality, signals and aggregate data	**Expert**	EMA GVP Module IX (Rev 1, 2017); EMA GVP Module VII (Rev 1, 2013)
Regulatory action and risk communication	**Intermediate**	EMA GVP Module XV (Rev 1, 2017)
Nomenclature and coding standards	**Intermediate**	MedDRA (ICH/MSSO; v29.0, Mar 2026); ISO IDMP (ISO 11615/11616/11238/11239/11240)
MedDRA and WHODrug coding conventions	**Intermediate**	MedDRA (ICH/MSSO; v29.0, Mar 2026); WHODrug Global (WHO-UMC)
Training, education and capacity building	**Basic**	WHO PV Core Curriculum for University Teaching (van Eekeren et al., Drug Saf 2018)
PV policy, legislation and guideline development	**Intermediate**	Dir 2001/83/EC (as amended by Dir 2010/84/EU); Reg (EC) 726/2004 (as amended by Reg (EU) 1235/2010)
PV quality management system (GVP Module I)	**Intermediate**	EMA GVP Module I (2012); Comm. Impl. Reg (EU) 520/2012, as amended

42. PV Inspector

Code **S.RA.INSP** *Scientific · Regulatory Authority* **DRAFT** competency standard

> *v2: Proposed citation mapping: each topic is paired with a source drawn from the verified base (all sources checked against their issuing body, 2026-07-12) and refreshed to the in-force version — confirm each topic→source fit on review. Blank-note gaps are filled and misfit template topics flagged. Job description and proficiency levels are unchanged from v0.3 for this role.*

Job description (v0.3 wording retained)

- Evaluate the compliance of sites inspected, with the requirements of national legislation.
- Prepare for, organize, and carry out inspections in accordance with NRA and all relevant procedures.
- Evaluate complex information, identify relevant standards, and assess compliance with relevant requirements.
- Compile inspection reports when acting as a lead inspector, contribute to the preparation of reports for joint or accompanied inspections.
- Assist in the compilation of data and preparation of management reports as required.
- Apply risk management principles.
- Submit reports as required and maintain appropriate records of meetings and activities.
- Ensure a database of inspection details is maintained.
- Assist in the introduction of new legislation, and development of policy and practice guidelines and procedures.
- Provide support to other areas of the NRA where appropriate.
- Assist the management team to ensure that effective mechanisms are in place to capture, store and communicate information, experience and knowledge gained.
- Assist the management team in ensuring that available information and knowledge across the regulatory authority is effectively used by the Inspection section.
- Assist the management team to ensure that inspection procedures remain up to date with relevant developments in national and international regulations, legislation, and guides.
- Participate and represent at national and international seminars in PV inspections.
- Respond to queries (technical and procedural) from internal and external customers.
- Contribute to transparency and communication initiatives through the provision of scientifically rigorous and consistent information to promote the safe and effective use of medicines.
- Liaise with and provide technical information, advice, and guidance on relevant PV matters to other regulatory colleagues, pharmaceutical companies, relevant national and international bodies, healthcare professionals and members of the public.
- Support external compliance monitoring with PV obligations.
- Participate at all levels (internally and externally) in the formulation and preparation of regulatory policies, guidelines, legislation, and opinions.
- Develop and deliver relevant training.

Competency claims with verified sources

General Knowledge

Competency claim (knowledge topic)	Level	Verified source
Pharmacovigilance principles and Good Pharmacovigilance Practices (GVP) overview	**Intermediate**	EMA GVP Module I (2012); Dir 2001/83/EC (as amended by Dir 2010/84/EU); Reg (EC) 726/2004 (as amended by Reg (EU) 1235/2010)
The pharmacovigilance system and Pharmacovigilance System Master File (PSMF)	**Intermediate**	EMA GVP Module II (Rev 2, 2017); Comm. Impl. Reg (EU) 520/2012, as amended
Individual case safety report (ICSR) management and regulatory reporting timelines	**Intermediate**	EMA GVP Module VI (Rev 2, 2017); ICH E2D(R1) (in force EU 18 Mar 2026); ICH E2B(R3) (v5.02, 2016)

Role-Specific Knowledge *Includes topics derived from this role's job description.*

Competency claim (knowledge topic)	Level	Verified source
PV legislation and regulatory assessment procedures	**Expert**	Dir 2001/83/EC (as amended by Dir 2010/84/EU); Reg (EC) 726/2004 (as amended by Reg (EU) 1235/2010)
Assessment of causality, signals and aggregate data	**Expert**	EMA GVP Module IX (Rev 1, 2017); EMA GVP Module VII (Rev 1, 2013)
Regulatory action and risk communication	**Intermediate**	EMA GVP Module XV (Rev 1, 2017)
Nomenclature and coding standards	**Intermediate**	MedDRA (ICH/MSSO; v29.0, Mar 2026); ISO IDMP (ISO 11615/11616/11238/11239/11240)
Risk management planning (GVP Module V): RMP structure and lifecycle	**Intermediate**	EMA GVP Module V (Rev 2, 2017)
Audits and regulatory inspections	**Intermediate**	EMA GVP Module IV (Rev 1, 2015); EMA GVP Module III (Rev 1, 2014)
Safety database administration and configuration	**Intermediate**	ICH E2B(R3) (v5.02, 2016); EMA EudraVigilance
Training, education and capacity building	**Basic**	WHO PV Core Curriculum for University Teaching (van Eekeren et al., Drug Saf 2018)
PV policy, legislation and guideline development	**Intermediate**	Dir 2001/83/EC (as amended by Dir 2010/84/EU); Reg (EC) 726/2004 (as amended by Reg (EU) 1235/2010)

43. Senior Researcher

Code **S.A.SR** *Scientific · Academia* **DRAFT** competency standard

Also known as: Senior Research Specialist; Research Associate

v2: Proposed citation mapping: each topic is paired with a source drawn from the verified base (all sources checked against their issuing body, 2026-07-12) and refreshed to the in-force version — confirm each topic→source fit on review. Blank-note gaps are filled and misfit template topics flagged. Job description and proficiency levels are unchanged from v0.3 for this role.

Job description (v0.3 wording retained)

- Plan and implement operations to achieve the highest quality and scientific level within the responsible research department.
- Review and author academic publications, study protocols, and reports.
- Consult medical and regulatory affairs.
- Mentor safety advisers regarding time management and quality performance.
- Participate at internal and public meetings, seminars, and university-level courses.
- Serve as a safety representative in communications with the regulatory authorities
- Develop and deliver relevant training.

Competency claims with verified sources

General Knowledge

Competency claim (knowledge topic)	Level	Verified source
Pharmacovigilance principles and Good Pharmacovigilance Practices (GVP) overview	**Intermediate**	EMA GVP Module I (2012); Dir 2001/83/EC (as amended by Dir 2010/84/EU); Reg (EC) 726/2004 (as amended by Reg (EU) 1235/2010)
The pharmacovigilance system and Pharmacovigilance System Master File (PSMF)	**Intermediate**	EMA GVP Module II (Rev 2, 2017); Comm. Impl. Reg (EU) 520/2012, as amended
Individual case safety report (ICSR) management and regulatory reporting timelines	**Intermediate**	EMA GVP Module VI (Rev 2, 2017); ICH E2D(R1) (in force EU 18 Mar 2026); ICH E2B(R3) (v5.02, 2016)

Role-Specific Knowledge

Includes topics derived from this role's job description.

Competency claim (knowledge topic)	Level	Verified source
PV curriculum and educational methods **VERIFY FIT**	**Expert**	WHO PV Core Curriculum for University Teaching (van Eekeren et al., Drug Saf 2018)
Pharmacovigilance science and research methodology **NEW CITATION**	**Intermediate**	ENCePP Guide on Methodological Standards (Rev 11, 2023); STROBE Statement (von Elm et al., 2007)
Regulatory framework and GVP overview	**Intermediate**	EMA GVP Module I (2012)
Scientific writing and publication **NEW CITATION**	**Intermediate**	ICMJE Recommendations (Jan 2026)
Training, education and capacity building	**Basic**	WHO PV Core Curriculum for University Teaching (van Eekeren et al., Drug Saf 2018)

44. PV Scientist

Code **S.A.SC** *Scientific · Academia* **DRAFT** competency standard

Also known as: Drug Safety Scientist; Safety Scientist

v2: Proposed citation mapping: each topic is paired with a source drawn from the verified base (all sources checked against their issuing body, 2026-07-12) and refreshed to the in-force version — confirm each topic→source fit on review. Blank-note gaps are filled and misfit template topics flagged. Job description and proficiency levels are unchanged from v0.3 for this role.

Job description (v0.3 wording retained)

- Support safety surveillance, aggregate data review, and reporting activities.
- Use scientific expertise and medical background to integrate case-related information including medical conditions, lab results and procedures and effectively identify potential signals in collaboration with their manager and the safety physician/medical staff.
- On request assist in the preparation of safety-related sections and associated documentation for clinical and regulatory documents (including clinical study protocols, patient informed consent forms, clinical study final reports, annual reports, DSUR, integrated summaries of safety, RMPs and clinical expert reports).
- Participate in internal PV committee meetings and joint safety meetings with internal/external stakeholders.
- On request review the safety data reports for scientific accuracy and verify data against source documents.
- Contribute to the scientific literature by developing novel PV analytics, e.g., signal detection methods.
- Perform literature search and evaluation associated with signal investigations.
- Track events of special interest and safety commitments associated with aggregate reporting if applicable.
- Assist in the creation/revision of department procedures and policies.
- Develop and deliver relevant training.

Competency claims with verified sources

General Knowledge

Competency claim (knowledge topic)	Level	Verified source
Pharmacovigilance principles and Good Pharmacovigilance Practices (GVP) overview	**Intermediate**	EMA GVP Module I (2012); Dir 2001/83/EC (as amended by Dir 2010/84/EU); Reg (EC) 726/2004 (as amended by Reg (EU) 1235/2010)
The pharmacovigilance system and Pharmacovigilance System Master File (PSMF)	**Intermediate**	EMA GVP Module II (Rev 2, 2017); Comm. Impl. Reg (EU) 520/2012, as amended
Individual case safety report (ICSR) management and regulatory reporting timelines	**Intermediate**	EMA GVP Module VI (Rev 2, 2017); ICH E2D(R1) (in force EU 18 Mar 2026); ICH E2B(R3) (v5.02, 2016)

Role-Specific Knowledge *Includes topics derived from this role's job description.*

Competency claim (knowledge topic)	Level	Verified source
PV curriculum and educational methods **VERIFY FIT**	**Expert**	WHO PV Core Curriculum for University Teaching (van Eekeren et al., Drug Saf 2018)
Pharmacovigilance science and	**Intermediate**	ENCePP Guide on Methodological

Competency claim (knowledge topic)	Level	Verified source
research methodology NEW CITATION		Standards (Rev 11, 2023); STROBE Statement (von Elm et al., 2007)
Regulatory framework and GVP overview	**Intermediate**	EMA GVP Module I (2012)
Scientific writing and publication NEW CITATION	**Intermediate**	ICMJE Recommendations (Jan 2026)
Signal management process (GVP Module IX)	**Intermediate**	EMA GVP Module IX (Rev 1, 2017)
Aggregate safety reports (PBRER/PSUR, DSUR)	**Intermediate**	EMA GVP Module VII (Rev 1, 2013); ICH E2C(R2) (PBRER); ICH E2F (DSUR, Step 4 2010)
Literature monitoring and review	**Basic**	EMA GVP Module VI (Rev 2, 2017) — literature monitoring
Training, education and capacity building	**Basic**	WHO PV Core Curriculum for University Teaching (van Eekeren et al., Drug Saf 2018)
Statistical, machine-learning and NLP methods for safety data NEW CITATION / · VERIFY FIT (NO SINGLE ML/NLP PV STANDARD)	**Intermediate**	CIOMS Working Group VIII (2010); Evans et al. PRR (Pharmacoepidemiol Drug Saf 2001)

45. PV Data Scientist

Code **S.A.DSC** *Scientific · Academia* **DRAFT** competency standard

> *v2: Proposed citation mapping: each topic is paired with a source drawn from the verified base (all sources checked against their issuing body, 2026-07-12) and refreshed to the in-force version — confirm each topic→source fit on review. Blank-note gaps are filled and misfit template topics flagged. Job description and proficiency levels are unchanged from v0.3 for this role.*

Job description (v0.3 wording retained)

- Perform complex simulation, modelling, and implementation of machine learning algorithms, natural language processing applications, network analysis, deep learning frameworks, etc.
- Collaborate with IT to understand the implications of relevant architectures for data analytics and data integration platforms.
- Analyse diverse internal and external sources for value-adding benefit/risk information concerning products by leveraging complex statistical and predictive models.
- Design digital strategies to extract benefit/risk information from unstructured information, including literature, social media, and adverse event source documents.
- Generate PV insight by identifying novel product benefit/ risk insights to protect the safety and well-being of patients and consumers.
- Ensure principles to guide the appropriate and ethical collection and use of data, securing the scientific integrity of the analyses it generates as well as complying with all applicable data privacy regulations.
- Design and implement novel methods for PV.
- Support inspection/audit-related activities.
- Develop and deliver relevant training.

Competency claims with verified sources

General Knowledge

Competency claim (knowledge topic)	Level	Verified source
Pharmacovigilance principles and Good Pharmacovigilance Practices (GVP) overview	**Intermediate**	EMA GVP Module I (2012); Dir 2001/83/EC (as amended by Dir 2010/84/EU); Reg (EC) 726/2004 (as amended by Reg (EU) 1235/2010)
The pharmacovigilance system and Pharmacovigilance System Master File (PSMF)	**Intermediate**	EMA GVP Module II (Rev 2, 2017); Comm. Impl. Reg (EU) 520/2012, as amended
Individual case safety report (ICSR) management and regulatory reporting timelines	**Intermediate**	EMA GVP Module VI (Rev 2, 2017); ICH E2D(R1) (in force EU 18 Mar 2026); ICH E2B(R3) (v5.02, 2016)

Role-Specific Knowledge *Includes topics derived from this role's job description.*

Competency claim (knowledge topic)	Level	Verified source
PV curriculum and educational methods **VERIFY FIT**	**Expert**	WHO PV Core Curriculum for University Teaching (van Eekeren et al., Drug Saf 2018)
Pharmacovigilance science and research methodology **NEW CITATION**	**Intermediate**	ENCePP Guide on Methodological Standards (Rev 11, 2023); STROBE Statement (von Elm et al., 2007)
Regulatory framework and GVP overview	**Intermediate**	EMA GVP Module I (2012)

Competency claim (knowledge topic)	Level	Verified source
Scientific writing and publication NEW CITATION	**Intermediate**	ICMJE Recommendations (Jan 2026)
Audits and regulatory inspections	**Intermediate**	EMA GVP Module IV (Rev 1, 2015); EMA GVP Module III (Rev 1, 2014)
Literature monitoring and review	**Basic**	EMA GVP Module VI (Rev 2, 2017) — literature monitoring
Training, education and capacity building	**Basic**	WHO PV Core Curriculum for University Teaching (van Eekeren et al., Drug Saf 2018)
Benefit–risk assessment methodology	**Intermediate**	ICH E2C(R2) (PBRER)
Biostatistics and quantitative safety analysis NEW CITATION	**Intermediate**	ICH E9 (1998) / E9(R1) estimands (2019); CIOMS Working Group VIII (2010)
Statistical, machine-learning and NLP methods for safety data NEW CITATION / · VERIFY FIT (NO SINGLE ML/NLP PV STANDARD)	**Intermediate**	CIOMS Working Group VIII (2010); Evans et al. PRR (Pharmacoepidemiol Drug Saf 2001)

46. PV Pharmacoepidemiologist

Code **S.A.PE** *Scientific · Academia* **DRAFT** competency standard

Also known as: PV Research Fellow

> *v2: Proposed citation mapping: each topic is paired with a source drawn from the verified base (all sources checked against their issuing body, 2026-07-12) and refreshed to the in-force version — confirm each topic→source fit on review. Blank-note gaps are filled and misfit template topics flagged. Job description and proficiency levels are unchanged from v0.3 for this role.*

Job description (v0.3 wording retained)

- Generate RWE and conduct required epidemiologic studies (e.g., PASS, PAES, PMR, DUS, the effectiveness of REMS and RMMs).
- Provide a critical review of relevant published literature.
- Build and maintain partnerships with Medical Affairs, Clinical Development, and Regulatory Affairs departments.
- Keep up to date with the latest epidemiologic methods and resources to be able to be responsive with cross-functional teams and to guide decision making where needed.
- Participate in inspection/audit related readiness activities and provide support for internal and external PV audits.
- Develop and deliver relevant training.
- Contribute, participate, and support team meetings, including materials preparation, meeting minutes writing, and action item tracking.

Competency claims with verified sources

General Knowledge

Competency claim (knowledge topic)	Level	Verified source
Pharmacovigilance principles and Good Pharmacovigilance Practices (GVP) overview	**Intermediate**	EMA GVP Module I (2012); Dir 2001/83/EC (as amended by Dir 2010/84/EU); Reg (EC) 726/2004 (as amended by Reg (EU) 1235/2010)
The pharmacovigilance system and Pharmacovigilance System Master File (PSMF)	**Intermediate**	EMA GVP Module II (Rev 2, 2017); Comm. Impl. Reg (EU) 520/2012, as amended
Individual case safety report (ICSR) management and regulatory reporting timelines	**Intermediate**	EMA GVP Module VI (Rev 2, 2017); ICH E2D(R1) (in force EU 18 Mar 2026); ICH E2B(R3) (v5.02, 2016)

Role-Specific Knowledge

Includes topics derived from this role's job description.

Competency claim (knowledge topic)	Level	Verified source
PV curriculum and educational methods **VERIFY FIT**	**Expert**	WHO PV Core Curriculum for University Teaching (van Eekeren et al., Drug Saf 2018)
Pharmacovigilance science and research methodology **NEW CITATION**	**Intermediate**	ENCePP Guide on Methodological Standards (Rev 11, 2023); STROBE Statement (von Elm et al., 2007)
Regulatory framework and GVP overview	**Intermediate**	EMA GVP Module I (2012)
Scientific writing and publication **NEW CITATION**	**Intermediate**	ICMJE Recommendations (Jan 2026)
Risk management planning (GVP Module V): RMP structure and lifecycle	**Intermediate**	EMA GVP Module V (Rev 2, 2017)

Competency claim (knowledge topic)	Level	Verified source
Audits and regulatory inspections	**Intermediate**	EMA GVP Module IV (Rev 1, 2015); EMA GVP Module III (Rev 1, 2014)
Literature monitoring and review	**Basic**	EMA GVP Module VI (Rev 2, 2017) — literature monitoring
Training, education and capacity building	**Basic**	WHO PV Core Curriculum for University Teaching (van Eekeren et al., Drug Saf 2018)
Budgeting, resourcing and business continuity **MANAGEMENT COMPETENCY (NO EXTERNAL REGULATORY SOURCE)**	**Intermediate**	—
Post-authorisation safety studies (PASS/PAES)	**Intermediate**	EMA GVP Module VIII (Rev 3, 2017)

47. PV Lecturer

Code **S.A.PVL** *Scientific · Academia* **DRAFT** competency standard

Also known as: Regulatory Science Instructor; PV Instructor

> *v2: Generated DRAFT. Job description tightened (fixes "a PV", removes duplication); academia citations depend heavily on the WHO-curriculum reference (flagged VERIFY) and two topics need a source (PROPOSED).*

Job description — v2 (revised wording)

- Teach university students the theory and practice of pharmacovigilance.
- Interpret and analyse current data (market data, scientific papers, requirements, questionnaires) to assess developments and innovation in the field.
- Interpret and analyse data collected during testing to formulate conclusions, new insights or solutions.
- Employ varied teaching approaches, learning styles and channels to instruct students.
- Deliver pharmacovigilance training and capacity building.
- Monitor developments in pharmacovigilance, keeping up with new research and regulations.
- Cooperate with other pharmacovigilance education professionals.
- Contribute to and support team meetings, including materials preparation, minutes and action-item tracking.

Competency claims with verified sources

General Knowledge

Competency claim (knowledge topic)	Level	Verified source
Pharmacovigilance principles and GVP overview **CURRENCY**	**Intermediate**	EMA GVP Module I (2012); Reg (EC) 726/2004 & Dir 2001/83/EC, as amended
The PV system and PSMF	**Intermediate**	EMA GVP Module II (Rev 2, 2017)
ICSR management and regulatory reporting timelines **CURRENCY**	**Intermediate**	EMA GVP Module VI (Rev 2, 2017); ICH E2D(R1); ICH E2B(R3)

Role-Specific Knowledge

Includes topics derived from this role's job description.

Competency claim (knowledge topic)	Level	Verified source
PV curriculum and educational methods **VERIFY**	**Expert**	WHO PV curriculum — citation imprecise; confirm exact title
Pharmacovigilance science and research methodology **PROPOSED**	**Intermediate**	No anchor in v0.3 — proposed: WHO-UMC methods; ISoP journal Drug Safety
Regulatory framework and GVP overview	**Intermediate**	EMA GVP Module I (2012)
Scientific writing and publication **PROPOSED**	**Intermediate**	No anchor in v0.3 — proposed: ICMJE Recommendations
Training, education and capacity building **VERIFY**	**Basic**	WHO PV curriculum — citation imprecise

48. Medication Safety Officer

Code **S.H.MSO** *Scientific · Healthcare* **DRAFT** competency standard

Also known as: Drug Safety Officer; PV Clinical Officer

v2: Generated DRAFT, now on the Healthcare (hospital medication-safety) template. The earlier finding — no Healthcare template, so this hospital role inherited the industry "data-management" topics — is RESOLVED: role-specific topics are re-authored for a hospital setting. Sources verified against their issuing bodies and refreshed to the in-force version; confirm each topic→source fit and the proposed levels on review.

Job description — v2 (revised wording)

- Work with medical, pharmacy, nursing and other relevant healthcare staff.
- Guide the design, implementation, maintenance and evaluation of safe medication-use systems within the hospital.
- Work collaboratively across the healthcare team, including pharmacists, nursing and medical leadership, on patient safety.
- Assess medication-use processes, identify opportunities to improve medication safety, and design and implement practice changes for system failures.
- Serve as subject-matter expert for medication-safety initiatives and investigate, implement and monitor them collaboratively.
- Foster respectful, collaborative working relationships across the care team.
- Develop and deliver relevant training.

Competency claims with verified sources

General Knowledge

Competency claim (knowledge topic)	Level	Verified source
Pharmacovigilance principles and GVP overview **CURRENCY**	**Intermediate**	EMA GVP Module I (2012); Reg (EC) 726/2004 & Dir 2001/83/EC, as amended
The PV system and PSMF	**Intermediate**	EMA GVP Module II (Rev 2, 2017)
ICSR management and regulatory reporting timelines **CURRENCY**	**Intermediate**	EMA GVP Module VI (Rev 2, 2017); ICH E2D(R1); ICH E2B(R3)

Role-Specific Knowledge

Re-authored for a hospital medication-safety setting (medication-error management; hospital ADR reporting; WHO patient-safety resources).

Competency claim (knowledge topic)	Level	Verified source
Medication error and adverse-drug-event management in healthcare settings **NEW CITATION**	**Expert**	EMA Good practice guide on recording, coding, reporting and assessment of medication errors (EMA/762563/2014, 2015)
Reporting of adverse drug reactions to national spontaneous-reporting systems	**Expert**	EMA GVP Module VI (Rev 2, 2017)
Safe medication-use systems and patient safety **NEW CITATION**	**Intermediate**	WHO Medication Without Harm — Global Patient Safety Challenge (WHO/HIS/SDS/2017.6, 2017)
Root-cause analysis and medication-safety improvement **MANAGEMENT COMPETENCY**	**Intermediate**	Hospital patient-safety practice — no single external regulatory source
Training, education and capacity building	**Basic**	WHO PV Core Curriculum for University Teaching (van Eekeren et al., Drug Saf 2018)

Technical

Roles that operate and administer PV systems, data entry, coding and quality processes.

27 roles

49. Safety Database Specialist

Code **T.I.DM.ITS.SDS** *Technical · Industry · PV IT Systems* **DRAFT** competency standard

> *v2: Job description tightened ("clinical"→"safety" database; adds data integrity); ALCOA+ now cited (MHRA/FDA), validation anchored to GAMP 5 2nd Ed., E2D refreshed to E2D(R1).*

Job description — v2 (revised wording)

- Perform database-administration activities and provide technical expertise on pharmacovigilance systems, including planning and validation.
- Serve as subject-matter expert for pharmacovigilance systems and their application integrations.
- Manage the computerised pharmacovigilance system.
- Conduct database-build user acceptance testing (UAT) and maintain quality-controlled, validated build documentation.
- Oversee the overall quality and integrity of the safety database.
- Use data to help determine root causes and identify trends to prevent recurrence.
- Provide support on operational and policy aspects of safety databases: configuration, data entry, dictionary values, application packages, event-reporting procedures and troubleshooting.
- Work closely with the division lead to ensure standardisation and accuracy of all data entered into and retrieved from the safety databases.

Competency claims with verified sources

General Knowledge

Competency claim (knowledge topic)	Level	Verified source
Pharmacovigilance principles and the PV system	**Intermediate**	EMA GVP Module I (2012)
ICSR data model and E2B(R3) structure	**Expert**	ICH E2B(R3) Implementation Guide v5.02 (2016)
Data-integrity principles (ALCOA+) **NEW CITATIONS**	**Expert**	MHRA GxP Data Integrity Guidance (2018); FDA Data Integrity & CGMP Q&A (2018)

Role-Specific Knowledge

Competency claim (knowledge topic)	Level	Verified source
Safety-database administration and configuration	**Expert**	ISPE GAMP 5, 2nd Ed. (2022)
Computer-system validation and UAT	**Expert**	ISPE GAMP 5, 2nd Ed. (2022)
Dictionary management (MedDRA, WHODrug) and coding up-versioning	**Intermediate**	MedDRA v29.0 (2026), MSSO; WHODrug Global, WHO-UMC
System integrations, gateways and reporting rules **CURRENCY**	**Intermediate**	EMA GVP Module VI (Rev 2, 2017); ICH E2B(R3); ICH E2D(R1)
Change control and documentation practices	**Intermediate**	ISPE GAMP 5, 2nd Ed. (2022)

50. IT PV Systems Supervisor

Code **T.I.DM.ITS.ITSS** *Technical · Industry · PV IT Systems* **DRAFT** competency standard

> *v2: Proposed citation mapping: each topic is paired with a source drawn from the verified base (all sources checked against their issuing body, 2026-07-12) and refreshed to the in-force version — confirm each topic→source fit on review. Blank-note gaps are filled and misfit template topics flagged. Job description and proficiency levels are unchanged from v0.3 for this role.*

Job description (v0.3 wording retained)

- Lead, track, and actively contribute to compiling SDLC throughout the development.
- Lead project's creation, validation, and configuration. Gather functional and technical requirements. Provide configuration solutions to support the case processing and reporting.
- Lead safety database and associated systems upgrades/patches for the IT team, including project planning, testing and implementation.
- Use familiarity with knowledge management techniques to support file migration to dedicated repositories.
- Manage the computerized PV System.
- Participate in inspection/audit related readiness activities and provide support for internal and external PV audits.
- Contribute, participate, and support team meetings, including materials preparation, meeting minutes writing, and action item tracking.

Competency claims with verified sources

General Knowledge

Competency claim (knowledge topic)	Level	Verified source
Pharmacovigilance principles and Good Pharmacovigilance Practices (GVP) overview	**Basic**	EMA GVP Module I (2012); Dir 2001/83/EC (as amended by Dir 2010/84/EU); Reg (EC) 726/2004 (as amended by Reg (EU) 1235/2010)
The pharmacovigilance system and Pharmacovigilance System Master File (PSMF)	**Intermediate**	EMA GVP Module II (Rev 2, 2017); Comm. Impl. Reg (EU) 520/2012, as amended
Individual case safety report (ICSR) management and regulatory reporting timelines	**Intermediate**	EMA GVP Module VI (Rev 2, 2017); ICH E2D(R1) (in force EU 18 Mar 2026); ICH E2B(R3) (v5.02, 2016)

Role-Specific Knowledge *Includes topics derived from this role's job description.*

Competency claim (knowledge topic)	Level	Verified source
Safety database administration and configuration	**Expert**	ICH E2B(R3) (v5.02, 2016); EMA EudraVigilance
Computer-system validation (CSV) and UAT	**Expert**	EU GMP Annex 11 — Computerised Systems (EudraLex Vol. 4, 2011); ISPE GAMP 5, 2nd Ed. (2022)
PSMF and Safety Data Exchange Agreements (SDEA)	**Intermediate**	EMA GVP Module II (Rev 2, 2017); EMA GVP Module I (2012)
System integrations, gateways and reporting rules	**Intermediate**	ICH E2B(R3) (v5.02, 2016); EMA EudraVigilance
Audits and regulatory inspections	**Intermediate**	EMA GVP Module IV (Rev 1, 2015); EMA GVP Module III (Rev 1, 2014)
ICSR lifecycle: receipt, triage,	**Intermediate**	EMA GVP Module VI (Rev 2, 2017)

Competency claim (knowledge topic)	Level	Verified source
data entry, quality control		

51. Data Entry Specialist

Code **T.I.DM.DE.DES** *Technical · Industry · Data Entry* **DRAFT** competency standard

Also known as: Medical Data Entry Specialist; Data Control Specialist

v2: Generated DRAFT (data-entry template — a good fit). Job description grammar fixed ("Entry data of"→"Enter … data"; SAE expanded); ALCOA+ citation gap filled and ICH E2D refreshed to E2D(R1).

Job description — v2 (revised wording)

- Handle case receipt / book-in: monitor inboxes for new cases, run duplicate checks, book cases into the safety database, attach electronic source documents and create/retrieve case files.
- Enter serious adverse event (SAE) data within strict regulatory and internal timelines.
- Drive quality and efficiency to meet data-management timelines and milestones, collaborating with cross-functional teams.
- Perform monthly maintenance and reconciliation of trackers for exchanged safety data.
- Run standard database searches/outputs to support clinical-safety database reconciliation.
- Support the identification of corrections and updates in the safety database following medical review.
- Participate in inspection- and audit-readiness activities and support internal and external pharmacovigilance audits.

Competency claims with verified sources

General Knowledge

Competency claim (knowledge topic)	Level	Verified source
Pharmacovigilance principles and GVP overview **CURRENCY**	**Basic**	EMA GVP Module I (2012); Reg (EC) 726/2004 & Dir 2001/83/EC, as amended
The PV system and PSMF	**Intermediate**	EMA GVP Module II (Rev 2, 2017)
ICSR management and regulatory reporting timelines **CURRENCY**	**Intermediate**	EMA GVP Module VI (Rev 2, 2017); ICH E2D(R1); ICH E2B(R3)

Role-Specific Knowledge *Includes topics derived from this role's job description.*

Competency claim (knowledge topic)	Level	Verified source
Case receipt, book-in and duplicate detection	**Expert**	EMA GVP Module VI (Rev 2, 2017), incl. Addendum I — duplicate management
MedDRA and WHODrug coding of terms and products	**Intermediate**	MedDRA v29.0 (2026), MSSO; WHODrug Global (WHO-UMC)
Regulatory and internal case-processing timelines **CURRENCY**	**Intermediate**	EMA GVP Module VI (Rev 2, 2017); ICH E2D(R1)
Data integrity principles (ALCOA+) **NEW CITATIONS**	**Basic**	MHRA GxP Data Integrity (2018); FDA Data Integrity & CGMP Q&A (2018)
Audits and regulatory inspections	**Intermediate**	EMA GVP Module IV (Rev 1, 2015); Module III (Rev 1, 2014)
Safety-database administration and configuration	**Intermediate**	ICH E2B(R3); EMA EudraVigilance
Medical review of ICSRs: seriousness, expectedness,	**Intermediate**	EMA GVP Module VI (Rev 2, 2017); ICH E2A

Competency claim (knowledge topic)	Level	Verified source
causality		

52. Terminology Coder

Code **T.I.DM.DE.TC** *Technical · Industry · Data Entry* **DRAFT** competency standard

Also known as: Medical Coder; Clinical Coder

> *v2: Proposed citation mapping: each topic is paired with a source drawn from the verified base (all sources checked against their issuing body, 2026-07-12) and refreshed to the in-force version — confirm each topic→source fit on review. Blank-note gaps are filled and misfit template topics flagged. Job description and proficiency levels are unchanged from v0.3 for this role.*

Job description (v0.3 wording retained)

- Responsible for AE coding using standardized terminology from a medical coding dictionary, such as MedDRA.
- Assist in gathering SAEs reports in a timely manner in the preparation of both internal and external RSI safety reports per internal SOPs.
- Medical code into standard dictionaries and writing of narratives based on information provided both on standard forms and from medical records and other documents of diseases and medications.
- Maintain coding processes, procedures, and training materials in compliance with global GCP and GVP requirements, internal quality standards and quality management system.
- Develop a consistent medical coding strategy for worldwide use across the global safety database.
- Develop and maintain coding convention materials; liaise with relevant company’s staff as well as other divisions in implementing coding standards.
- Review and assess the mapping of terms that are not auto encoded.
- Manage and maintain the MedDRA synonym list.
- Create coding conventions reviews.
- Maintain the Library of Standardised MedDRA Queries.
- Generate and review reports to support MedDRA coding.
- Develop coding conventions required across safety databases and develop coding conventions and associated reports to support oversight and consistency of coding where necessary supporting specific coding strategy.
- Manage medical terminologies in different product documents, including labelling information, package insert, etc.
- Assist with coding efforts associated with various reports.
- Execute auto-batch update of terms when necessary.
- Maintain EOI/Search Strategies and update as needed.
- Manage the communication of key coding synonym list changes to applicable stakeholders.
- Provide feedback regarding improper coding.
- Participate in inspection/audit related readiness activities and provide support for internal and external PV audits.
- Contribute, participate, and support team meetings, including materials preparation, meeting minutes writing, and action item tracking.

Competency claims with verified sources

General Knowledge

Competency claim (knowledge topic)	Level	Verified source
Pharmacovigilance principles and Good Pharmacovigilance Practices (GVP) overview	**Basic**	EMA GVP Module I (2012); Dir 2001/83/EC (as amended by Dir 2010/84/EU); Reg (EC) 726/2004 (as amended by Reg (EU) 1235/2010)
The pharmacovigilance system and Pharmacovigilance System Master File (PSMF)	**Intermediate**	EMA GVP Module II (Rev 2, 2017); Comm. Impl. Reg (EU) 520/2012, as amended
Individual case safety report (ICSR) management and regulatory reporting timelines	**Intermediate**	EMA GVP Module VI (Rev 2, 2017); ICH E2D(R1) (in force EU 18 Mar 2026); ICH E2B(R3) (v5.02, 2016)

Role-Specific Knowledge

Includes topics derived from this role's job description.

Competency claim (knowledge topic)	Level	Verified source
Case receipt, book-in and duplicate detection	**Expert**	EMA GVP Module VI (Rev 2, 2017), incl. Addendum I — Duplicate management
MedDRA and WHODrug coding of terms and products	**Intermediate**	MedDRA (ICH/MSSO; v29.0, Mar 2026); WHODrug Global (WHO-UMC)
Regulatory and internal case-processing timelines	**Intermediate**	EMA GVP Module VI (Rev 2, 2017); ICH E2D(R1) (in force EU 18 Mar 2026)
Data integrity principles (ALCOA+) **NEW CITATION**	**Basic**	MHRA 'GXP' Data Integrity (2018); FDA Data Integrity (2018) — ALCOA+; EU GMP Annex 11 — Computerised Systems (EudraLex Vol. 4, 2011)
Audits and regulatory inspections	**Intermediate**	EMA GVP Module IV (Rev 1, 2015); EMA GVP Module III (Rev 1, 2014)
MedDRA and WHODrug coding conventions	**Intermediate**	MedDRA (ICH/MSSO; v29.0, Mar 2026); WHODrug Global (WHO-UMC)
Safety database administration and configuration	**Intermediate**	ICH E2B(R3) (v5.02, 2016); EMA EudraVigilance
Training, education and capacity building	**Basic**	WHO PV Core Curriculum for University Teaching (van Eekeren et al., Drug Saf 2018)
PV quality management system (GVP Module I)	**Intermediate**	EMA GVP Module I (2012); Comm. Impl. Reg (EU) 520/2012, as amended

53. Product Coder

Code **T.I.DM.DE.PC** *Technical · Industry · Data Entry* **DRAFT** competency standard

> *v2: Proposed citation mapping: each topic is paired with a source drawn from the verified base (all sources checked against their issuing body, 2026-07-12) and refreshed to the in-force version — confirm each topic→source fit on review. Blank-note gaps are filled and misfit template topics flagged. Job description and proficiency levels are unchanged from v0.3 for this role.*

Job description (v0.3 wording retained)

- Responsible for coding reported drugs verbatim originated from postmarketing data and clinical development data in individual case safety reports and other PV regulatory documents.
- Validate and classify drug information in controlled vocabulary/adopted drug dictionaries to ensure the completeness, accuracy, and consistency of the reported drug verbatim from postmarketing experience or clinical development data.
- Use internal tools and systems as well as external references to find information about correct trade names and marketing authorisation holder information and identifying substances and ATC assignments.
- Develop and maintain an internal repository of synonyms of medical products and/or actions to be used in mapping drug verbatim or auto-coding or auto-actioned.
- Create and update customized drug groupings either independently or via amending implemented standardized drug groupings, as appropriate.
- Contribute to the development of internal coding conventions of medicinal products, with specific considerations, eg., (prodrugs, chemotherapy regimens, non-unique trade names, umbrella terms, diagnostic agents/non– drug therapies, etc.).
- May participate in decisions relating to the retirement of certain adopted customized drug groupings.
- If applicable, contribute to writing stringent coding guidelines for coding concomitant drugs within PV study protocols, including the development of the prohibited list of medications.
- Flag non-unique trade names to the relevant PV scientist or study team.
- Support internal stakeholders and external business partners with questions relevant to drug/vaccine coded data.
- Cooperate with internal stakeholders and external business partners via providing custom drug queries when requested to support analysis of PV data.
- Might contribute with external stakeholders as a working group member to the development of standardized drug groupings.
- Participate in inspection/audit related readiness activities and provide support for internal and external PV audits.
- Contribute, participate, and support team meetings, including materials preparation, meeting minutes writing, and action item tracking.

Competency claims with verified sources

General Knowledge

Competency claim (knowledge topic)	Level	Verified source
Pharmacovigilance principles and Good Pharmacovigilance Practices (GVP) overview	**Basic**	EMA GVP Module I (2012); Dir 2001/83/EC (as amended by Dir 2010/84/EU); Reg (EC) 726/2004 (as amended by Reg (EU) 1235/2010)
The pharmacovigilance system and Pharmacovigilance System	**Intermediate**	EMA GVP Module II (Rev 2, 2017); Comm. Impl. Reg (EU) 520/2012, as

Competency claim (knowledge topic)	Level	Verified source
Master File (PSMF)		amended
Individual case safety report (ICSR) management and regulatory reporting timelines	**Intermediate**	EMA GVP Module VI (Rev 2, 2017); ICH E2D(R1) (in force EU 18 Mar 2026); ICH E2B(R3) (v5.02, 2016)

Role-Specific Knowledge

Includes topics derived from this role's job description.

Competency claim (knowledge topic)	Level	Verified source
Case receipt, book-in and duplicate detection	**Expert**	EMA GVP Module VI (Rev 2, 2017), incl. Addendum I — Duplicate management
MedDRA and WHODrug coding of terms and products	**Intermediate**	MedDRA (ICH/MSSO; v29.0, Mar 2026); WHODrug Global (WHO-UMC)
Regulatory and internal case-processing timelines	**Intermediate**	EMA GVP Module VI (Rev 2, 2017); ICH E2D(R1) (in force EU 18 Mar 2026)
Data integrity principles (ALCOA+) NEW CITATION	**Basic**	MHRA 'GXP' Data Integrity (2018); FDA Data Integrity (2018) — ALCOA+; EU GMP Annex 11 — Computerised Systems (EudraLex Vol. 4, 2011)
Audits and regulatory inspections	**Intermediate**	EMA GVP Module IV (Rev 1, 2015); EMA GVP Module III (Rev 1, 2014)
MedDRA and WHODrug coding conventions	**Intermediate**	MedDRA (ICH/MSSO; v29.0, Mar 2026); WHODrug Global (WHO-UMC)
ICSR lifecycle: receipt, triage, data entry, quality control	**Intermediate**	EMA GVP Module VI (Rev 2, 2017)
PV policy, legislation and guideline development	**Intermediate**	Dir 2001/83/EC (as amended by Dir 2010/84/EU); Reg (EC) 726/2004 (as amended by Reg (EU) 1235/2010)

54. Data Entry Supervisor

Code **T.I.DM.DE.DESUP** *Technical · Industry · Data Entry* **DRAFT** competency standard

> *v2: Proposed citation mapping: each topic is paired with a source drawn from the verified base (all sources checked against their issuing body, 2026-07-12) and refreshed to the in-force version — confirm each topic→source fit on review. Blank-note gaps are filled and misfit template topics flagged. Job description and proficiency levels are unchanged from v0.3 for this role.*

Job description (v0.3 wording retained)

- Provide oversight of data management projects to ensure high-quality deliverables.
- Collaborate with Project Management, Clinical Operations, Quality Control, Quality Assurance, PV, and other divisions on data management aspects of projects and support project teams and staff.
- Supervisory responsibilities include, but are not limited to, providing technical and operational guidance and direction, checking the output of work, ensuring deliverables are met, and administering company policies and performance management.
- Ensure that standards are observed for database administration, database design, data capture and data quality control.
- Lead data transfers (data imports and exports).
- Review data in the electronic data capture (EDC) system against source documents.
- Participate in inspection/audit related readiness activities and provide support for internal and external PV audits.
- Contribute, participate, and support team meetings, including materials preparation, meeting minutes writing, and action item tracking.

Competency claims with verified sources

General Knowledge

Competency claim (knowledge topic)	Level	Verified source
Pharmacovigilance principles and Good Pharmacovigilance Practices (GVP) overview	**Basic**	EMA GVP Module I (2012); Dir 2001/83/EC (as amended by Dir 2010/84/EU); Reg (EC) 726/2004 (as amended by Reg (EU) 1235/2010)
The pharmacovigilance system and Pharmacovigilance System Master File (PSMF)	**Intermediate**	EMA GVP Module II (Rev 2, 2017); Comm. Impl. Reg (EU) 520/2012, as amended
Individual case safety report (ICSR) management and regulatory reporting timelines	**Intermediate**	EMA GVP Module VI (Rev 2, 2017); ICH E2D(R1) (in force EU 18 Mar 2026); ICH E2B(R3) (v5.02, 2016)

Role-Specific Knowledge *Includes topics derived from this role's job description.*

Competency claim (knowledge topic)	Level	Verified source
Case receipt, book-in and duplicate detection	**Expert**	EMA GVP Module VI (Rev 2, 2017), incl. Addendum I — Duplicate management
MedDRA and WHODrug coding of terms and products	**Intermediate**	MedDRA (ICH/MSSO; v29.0, Mar 2026); WHODrug Global (WHO-UMC)
Regulatory and internal case-processing timelines	**Intermediate**	EMA GVP Module VI (Rev 2, 2017); ICH E2D(R1) (in force EU 18 Mar 2026)
Data integrity principles (ALCOA+) **NEW CITATION**	**Basic**	MHRA 'GXP' Data Integrity (2018); FDA Data Integrity (2018) — ALCOA+; EU GMP Annex 11 —

Competency claim (knowledge topic)	Level	Verified source
		Computerised Systems (EudraLex Vol. 4, 2011)
Audits and regulatory inspections	**Intermediate**	EMA GVP Module IV (Rev 1, 2015); EMA GVP Module III (Rev 1, 2014)
Safety database administration and configuration	**Intermediate**	ICH E2B(R3) (v5.02, 2016); EMA EudraVigilance

55. Signal Management Administrator

Code **T.I.SM.SMA** *Technical · Industry · Signal Management* **DRAFT** competency standard

v2: Proposed citation mapping: each topic is paired with a source drawn from the verified base (all sources checked against their issuing body, 2026-07-12) and refreshed to the in-force version — confirm each topic→source fit on review. Blank-note gaps are filled and misfit template topics flagged. Job description and proficiency levels are unchanged from v0.3 for this role.

Job description (v0.3 wording retained)

- Identify and assess (validate) new safety signals and trends by conducting systematic reviews of aggregate data with a focus on spontaneous adverse event reports.
- Prepare reviews of topics and summary analysis reports of safety data.
- Provide recommendations for further signal evaluation.
- Work on implementing product-specific surveillance plans.
- Participate as a member of the matrix teams to address product-specific safety issues, assist in the development of signal evaluation strategies, and participate in signal evaluation.
- Communicate findings from routine and ad hoc signal detection and assessment activities.
- Assist in the development and implementation of programmatic surveillance of adverse event reports for potential safety and product quality issues.
- Assist in the evaluation of novel, computer-assisted tools, and methodologies for the analysis of safety data, including piloting new data sources and methodologies.
- Participate in inspection/audit related readiness activities and provide support for internal and external PV audits.
- Contribute, participate, and support team meetings, including materials preparation, meeting minutes writing, and action item tracking.

Competency claims with verified sources

General Knowledge

Competency claim (knowledge topic)	Level	Verified source
Pharmacovigilance principles and Good Pharmacovigilance Practices (GVP) overview	**Basic**	EMA GVP Module I (2012); Dir 2001/83/EC (as amended by Dir 2010/84/EU); Reg (EC) 726/2004 (as amended by Reg (EU) 1235/2010)
The pharmacovigilance system and Pharmacovigilance System Master File (PSMF)	**Intermediate**	EMA GVP Module II (Rev 2, 2017); Comm. Impl. Reg (EU) 520/2012, as amended
Individual case safety report (ICSR) management and regulatory reporting timelines	**Intermediate**	EMA GVP Module VI (Rev 2, 2017); ICH E2D(R1) (in force EU 18 Mar 2026); ICH E2B(R3) (v5.02, 2016)

Role-Specific Knowledge *Includes topics derived from this role's job description.*

Competency claim (knowledge topic)	Level	Verified source
Signal management process (GVP Module IX)	**Expert**	EMA GVP Module IX (Rev 1, 2017)
Signal detection methodologies and disproportionality analysis **NEW CITATION**	**Expert**	EMA GVP Module IX (Rev 1, 2017) Addendum I; CIOMS Working Group VIII (2010); Evans et al. PRR (Pharmacoepidemiol Drug Saf 2001)
Signal validation, assessment	**Intermediate**	EMA GVP Module IX (Rev 1, 2017)

Competency claim (knowledge topic)	Level	Verified source
and prioritisation		
Aggregate safety data sources and their limitations	**Intermediate**	CIOMS Working Group VIII (2010)
Audits and regulatory inspections	**Intermediate**	EMA GVP Module IV (Rev 1, 2015); EMA GVP Module III (Rev 1, 2014)

56. Risk Management Administrator

Code **T.I.RM.RMA** *Technical · Industry · Risk Management* **DRAFT** competency standard

Also known as: Risk System Administrator; Risk Operation Administrator

v2: Proposed citation mapping: each topic is paired with a source drawn from the verified base (all sources checked against their issuing body, 2026-07-12) and refreshed to the in-force version — confirm each topic→source fit on review. Blank-note gaps are filled and misfit template topics flagged. Job description and proficiency levels are unchanged from v0.3 for this role.

Job description (v0.3 wording retained)

- Participate in REMS meetings and manage the development, implementation and/or maintenance of RMPs/REMS.
- Ensure timely execution of operational aspects of REMS and related activities.
- Monitor the external environment for regulatory changes impacting PV and risk management.
- Perform and contribute to safety analyses through review of case series, tabulated data and/or AE trend information for assigned product(s).
- Contribute to document authoring, describing the evaluated safety data.
- Perform and contribute with more senior scientists and safety physicians to signal detection activities and the signal management process.
- Collaborate with more senior scientists and safety physicians on risk management activities.
- Participate in the review of medical/scientific literature to identify literature relevant for signal detection activities and aggregate reporting.
- Participate in the preparation of aggregate safety.
- Contribute to the creation and maintenance of the RSI and company core labelling.
- Contribute to a health authority or safety-related query responses.
- Participate in inspection/audit related readiness activities and provide support for internal and external PV audits.
- Contribute, participate, and support team meetings, including materials preparation, meeting minutes writing, and action item tracking.

Competency claims with verified sources

General Knowledge

Competency claim (knowledge topic)	Level	Verified source
Pharmacovigilance principles and Good Pharmacovigilance Practices (GVP) overview	**Basic**	EMA GVP Module I (2012); Dir 2001/83/EC (as amended by Dir 2010/84/EU); Reg (EC) 726/2004 (as amended by Reg (EU) 1235/2010)
The pharmacovigilance system and Pharmacovigilance System Master File (PSMF)	**Intermediate**	EMA GVP Module II (Rev 2, 2017); Comm. Impl. Reg (EU) 520/2012, as amended
Individual case safety report (ICSR) management and regulatory reporting timelines	**Intermediate**	EMA GVP Module VI (Rev 2, 2017); ICH E2D(R1) (in force EU 18 Mar 2026); ICH E2B(R3) (v5.02, 2016)

Role-Specific Knowledge *Includes topics derived from this role's job description.*

Competency claim (knowledge topic)	Level	Verified source
Risk management planning (GVP Module V): RMP structure and	**Expert**	EMA GVP Module V (Rev 2, 2017)

Competency claim (knowledge topic)	Level	Verified source
lifecycle		
Risk minimisation measures and REMS CURRENCY	**Expert**	EMA GVP Module XVI (Rev 3, 2024); FDA REMS — FDAAA 2007, FD&C Act §505-1
Benefit–risk assessment methodology	**Intermediate**	ICH E2C(R2) (PBRER)
Post-authorisation safety studies (PASS/PAES)	**Intermediate**	EMA GVP Module VIII (Rev 3, 2017)
Signal management process (GVP Module IX)	**Intermediate**	EMA GVP Module IX (Rev 1, 2017)
Aggregate safety reports (PBRER/PSUR, DSUR)	**Intermediate**	EMA GVP Module VII (Rev 1, 2013); ICH E2C(R2) (PBRER); ICH E2F (DSUR, Step 4 2010)
Audits and regulatory inspections	**Intermediate**	EMA GVP Module IV (Rev 1, 2015); EMA GVP Module III (Rev 1, 2014)
Literature monitoring and review	**Basic**	EMA GVP Module VI (Rev 2, 2017) — literature monitoring

57. PV Quality Assurance Administrator

Code **T.I.QA.QAA** *Technical · Industry · Quality Assurance* **DRAFT** competency standard

Also known as: PV Regulatory Compliance; Clinical QA Associate; Quality Auditor

v2: Proposed citation mapping: each topic is paired with a source drawn from the verified base (all sources checked against their issuing body, 2026-07-12) and refreshed to the in-force version — confirm each topic→source fit on review. Blank-note gaps are filled and misfit template topics flagged. Job description and proficiency levels are unchanged from v0.3 for this role.

Job description (v0.3 wording retained)

- Ensure that standards are observed for database administration, database design, data capture and data quality control.
- Support quality management activities to ensure compliance with local and international safety requirements and regulatory inspection readiness in collaboration with QA.
- Support the management of the documentation system.
- Support identification of gaps, risks, and opportunities for continuous improvement of the QMS and work on their remediation and implementation respectively.
- Responsible for identifying training needs and supporting development and training conduct.
- Participate in inspection/audit related readiness activities and provide support for internal and external PV audits.
- Contribute, participate, and support team meetings, including materials preparation, meeting minutes writing, and action item tracking.

Competency claims with verified sources

General Knowledge

Competency claim (knowledge topic)	Level	Verified source
Pharmacovigilance principles and Good Pharmacovigilance Practices (GVP) overview	**Basic**	EMA GVP Module I (2012); Dir 2001/83/EC (as amended by Dir 2010/84/EU); Reg (EC) 726/2004 (as amended by Reg (EU) 1235/2010)
The pharmacovigilance system and Pharmacovigilance System Master File (PSMF)	**Intermediate**	EMA GVP Module II (Rev 2, 2017); Comm. Impl. Reg (EU) 520/2012, as amended
Individual case safety report (ICSR) management and regulatory reporting timelines	**Intermediate**	EMA GVP Module VI (Rev 2, 2017); ICH E2D(R1) (in force EU 18 Mar 2026); ICH E2B(R3) (v5.02, 2016)

Role-Specific Knowledge *Includes topics derived from this role's job description.*

Competency claim (knowledge topic)	Level	Verified source
PV quality management system (GVP Module I)	**Expert**	EMA GVP Module I (2012); Comm. Impl. Reg (EU) 520/2012, as amended
Audits and regulatory inspections	**Expert**	EMA GVP Module IV (Rev 1, 2015); EMA GVP Module III (Rev 1, 2014)
CAPA (corrective and preventive action) management	**Intermediate**	EMA GVP Module IV (Rev 1, 2015)
Deviation and non-compliance handling	**Intermediate**	EMA GVP Module I (2012)
Safety database administration	**Intermediate**	ICH E2B(R3) (v5.02, 2016); EMA

Competency claim (knowledge topic)	Level	Verified source
and configuration		EudraVigilance
Training, education and capacity building	**Basic**	WHO PV Core Curriculum for University Teaching (van Eekeren et al., Drug Saf 2018)

58. PV Auditor

Code **T.I.QA.AUD** *Technical · Industry · Quality Assurance* **DRAFT** competency standard

> *v2: Proposed citation mapping: each topic is paired with a source drawn from the verified base (all sources checked against their issuing body, 2026-07-12) and refreshed to the in-force version — confirm each topic→source fit on review. Blank-note gaps are filled and misfit template topics flagged. Job description and proficiency levels are unchanged from v0.3 for this role.*

Job description (v0.3 wording retained)

- Responsible for management and conduct of internal audits of the PV system and partners with PV responsibilities.
- Develop and maintain the PV audit strategy.
- Develop the annual audit schedule for PV audits based on annual risk assessments and PV audit strategy plan.
- Lead, plan, conduct PV audits, and report out of both routine and for-cause/ad hoc PV audits in accordance with the approved schedule.
- Deliver PV audit reports and review and/or approve proposed CAPA plans in accordance with internal timelines.
- Maintain responsibility for and oversight of audits conducted by PV contractors, when applicable. This includes identifying suitable PV audit consultants, working with Procurement to establish contracts and providing relevant training in accordance with company procedures.
- Participate in PV inspections in core and supporting roles, assist with the preparation and delivery of appropriate training materials, advise and contribute to interview coaching.
- Contribute to quality standards of internal cross-functional processes.
- Interpret and apply PV-related regulations/policies to processes and decisions made when required; provide cross-training to other team members in matters of PV, when appropriate.
- Cooperate with the audited functions and provide advice and support where required in the execution of remediation actions (CAPAs) to ensure compliance with regulatory and quality expectations and requirements.
- Approve CAPAs and regularly review progress and provide ongoing support in all PV compliance matters.
- Contribute to the QA team by conducting peer-review of audit reports conducted by other team members.
- Contribute to the continuous improvement and maintenance of the QA and QMS by writing relevant SOPs and guidance documents.
- Provide expertise to enhance audit tools and templates in PV and update PV report templates, checklists, and other documents as required.
- Act as subject matter expert to provide expertise and knowledge to less experienced auditors, business partners and company entities on quality and compliance processes/procedures.
- Maintain and enhance quality audit standards and procedures for the harmonized audit process.
- Complete all training requirements in a timely manner.
- Responsible for ongoing maintenance of personal training records to ensure audit and inspection readiness at all times.
- Contribute, participate, and support team meetings, including materials preparation, meeting minutes writing, and action item tracking.

Competency claims with verified sources

General Knowledge

Competency claim (knowledge topic)	Level	Verified source
Pharmacovigilance principles and Good Pharmacovigilance Practices (GVP) overview	**Basic**	EMA GVP Module I (2012); Dir 2001/83/EC (as amended by Dir 2010/84/EU); Reg (EC) 726/2004 (as amended by Reg (EU) 1235/2010)
The pharmacovigilance system and Pharmacovigilance System Master File (PSMF)	**Intermediate**	EMA GVP Module II (Rev 2, 2017); Comm. Impl. Reg (EU) 520/2012, as amended
Individual case safety report (ICSR) management and regulatory reporting timelines	**Intermediate**	EMA GVP Module VI (Rev 2, 2017); ICH E2D(R1) (in force EU 18 Mar 2026); ICH E2B(R3) (v5.02, 2016)

Role-Specific Knowledge *Includes topics derived from this role's job description.*

Competency claim (knowledge topic)	Level	Verified source
PV quality management system (GVP Module I)	**Expert**	EMA GVP Module I (2012); Comm. Impl. Reg (EU) 520/2012, as amended
Audits and regulatory inspections	**Expert**	EMA GVP Module IV (Rev 1, 2015); EMA GVP Module III (Rev 1, 2014)
CAPA (corrective and preventive action) management	**Intermediate**	EMA GVP Module IV (Rev 1, 2015)
Deviation and non-compliance handling	**Intermediate**	EMA GVP Module I (2012)
Training, education and capacity building	**Basic**	WHO PV Core Curriculum for University Teaching (van Eekeren et al., Drug Saf 2018)

59. PSMF Administrator

Code **T.I.PVS.PSMF** *Technical · Industry · PV Systems* **DRAFT** competency standard

Also known as: PSMF Specialist; PSMF Associate

> *v2: Proposed citation mapping: each topic is paired with a source drawn from the verified base (all sources checked against their issuing body, 2026-07-12) and refreshed to the in-force version — confirm each topic→source fit on review. Blank-note gaps are filled and misfit template topics flagged. Job description and proficiency levels are unchanged from v0.3 for this role.*

Job description (v0.3 wording retained)

- Maintenance of the PSMF.
- Schedule data requirements for the PSMF.
- Coordinate the call for information/email reminders to contributors ahead of due dates for submission.
- Ensure that contributors have completed appropriate quality control review of all content provided for inclusion in the PSMF.
- Liaise with other global functions to collate required information within timelines.
- Circulate sections of PSMF and annexes as appropriate for review.
- Coordinate final quality review of the PSMF after an update and prior to it.
- Upload completed PSMF and PSMF Summary into the document management system and ensure contributing documentation is archived in accordance with relevant SOP.
- Liaise with concerned parties to ensure providing appropriate updates to the PSMF in accordance with the applicable GVP guidelines.
- Support QPPV oversight of submission of the PSMF.
- Develop and maintain a tracker of requests for the PSMF and Summary PSMF.
- Actively maintain awareness of any updates in regulatory requirements regarding local and regional PSMFs and ensure these are reflected in the applicable PSMF.
- Participate in inspection/audit related readiness activities and provide support for internal and external PV audits.
- Contribute, participate, and support team meetings, including materials preparation, meeting minutes writing, and action item tracking.

Competency claims with verified sources

General Knowledge

Competency claim (knowledge topic)	Level	Verified source
Pharmacovigilance principles and Good Pharmacovigilance Practices (GVP) overview	**Basic**	EMA GVP Module I (2012); Dir 2001/83/EC (as amended by Dir 2010/84/EU); Reg (EC) 726/2004 (as amended by Reg (EU) 1235/2010)
The pharmacovigilance system and Pharmacovigilance System Master File (PSMF)	**Intermediate**	EMA GVP Module II (Rev 2, 2017); Comm. Impl. Reg (EU) 520/2012, as amended
Individual case safety report (ICSR) management and regulatory reporting timelines	**Intermediate**	EMA GVP Module VI (Rev 2, 2017); ICH E2D(R1) (in force EU 18 Mar 2026); ICH E2B(R3) (v5.02, 2016)

Role-Specific Knowledge *Includes topics derived from this role's job description.*

Competency claim (knowledge topic)	Level	Verified source
Safety database administration and configuration	**Expert**	ICH E2B(R3) (v5.02, 2016); EMA EudraVigilance

Competency claim (knowledge topic)	Level	Verified source
Computer-system validation (CSV) and UAT	**Expert**	EU GMP Annex 11 — Computerised Systems (EudraLex Vol. 4, 2011); ISPE GAMP 5, 2nd Ed. (2022)
PSMF and Safety Data Exchange Agreements (SDEA)	**Intermediate**	EMA GVP Module II (Rev 2, 2017); EMA GVP Module I (2012)
System integrations, gateways and reporting rules	**Intermediate**	ICH E2B(R3) (v5.02, 2016); EMA EudraVigilance
Audits and regulatory inspections	**Intermediate**	EMA GVP Module IV (Rev 1, 2015); EMA GVP Module III (Rev 1, 2014)
PV policy, legislation and guideline development	**Intermediate**	Dir 2001/83/EC (as amended by Dir 2010/84/EU); Reg (EC) 726/2004 (as amended by Reg (EU) 1235/2010)

60. SDEA Administrator

Code **T.I.PVS.SDEA** *Technical · Industry · PV Systems* **DRAFT** competency standard

v2: Proposed citation mapping: each topic is paired with a source drawn from the verified base (all sources checked against their issuing body, 2026-07-12) and refreshed to the in-force version — confirm each topic→source fit on review. Blank-note gaps are filled and misfit template topics flagged. Job description and proficiency levels are unchanged from v0.3 for this role.

Job description (v0.3 wording retained)

- Responsible for an effective and rational set-up and maintenance of SDEA and PV clauses in Master Agreements consistently with internal standards, national and international regulation.
- Responsible for effective communication with relevant stakeholders, both internal and external.
- Gain consensus; negotiate SDEAs; end-to-end process including tracking and archiving.
- Support PV teams in the implementation of SDEAs.
- SDEA compliance monitoring (Periodic Partner Reviews, contact up-dates)
- Participate in inspection/audit related readiness activities and provide support for internal and external PV audits.
- Contribute, participate, and support team meetings, including materials preparation, meeting minutes writing, and action item tracking.

Competency claims with verified sources

General Knowledge

Competency claim (knowledge topic)	Level	Verified source
Pharmacovigilance principles and Good Pharmacovigilance Practices (GVP) overview	**Basic**	EMA GVP Module I (2012); Dir 2001/83/EC (as amended by Dir 2010/84/EU); Reg (EC) 726/2004 (as amended by Reg (EU) 1235/2010)
The pharmacovigilance system and Pharmacovigilance System Master File (PSMF)	**Intermediate**	EMA GVP Module II (Rev 2, 2017); Comm. Impl. Reg (EU) 520/2012, as amended
Individual case safety report (ICSR) management and regulatory reporting timelines	**Intermediate**	EMA GVP Module VI (Rev 2, 2017); ICH E2D(R1) (in force EU 18 Mar 2026); ICH E2B(R3) (v5.02, 2016)

Role-Specific Knowledge

Includes topics derived from this role's job description.

Competency claim (knowledge topic)	Level	Verified source
Safety database administration and configuration	**Expert**	ICH E2B(R3) (v5.02, 2016); EMA EudraVigilance
Computer-system validation (CSV) and UAT	**Expert**	EU GMP Annex 11 — Computerised Systems (EudraLex Vol. 4, 2011); ISPE GAMP 5, 2nd Ed. (2022)
PSMF and Safety Data Exchange Agreements (SDEA)	**Intermediate**	EMA GVP Module II (Rev 2, 2017); EMA GVP Module I (2012)
System integrations, gateways and reporting rules	**Intermediate**	ICH E2B(R3) (v5.02, 2016); EMA EudraVigilance
Aggregate safety reports (PBRER/PSUR, DSUR)	**Intermediate**	EMA GVP Module VII (Rev 1, 2013); ICH E2C(R2) (PBRER); ICH E2F (DSUR, Step 4 2010)
Audits and regulatory inspections	**Intermediate**	EMA GVP Module IV (Rev 1, 2015); EMA GVP Module III (Rev 1, 2014)

61. Local Responsible Person

Code **T.I.PVS.LRP** *Technical · Industry · PV Systems* **DRAFT** competency standard

Also known as: LSR – Local Safety Responsible; LPPV – Local Contact Person for PV

> *v2: Proposed citation mapping: each topic is paired with a source drawn from the verified base (all sources checked against their issuing body, 2026-07-12) and refreshed to the in-force version — confirm each topic→source fit on review. Blank-note gaps are filled and misfit template topics flagged. Job description and proficiency levels are unchanged from v0.3 for this role.*

Job description (v0.3 wording retained)

- Act as a single contact point for the NCA on a 24-hour basis, if applicable.
- Oversee the local PV system for collection and reporting of safety information to the concerned NCA.
- Monitor local literature for relevant safety information.
- Oversee PSMF, its content and maintenance, and ensure the availability of the PSMF to the NCA, if applicable.
- Aware of safety profiles and any emerging safety concerns in relation to the medicinal products for which the MAH holds authorizations.
- Inform about local requirements and needs for local access in regards to information about all suspected adverse events that have been reported to employees of the MAH.
- Coordinate the provision of support for third party safety agreements with PV implications at the local level and ensure the PV agreement is implemented locally, as appropriate.
- Collaborate with RA to forward any safety-related inquiry or relevant communication from the local RA to the appropriate global and regional groups as appropriate. Collaborate with appropriate departments to identify the resources and expertise needed to address the question. This may include local, regional and/or global expertise.
- Collaboration with MA for the review and approval of safety aspects of local study protocols or PSP to ensure appropriate safety reporting to appropriate case management centres and RAs, as required.
- Provide technical and strategic input and participate in projects led by the regional PV team and international PV workstreams.
- Contribute, participate, and support team meetings, including materials preparation, meeting minutes writing, and action item tracking.
- Participate in inspection/audit related readiness activities and provide support for internal and external PV audits.

Competency claims with verified sources

General Knowledge

Competency claim (knowledge topic)	Level	Verified source
Pharmacovigilance principles and Good Pharmacovigilance Practices (GVP) overview	**Basic**	EMA GVP Module I (2012); Dir 2001/83/EC (as amended by Dir 2010/84/EU); Reg (EC) 726/2004 (as amended by Reg (EU) 1235/2010)
The pharmacovigilance system and Pharmacovigilance System Master File (PSMF)	**Intermediate**	EMA GVP Module II (Rev 2, 2017); Comm. Impl. Reg (EU) 520/2012, as amended
Individual case safety report (ICSR) management and regulatory reporting timelines	**Intermediate**	EMA GVP Module VI (Rev 2, 2017); ICH E2D(R1) (in force EU 18 Mar 2026); ICH E2B(R3) (v5.02, 2016)

Role-Specific Knowledge *Includes topics derived from this role's job description.*

Competency claim (knowledge topic)	Level	Verified source
Safety database administration and configuration	**Expert**	ICH E2B(R3) (v5.02, 2016); EMA EudraVigilance
Computer-system validation (CSV) and UAT	**Expert**	EU GMP Annex 11 — Computerised Systems (EudraLex Vol. 4, 2011); ISPE GAMP 5, 2nd Ed. (2022)
PSMF and Safety Data Exchange Agreements (SDEA)	**Intermediate**	EMA GVP Module II (Rev 2, 2017); EMA GVP Module I (2012)
System integrations, gateways and reporting rules	**Intermediate**	ICH E2B(R3) (v5.02, 2016); EMA EudraVigilance
Audits and regulatory inspections	**Intermediate**	EMA GVP Module IV (Rev 1, 2015); EMA GVP Module III (Rev 1, 2014)
ICSR lifecycle: receipt, triage, data entry, quality control	**Intermediate**	EMA GVP Module VI (Rev 2, 2017)
Literature monitoring and review	**Basic**	EMA GVP Module VI (Rev 2, 2017) — literature monitoring
Budgeting, resourcing and business continuity **MANAGEMENT COMPETENCY (NO EXTERNAL REGULATORY SOURCE)**	**Intermediate**	—

62. PV Studies Administrator

Code **T.I.DCS.SA** *Technical · Industry · Data Collection Schemes* **DRAFT** competency standard

Also known as: PV Officer

> *v2: Proposed citation mapping: each topic is paired with a source drawn from the verified base (all sources checked against their issuing body, 2026-07-12) and refreshed to the in-force version — confirm each topic→source fit on review. Blank-note gaps are filled and misfit template topics flagged. Job description and proficiency levels are unchanged from v0.3 for this role.*

Job description (v0.3 wording retained)

- Set up, design, and maintain the study files.
- Develop, review, and edit studies related documentation including but not limited to Case Report Forms, Informed Consent Forms, study-specific handbooks, guidelines, and checklists.
- Oblige to notify the start and end of the safety study to regulatory authorities.
- Responsible for submission of a study protocol, submission of a final report as soon as possible within 12 months of the end of the data collection.
- Monitor studies to ensure absolute adherence to GVPs.
- Assist with study protocol design, development and/or review, if required.
- Complete and compile all necessary study documentation and information to gain appropriate regulatory and ethics committees' approval, where required.
- Perform pre-study initiation, interim monitoring, and closeout visits as required.
- Liaise with the Principal Investigator, clinical operations staff and Sponsor representatives as required.
- Organise/attend investigator meetings as required.
- Prepare monitoring status reports for the Sponsor.
- Archive study documentation and correspondence.
- Participate in inspection/audit related readiness activities and provide support for internal and external PV audits.

Competency claims with verified sources

General Knowledge

Competency claim (knowledge topic)	Level	Verified source
Pharmacovigilance principles and Good Pharmacovigilance Practices (GVP) overview	**Basic**	EMA GVP Module I (2012); Dir 2001/83/EC (as amended by Dir 2010/84/EU); Reg (EC) 726/2004 (as amended by Reg (EU) 1235/2010)
The pharmacovigilance system and Pharmacovigilance System Master File (PSMF)	**Intermediate**	EMA GVP Module II (Rev 2, 2017); Comm. Impl. Reg (EU) 520/2012, as amended
Individual case safety report (ICSR) management and regulatory reporting timelines	**Intermediate**	EMA GVP Module VI (Rev 2, 2017); ICH E2D(R1) (in force EU 18 Mar 2026); ICH E2B(R3) (v5.02, 2016)

Role-Specific Knowledge *Includes topics derived from this role's job description.*

Competency claim (knowledge topic)	Level	Verified source
Pharmacoepidemiology study design (PASS/PAES)	**Expert**	EMA GVP Module VIII (Rev 3, 2017); ENCePP Guide on Methodological Standards (Rev 11, 2023); STROBE Statement (von Elm et al., 2007)

Competency claim (knowledge topic)	Level	Verified source
Real-world evidence (RWE) and data sources	**Intermediate**	ENCePP Guide on Methodological Standards (Rev 11, 2023)
Biostatistics and study analysis **NEW CITATION**	**Intermediate**	ICH E9 (1998) / E9(R1) estimands (2019)
GVP Module VIII (post-authorisation safety studies)	**Intermediate**	EMA GVP Module VIII (Rev 3, 2017)
Audits and regulatory inspections	**Intermediate**	EMA GVP Module IV (Rev 1, 2015); EMA GVP Module III (Rev 1, 2014)
PV policy, legislation and guideline development	**Intermediate**	Dir 2001/83/EC (as amended by Dir 2010/84/EU); Reg (EC) 726/2004 (as amended by Reg (EU) 1235/2010)

63. Safety Database Specialist

Code **T.RA.DM.ITS.SDS** *Technical · Regulatory Authority · PV IT Systems* **DRAFT** competency standard

> *v2: Proposed citation mapping: each topic is paired with a source drawn from the verified base (all sources checked against their issuing body, 2026-07-12) and refreshed to the in-force version — confirm each topic→source fit on review. Blank-note gaps are filled and misfit template topics flagged. Job description and proficiency levels are unchanged from v0.3 for this role.*

Job description (v0.3 wording retained)

- Responsible for database administration activities, for providing technical expertise on PV systems, including planning and validation.
- Serve as a subject matter expert for PV systems and associated application integrations.
- Manage the computerized PV System.
- May conduct database build UAT and maintain quality-controlled database build documentation.
- Oversee the overall quality of the database.
- Use data to help determine mishap causes and identify trends to prevent mishaps.
- Provide support in matters relating to operational and policy aspects of safety databases.
- Contribute to transparency and communication initiatives through the provision of scientifically rigorous and consistent information to promote the safe and effective use of medicines.
- Liaise with and provide technical information, advice, and guidance on relevant PV matters to other regulatory colleagues, pharmaceutical companies, relevant national and international bodies, healthcare professionals and members of the public.
- Support external compliance monitoring with PV obligations.
- Participate at all levels (internally and externally) in the formulation and preparation of regulatory policies, guidelines, legislation, and opinions.
- Contribute, participate, and support team meetings, including materials preparation, meeting minutes writing, and action item tracking.

Competency claims with verified sources

General Knowledge

Competency claim (knowledge topic)	Level	Verified source
Pharmacovigilance principles and Good Pharmacovigilance Practices (GVP) overview	**Basic**	EMA GVP Module I (2012); Dir 2001/83/EC (as amended by Dir 2010/84/EU); Reg (EC) 726/2004 (as amended by Reg (EU) 1235/2010)
The pharmacovigilance system and Pharmacovigilance System Master File (PSMF)	**Intermediate**	EMA GVP Module II (Rev 2, 2017); Comm. Impl. Reg (EU) 520/2012, as amended
Individual case safety report (ICSR) management and regulatory reporting timelines	**Intermediate**	EMA GVP Module VI (Rev 2, 2017); ICH E2D(R1) (in force EU 18 Mar 2026); ICH E2B(R3) (v5.02, 2016)

Role-Specific Knowledge *Includes topics derived from this role's job description.*

Competency claim (knowledge topic)	Level	Verified source
Safety database administration and configuration	**Expert**	ICH E2B(R3) (v5.02, 2016); EMA EudraVigilance

Competency claim (knowledge topic)	Level	Verified source
Computer-system validation (CSV) and UAT	**Expert**	EU GMP Annex 11 — Computerised Systems (EudraLex Vol. 4, 2011); ISPE GAMP 5, 2nd Ed. (2022)
PSMF and Safety Data Exchange Agreements (SDEA)	**Intermediate**	EMA GVP Module II (Rev 2, 2017); EMA GVP Module I (2012)
System integrations, gateways and reporting rules	**Intermediate**	ICH E2B(R3) (v5.02, 2016); EMA EudraVigilance
PV policy, legislation and guideline development	**Intermediate**	Dir 2001/83/EC (as amended by Dir 2010/84/EU); Reg (EC) 726/2004 (as amended by Reg (EU) 1235/2010)

64. IT PV Systems Supervisor

Code **T.RA.DM.ITS.ITSS** *Technical · Regulatory Authority · PV IT Systems* **DRAFT** competency standard

v2: Proposed citation mapping: each topic is paired with a source drawn from the verified base (all sources checked against their issuing body, 2026-07-12) and refreshed to the in-force version — confirm each topic→source fit on review. Blank-note gaps are filled and misfit template topics flagged. Job description and proficiency levels are unchanged from v0.3 for this role.

Job description (v0.3 wording retained)

- Support the Head of PV Systems to manage change control and validation efforts to maintain validated PV AE systems in compliance with Computer Systems Validation Policy and Computer Systems Validation Guidelines.
- Provide technical expertise.
- Work with Business Users to compile, validate and run searches of the database.
- Assist Head of PV Systems in troubleshooting issues.
- Support local, regional, and global users as a system administrator.
- Review and writing of relevant system administrator SOPs and WINs.
- Contribute to transparency and communication initiatives through the provision of scientifically rigorous and consistent information to promote the safe and effective use of medicines.
- Liaise with and provide technical information, advice, and guidance on PV matters to other regulatory colleagues, pharmaceutical companies, relevant national and international bodies, healthcare professionals and members of the public.
- Support external compliance monitoring with PV obligations.
- Participate at all levels (internally and externally) in the formulation and preparation of regulatory policies, guidelines, legislation, and opinions.
- Contribute, participate, and support team meetings, including materials preparation, meeting minutes writing, and action item tracking.

Competency claims with verified sources

General Knowledge

Competency claim (knowledge topic)	Level	Verified source
Pharmacovigilance principles and Good Pharmacovigilance Practices (GVP) overview	**Basic**	EMA GVP Module I (2012); Dir 2001/83/EC (as amended by Dir 2010/84/EU); Reg (EC) 726/2004 (as amended by Reg (EU) 1235/2010)
The pharmacovigilance system and Pharmacovigilance System Master File (PSMF)	**Intermediate**	EMA GVP Module II (Rev 2, 2017); Comm. Impl. Reg (EU) 520/2012, as amended
Individual case safety report (ICSR) management and regulatory reporting timelines	**Intermediate**	EMA GVP Module VI (Rev 2, 2017); ICH E2D(R1) (in force EU 18 Mar 2026); ICH E2B(R3) (v5.02, 2016)

Role-Specific Knowledge *Includes topics derived from this role's job description.*

Competency claim (knowledge topic)	Level	Verified source
Safety database administration and configuration	**Expert**	ICH E2B(R3) (v5.02, 2016); EMA EudraVigilance
Computer-system validation (CSV) and UAT	**Expert**	EU GMP Annex 11 — Computerised Systems (EudraLex Vol. 4, 2011); ISPE GAMP 5, 2nd Ed. (2022)

Competency claim (knowledge topic)	Level	Verified source
PSMF and Safety Data Exchange Agreements (SDEA)	**Intermediate**	EMA GVP Module II (Rev 2, 2017); EMA GVP Module I (2012)
System integrations, gateways and reporting rules	**Intermediate**	ICH E2B(R3) (v5.02, 2016); EMA EudraVigilance
PV policy, legislation and guideline development	**Intermediate**	Dir 2001/83/EC (as amended by Dir 2010/84/EU); Reg (EC) 726/2004 (as amended by Reg (EU) 1235/2010)

65. Data Entry Specialist

Code **T.RA.DM.DE.DES** *Technical · Regulatory Authority · Data Entry* **DRAFT** competency standard

Also known as: Medical Data Entry Specialist; Data Control Specialist

v2: Proposed citation mapping: each topic is paired with a source drawn from the verified base (all sources checked against their issuing body, 2026-07-12) and refreshed to the in-force version — confirm each topic→source fit on review. Blank-note gaps are filled and misfit template topics flagged. Job description and proficiency levels are unchanged from v0.3 for this role.

Job description (v0.3 wording retained)

- Responsible for case receipt/book-in processes. This includes monitoring email boxes for new cases, performing duplicate checks, booking cases into the safety database, attaching electronic source documents, as well as creating/retrieving case file folders.
- Perform standard database searches/output in support of clinical-safety database reconciliation, as well for routine recurring monthly requests safety data.
- May assist with monthly maintenance and reconciliation of various trackers.
- Contribute to transparency and communication initiatives through the provision of scientifically rigorous and consistent information to promote the safe and effective use of medicines.
- Liaise with and provide technical information, advice, and guidance on PV matters to other regulatory colleagues, pharmaceutical companies, relevant national and international bodies, healthcare professionals and members of the public.
- Support external compliance monitoring with PV obligations.
- Participate at all levels (internally and externally) in the formulation and preparation of regulatory policies, guidelines, legislation, and opinions.
- Contribute, participate, and support team meetings, including materials preparation, meeting minutes writing, and action item tracking.

Competency claims with verified sources

General Knowledge

Competency claim (knowledge topic)	Level	Verified source
Pharmacovigilance principles and Good Pharmacovigilance Practices (GVP) overview	**Basic**	EMA GVP Module I (2012); Dir 2001/83/EC (as amended by Dir 2010/84/EU); Reg (EC) 726/2004 (as amended by Reg (EU) 1235/2010)
The pharmacovigilance system and Pharmacovigilance System Master File (PSMF)	**Intermediate**	EMA GVP Module II (Rev 2, 2017); Comm. Impl. Reg (EU) 520/2012, as amended
Individual case safety report (ICSR) management and regulatory reporting timelines	**Intermediate**	EMA GVP Module VI (Rev 2, 2017); ICH E2D(R1) (in force EU 18 Mar 2026); ICH E2B(R3) (v5.02, 2016)

Role-Specific Knowledge *Includes topics derived from this role's job description.*

Competency claim (knowledge topic)	Level	Verified source
Case receipt, book-in and duplicate detection	**Expert**	EMA GVP Module VI (Rev 2, 2017), incl. Addendum I — Duplicate management
MedDRA and WHODrug coding of terms and products	**Intermediate**	MedDRA (ICH/MSSO; v29.0, Mar 2026); WHODrug Global (WHO-UMC)
Regulatory and internal case-processing timelines	**Intermediate**	EMA GVP Module VI (Rev 2, 2017); ICH E2D(R1) (in force EU 18 Mar

Competency claim (knowledge topic)	Level	Verified source
		2026)
Data integrity principles (ALCOA+) **NEW CITATION**	**Basic**	MHRA 'GXP' Data Integrity (2018); FDA Data Integrity (2018) — ALCOA+; EU GMP Annex 11 — Computerised Systems (EudraLex Vol. 4, 2011)
Safety database administration and configuration	**Intermediate**	ICH E2B(R3) (v5.02, 2016); EMA EudraVigilance
ICSR lifecycle: receipt, triage, data entry, quality control	**Intermediate**	EMA GVP Module VI (Rev 2, 2017)
PV policy, legislation and guideline development	**Intermediate**	Dir 2001/83/EC (as amended by Dir 2010/84/EU); Reg (EC) 726/2004 (as amended by Reg (EU) 1235/2010)

66. Terminology Coder

Code **T.RA.DM.DE.TC** *Technical · Regulatory Authority · Data Entry* **DRAFT** competency standard

Also known as: Medical Coder; Clinical Coder

> *v2: Proposed citation mapping: each topic is paired with a source drawn from the verified base (all sources checked against their issuing body, 2026-07-12) and refreshed to the in-force version — confirm each topic→source fit on review. Blank-note gaps are filled and misfit template topics flagged. Job description and proficiency levels are unchanged from v0.3 for this role.*

Job description (v0.3 wording retained)

- Maintain coding processes, procedures, and training materials in compliance with global GCP, GVP requirements, and other relevant regulatory requirements.
- Develop a consistent medical coding strategy for worldwide use across the global safety database.
- Develop and maintain coding convention materials.
- Review and assess the mapping of terms that are not auto encoded.
- Manage and maintain the MedDRA synonym list.
- Create coding conventions reviews.
- Maintain the Library of Standardised MedDRA Queries.
- When necessary, develop and maintain the custom MedDRA queries.
- Generate and review reports to support MedDRA coding.
- Assist with coding efforts associated with various reports.
- Execute auto-batch update of terms when necessary.
- Provide feedback regarding improper coding.
- Ensure that all pre and post MedDRA upgrade tasks are completed.
- Facilitate effective coordination around MedDRA understanding and utilization across relevant departments and provide training on medical coding as required.
- Liaise with and provide technical information, advice, and guidance on PV matters to other regulatory colleagues, pharmaceutical companies, relevant national and international bodies, healthcare professionals and members of the public.
- Support external compliance monitoring with PV obligations.
- Participate at all levels (internally and externally) in the formulation and preparation of regulatory policies, guidelines, legislation, and opinions.
- Contribute, participate, and support team meetings, including materials preparation, meeting minutes writing, and action item tracking.

Competency claims with verified sources

General Knowledge

Competency claim (knowledge topic)	Level	Verified source
Pharmacovigilance principles and Good Pharmacovigilance Practices (GVP) overview	**Basic**	EMA GVP Module I (2012); Dir 2001/83/EC (as amended by Dir 2010/84/EU); Reg (EC) 726/2004 (as amended by Reg (EU) 1235/2010)
The pharmacovigilance system and Pharmacovigilance System Master File (PSMF)	**Intermediate**	EMA GVP Module II (Rev 2, 2017); Comm. Impl. Reg (EU) 520/2012, as amended
Individual case safety report (ICSR) management and regulatory reporting timelines	**Intermediate**	EMA GVP Module VI (Rev 2, 2017); ICH E2D(R1) (in force EU 18 Mar 2026); ICH E2B(R3) (v5.02, 2016)

Role-Specific Knowledge *Includes topics derived from this role's job description.*

Competency claim (knowledge topic)	Level	Verified source
Case receipt, book-in and duplicate detection	**Expert**	EMA GVP Module VI (Rev 2, 2017), incl. Addendum I — Duplicate management
MedDRA and WHODrug coding of terms and products	**Intermediate**	MedDRA (ICH/MSSO; v29.0, Mar 2026); WHODrug Global (WHO-UMC)
Regulatory and internal case-processing timelines	**Intermediate**	EMA GVP Module VI (Rev 2, 2017); ICH E2D(R1) (in force EU 18 Mar 2026)
Data integrity principles (ALCOA+) **NEW CITATION**	**Basic**	MHRA 'GXP' Data Integrity (2018); FDA Data Integrity (2018) — ALCOA+; EU GMP Annex 11 — Computerised Systems (EudraLex Vol. 4, 2011)
MedDRA and WHODrug coding conventions	**Intermediate**	MedDRA (ICH/MSSO; v29.0, Mar 2026); WHODrug Global (WHO-UMC)
Safety database administration and configuration	**Intermediate**	ICH E2B(R3) (v5.02, 2016); EMA EudraVigilance
Training, education and capacity building	**Basic**	WHO PV Core Curriculum for University Teaching (van Eekeren et al., Drug Saf 2018)
PV policy, legislation and guideline development	**Intermediate**	Dir 2001/83/EC (as amended by Dir 2010/84/EU); Reg (EC) 726/2004 (as amended by Reg (EU) 1235/2010)

67. Product Coder

Code **T.RA.DM.DE.PC** *Technical · Regulatory Authority · Data Entry* **DRAFT** competency standard

v2: Proposed citation mapping: each topic is paired with a source drawn from the verified base (all sources checked against their issuing body, 2026-07-12) and refreshed to the in-force version — confirm each topic→source fit on review. Blank-note gaps are filled and misfit template topics flagged. Job description and proficiency levels are unchanged from v0.3 for this role.

Competency claims with verified sources

General Knowledge

Competency claim (knowledge topic)	Level	Verified source
Pharmacovigilance principles and Good Pharmacovigilance Practices (GVP) overview	**Basic**	EMA GVP Module I (2012); Dir 2001/83/EC (as amended by Dir 2010/84/EU); Reg (EC) 726/2004 (as amended by Reg (EU) 1235/2010)
The pharmacovigilance system and Pharmacovigilance System Master File (PSMF)	**Intermediate**	EMA GVP Module II (Rev 2, 2017); Comm. Impl. Reg (EU) 520/2012, as amended
Individual case safety report (ICSR) management and regulatory reporting timelines	**Intermediate**	EMA GVP Module VI (Rev 2, 2017); ICH E2D(R1) (in force EU 18 Mar 2026); ICH E2B(R3) (v5.02, 2016)

Role-Specific Knowledge

Competency claim (knowledge topic)	Level	Verified source
Case receipt, book-in and duplicate detection	**Expert**	EMA GVP Module VI (Rev 2, 2017), incl. Addendum I — Duplicate management
MedDRA and WHODrug coding of terms and products	**Intermediate**	MedDRA (ICH/MSSO; v29.0, Mar 2026); WHODrug Global (WHO-UMC)
Regulatory and internal case-processing timelines	**Intermediate**	EMA GVP Module VI (Rev 2, 2017); ICH E2D(R1) (in force EU 18 Mar 2026)
Data integrity principles (ALCOA+) **NEW CITATION**	**Basic**	MHRA 'GXP' Data Integrity (2018); FDA Data Integrity (2018) — ALCOA+; EU GMP Annex 11 — Computerised Systems (EudraLex Vol. 4, 2011)

68. Data Entry Supervisor

Code **T.RA.DM.DE.DESUP** *Technical · Regulatory Authority · Data Entry* **DRAFT** competency standard

> *v2: Proposed citation mapping: each topic is paired with a source drawn from the verified base (all sources checked against their issuing body, 2026-07-12) and refreshed to the in-force version — confirm each topic→source fit on review. Blank-note gaps are filled and misfit template topics flagged. Job description and proficiency levels are unchanged from v0.3 for this role.*

Job description (v0.3 wording retained)

- Provide oversight of data entry management to ensure high-quality deliverables.
- Ensure that standards are observed for database administration, database design, data capture and data quality control.
- Lead data transfers (data imports and exports).
- Review data in the electronic data capture (EDC) system against source documents.
- Contribute to transparency and communication initiatives through the provision of scientifically rigorous and consistent information to promote the safe and effective use of medicines.
- Liaise with and provide technical information, advice, and guidance on PV matters to other regulatory colleagues, pharmaceutical companies, relevant national and international bodies, healthcare professionals and members of the public.
- Support external compliance monitoring with PV obligations.
- Participate at all levels (internally and externally) in the formulation and preparation of regulatory policies, guidelines, legislation, and opinions.
- Contribute, participate, and support team meetings, including materials preparation, meeting minutes writing, and action item tracking.

Competency claims with verified sources

General Knowledge

Competency claim (knowledge topic)	Level	Verified source
Pharmacovigilance principles and Good Pharmacovigilance Practices (GVP) overview	**Basic**	EMA GVP Module I (2012); Dir 2001/83/EC (as amended by Dir 2010/84/EU); Reg (EC) 726/2004 (as amended by Reg (EU) 1235/2010)
The pharmacovigilance system and Pharmacovigilance System Master File (PSMF)	**Intermediate**	EMA GVP Module II (Rev 2, 2017); Comm. Impl. Reg (EU) 520/2012, as amended
Individual case safety report (ICSR) management and regulatory reporting timelines	**Intermediate**	EMA GVP Module VI (Rev 2, 2017); ICH E2D(R1) (in force EU 18 Mar 2026); ICH E2B(R3) (v5.02, 2016)

Role-Specific Knowledge *Includes topics derived from this role's job description.*

Competency claim (knowledge topic)	Level	Verified source
Case receipt, book-in and duplicate detection	**Expert**	EMA GVP Module VI (Rev 2, 2017), incl. Addendum I — Duplicate management
MedDRA and WHODrug coding of terms and products	**Intermediate**	MedDRA (ICH/MSSO; v29.0, Mar 2026); WHODrug Global (WHO-UMC)
Regulatory and internal case-processing timelines	**Intermediate**	EMA GVP Module VI (Rev 2, 2017); ICH E2D(R1) (in force EU 18 Mar 2026)
Data integrity principles	**Basic**	MHRA 'GXP' Data Integrity (2018);

Competency claim (knowledge topic)	Level	Verified source
(ALCOA+) **NEW CITATION**		FDA Data Integrity (2018) — ALCOA+; EU GMP Annex 11 — Computerised Systems (EudraLex Vol. 4, 2011)
Safety database administration and configuration	**Intermediate**	ICH E2B(R3) (v5.02, 2016); EMA EudraVigilance
PV policy, legislation and guideline development	**Intermediate**	Dir 2001/83/EC (as amended by Dir 2010/84/EU); Reg (EC) 726/2004 (as amended by Reg (EU) 1235/2010)

69. Signal Management Administrator

Code **T.RA.SM.SMA** *Technical · Regulatory Authority · Signal Management* **DRAFT** competency standard

> *v2: Proposed citation mapping: each topic is paired with a source drawn from the verified base (all sources checked against their issuing body, 2026-07-12) and refreshed to the in-force version — confirm each topic→source fit on review. Blank-note gaps are filled and misfit template topics flagged. Job description and proficiency levels are unchanged from v0.3 for this role.*

Job description (v0.3 wording retained)

- Ensure adheres to and is aligned with relevant regulations regarding signal management practices.
- Support creation of signal management strategy for the department.
- Serve as an expert for internal signal tracking tools.
- Support creation of signal metrics and reports for management.
- Support oversight of the Data mining process. Implementation of data mining. Oversee data mining runs and tracking outputs and signals.
- Maintain respective standards and schedules and ensure state of the art signal detection methodology.
- Serve as a subject matter expert on Signal management.
- Contribute to cross-functional initiatives aimed to improve PV capabilities related to signal detection.
- Contribute to transparency and communication initiatives through the provision of scientifically rigorous and consistent information to promote the safe and effective use of medicines.
- Liaise with and provide technical information, advice, and guidance on PV matters to other regulatory colleagues, pharmaceutical companies, relevant national and international bodies, healthcare professionals and members of the public.
- Support external compliance monitoring with PV obligations.
- Participate at all levels (internally and externally) in the formulation and preparation of regulatory policies, guidelines, legislation, and opinions.
- Contribute, participate, and support team meetings, including materials preparation, meeting minutes writing, and action item tracking.

Competency claims with verified sources

General Knowledge

Competency claim (knowledge topic)	Level	Verified source
Pharmacovigilance principles and Good Pharmacovigilance Practices (GVP) overview	**Basic**	EMA GVP Module I (2012); Dir 2001/83/EC (as amended by Dir 2010/84/EU); Reg (EC) 726/2004 (as amended by Reg (EU) 1235/2010)
The pharmacovigilance system and Pharmacovigilance System Master File (PSMF)	**Intermediate**	EMA GVP Module II (Rev 2, 2017); Comm. Impl. Reg (EU) 520/2012, as amended
Individual case safety report (ICSR) management and regulatory reporting timelines	**Intermediate**	EMA GVP Module VI (Rev 2, 2017); ICH E2D(R1) (in force EU 18 Mar 2026); ICH E2B(R3) (v5.02, 2016)

Role-Specific Knowledge *Includes topics derived from this role's job description.*

Competency claim (knowledge topic)	Level	Verified source
Signal management process	**Expert**	EMA GVP Module IX (Rev 1, 2017)

Competency claim (knowledge topic)	Level	Verified source
(GVP Module IX)		
Signal detection methodologies and disproportionality analysis **NEW CITATION**	**Expert**	EMA GVP Module IX (Rev 1, 2017) Addendum I; CIOMS Working Group VIII (2010); Evans et al. PRR (Pharmacoepidemiol Drug Saf 2001)
Signal validation, assessment and prioritisation	**Intermediate**	EMA GVP Module IX (Rev 1, 2017)
Aggregate safety data sources and their limitations	**Intermediate**	CIOMS Working Group VIII (2010)
PV policy, legislation and guideline development	**Intermediate**	Dir 2001/83/EC (as amended by Dir 2010/84/EU); Reg (EC) 726/2004 (as amended by Reg (EU) 1235/2010)

70. Risk Management Administrator

Code **T.RA.RM.RMA** *Technical · Regulatory Authority · Risk Management* **DRAFT** competency standard

Also known as: Risk System Administrator; Risk Operation Administrator

v2: Proposed citation mapping: each topic is paired with a source drawn from the verified base (all sources checked against their issuing body, 2026-07-12) and refreshed to the in-force version — confirm each topic→source fit on review. Blank-note gaps are filled and misfit template topics flagged. Job description and proficiency levels are unchanged from v0.3 for this role.

Job description (v0.3 wording retained)

- Perform and contribute to safety analyses through review of case series, tabulated data and/or AE trend information for assigned products.
- Perform and contribute with more senior scientists and safety physicians to signal detection activities.
- Participate in the review of medical/scientific literature to identify literature relevant for signal detection activities and aggregate reporting.
- Contribute to transparency and communication initiatives through the provision of scientifically rigorous and consistent information to promote the safe and effective use of medicines.
- Liaise with and provide technical information, advice, and guidance on PV matters to other regulatory colleagues, pharmaceutical companies, relevant national and international bodies, healthcare professionals and members of the public.
- Support external compliance monitoring with PV obligations.
- Participate at all levels (internally and externally) in the formulation and preparation of regulatory policies, guidelines, legislation, and opinions.
- Contribute, participate, and support team meetings, including materials preparation, meeting minutes writing, and action item tracking.

Competency claims with verified sources

General Knowledge

Competency claim (knowledge topic)	Level	Verified source
Pharmacovigilance principles and Good Pharmacovigilance Practices (GVP) overview	**Basic**	EMA GVP Module I (2012); Dir 2001/83/EC (as amended by Dir 2010/84/EU); Reg (EC) 726/2004 (as amended by Reg (EU) 1235/2010)
The pharmacovigilance system and Pharmacovigilance System Master File (PSMF)	**Intermediate**	EMA GVP Module II (Rev 2, 2017); Comm. Impl. Reg (EU) 520/2012, as amended
Individual case safety report (ICSR) management and regulatory reporting timelines	**Intermediate**	EMA GVP Module VI (Rev 2, 2017); ICH E2D(R1) (in force EU 18 Mar 2026); ICH E2B(R3) (v5.02, 2016)

Role-Specific Knowledge *Includes topics derived from this role's job description.*

Competency claim (knowledge topic)	Level	Verified source
Risk management planning (GVP Module V): RMP structure and lifecycle	**Expert**	EMA GVP Module V (Rev 2, 2017)
Risk minimisation measures and REMS **CURRENCY**	**Expert**	EMA GVP Module XVI (Rev 3, 2024); FDA REMS — FDAAA 2007, FD&C Act §505-1
Benefit–risk assessment methodology	**Intermediate**	ICH E2C(R2) (PBRER)

Competency claim (knowledge topic)	Level	Verified source
Post-authorisation safety studies (PASS/PAES)	**Intermediate**	EMA GVP Module VIII (Rev 3, 2017)
Signal management process (GVP Module IX)	**Intermediate**	EMA GVP Module IX (Rev 1, 2017)
Aggregate safety reports (PBRER/PSUR, DSUR)	**Intermediate**	EMA GVP Module VII (Rev 1, 2013); ICH E2C(R2) (PBRER); ICH E2F (DSUR, Step 4 2010)
Literature monitoring and review	**Basic**	EMA GVP Module VI (Rev 2, 2017) — literature monitoring
PV policy, legislation and guideline development	**Intermediate**	Dir 2001/83/EC (as amended by Dir 2010/84/EU); Reg (EC) 726/2004 (as amended by Reg (EU) 1235/2010)

71. PSMF Assessor

Code **T.RA.PVS.PSMF** *Technical · Regulatory Authority · PV Systems* **DRAFT** competency standard

> *v2: Proposed citation mapping: each topic is paired with a source drawn from the verified base (all sources checked against their issuing body, 2026-07-12) and refreshed to the in-force version — confirm each topic→source fit on review. Blank-note gaps are filled and misfit template topics flagged. Job description and proficiency levels are unchanged from v0.3 for this role.*

Job description (v0.3 wording retained)

- Review and evaluate PSMFs.
- Lead and supervise the technical team dealing with AE reporting in line with the goals and objectives of the PV section and the health authority department
- Act as a subject matter expert regarding case processing and associated regulatory and scientific guidance.
- Monitor trends in national reporting of PSMF.
- Collate, evaluate, and present summary overviews of national reporting data.
- Encourage and facilitate adverse reaction reporting by healthcare professionals and patients/consumers.
- Contribute to transparency and communication initiatives through the provision of scientifically rigorous and consistent information to promote the safe and effective use of medicines.
- Liaise with and provide technical information, advice, and guidance on PV matters to other regulatory colleagues, pharmaceutical companies, relevant national and international bodies, healthcare professionals and members of the public.
- Support external compliance monitoring with PV obligations.
- Participate at all levels (internally and externally) in the formulation and preparation of regulatory policies, guidelines, legislation, and opinions.
- Contribute, participate, and support team meetings, including materials preparation, meeting minutes writing, and action item tracking.

Competency claims with verified sources

General Knowledge

Competency claim (knowledge topic)	Level	Verified source
Pharmacovigilance principles and Good Pharmacovigilance Practices (GVP) overview	**Basic**	EMA GVP Module I (2012); Dir 2001/83/EC (as amended by Dir 2010/84/EU); Reg (EC) 726/2004 (as amended by Reg (EU) 1235/2010)
The pharmacovigilance system and Pharmacovigilance System Master File (PSMF)	**Intermediate**	EMA GVP Module II (Rev 2, 2017); Comm. Impl. Reg (EU) 520/2012, as amended
Individual case safety report (ICSR) management and regulatory reporting timelines	**Intermediate**	EMA GVP Module VI (Rev 2, 2017); ICH E2D(R1) (in force EU 18 Mar 2026); ICH E2B(R3) (v5.02, 2016)

Role-Specific Knowledge *Includes topics derived from this role's job description.*

Competency claim (knowledge topic)	Level	Verified source
Safety database administration and configuration	**Expert**	ICH E2B(R3) (v5.02, 2016); EMA EudraVigilance
Computer-system validation (CSV) and UAT	**Expert**	EU GMP Annex 11 — Computerised Systems (EudraLex Vol. 4, 2011); ISPE GAMP 5, 2nd Ed. (2022)

Competency claim (knowledge topic)	Level	Verified source
PSMF and Safety Data Exchange Agreements (SDEA)	**Intermediate**	EMA GVP Module II (Rev 2, 2017); EMA GVP Module I (2012)
System integrations, gateways and reporting rules	**Intermediate**	ICH E2B(R3) (v5.02, 2016); EMA EudraVigilance
ICSR lifecycle: receipt, triage, data entry, quality control	**Intermediate**	EMA GVP Module VI (Rev 2, 2017)
PV policy, legislation and guideline development	**Intermediate**	Dir 2001/83/EC (as amended by Dir 2010/84/EU); Reg (EC) 726/2004 (as amended by Reg (EU) 1235/2010)

72. PV Inspector

Code **T.RA.QA.INSP** *Technical · Regulatory Authority · Quality Assurance* **DRAFT** competency standard

Also known as: PV Auditor

v2: Proposed citation mapping: each topic is paired with a source drawn from the verified base (all sources checked against their issuing body, 2026-07-12) and refreshed to the in-force version — confirm each topic→source fit on review. Blank-note gaps are filled and misfit template topics flagged. Job description and proficiency levels are unchanged from v0.3 for this role.

Job description (v0.3 wording retained)

- Prepare for, organise, and carry out inspections.
- Evaluate complex information, identify relevant standards, and assess compliance.
- Compile inspection reports when acting as a lead inspector, contribute to the preparation of reports for joint or accompanied inspections.
- Assist in the introduction of new legislation, and development of policy and practice guidelines and procedures.
- Contribute to transparency and communication initiatives through the provision of scientifically rigorous and consistent information to promote the safe and effective use of medicines.
- Liaise with and provide technical information, advice, and guidance on PV matters to other regulatory colleagues, pharmaceutical companies, relevant national and international bodies, healthcare professionals and members of the public.
- Support external compliance monitoring with PV obligations.
- Participate at all levels (internally and externally) in the formulation and preparation of regulatory policies, guidelines, legislation, and opinions.
- Contribute, participate, and support team meetings, including materials preparation, meeting minutes writing, and action item tracking.

Competency claims with verified sources

General Knowledge

Competency claim (knowledge topic)	Level	Verified source
Pharmacovigilance principles and Good Pharmacovigilance Practices (GVP) overview	**Basic**	EMA GVP Module I (2012); Dir 2001/83/EC (as amended by Dir 2010/84/EU); Reg (EC) 726/2004 (as amended by Reg (EU) 1235/2010)
The pharmacovigilance system and Pharmacovigilance System Master File (PSMF)	**Intermediate**	EMA GVP Module II (Rev 2, 2017); Comm. Impl. Reg (EU) 520/2012, as amended
Individual case safety report (ICSR) management and regulatory reporting timelines	**Intermediate**	EMA GVP Module VI (Rev 2, 2017); ICH E2D(R1) (in force EU 18 Mar 2026); ICH E2B(R3) (v5.02, 2016)

Role-Specific Knowledge *Includes topics derived from this role's job description.*

Competency claim (knowledge topic)	Level	Verified source
PV quality management system (GVP Module I)	**Expert**	EMA GVP Module I (2012); Comm. Impl. Reg (EU) 520/2012, as amended
Audits and regulatory inspections	**Expert**	EMA GVP Module IV (Rev 1, 2015); EMA GVP Module III (Rev 1, 2014)
CAPA (corrective and preventive action) management	**Intermediate**	EMA GVP Module IV (Rev 1, 2015)

Competency claim (knowledge topic)	Level	Verified source
Deviation and non-compliance handling	**Intermediate**	EMA GVP Module I (2012)
PV policy, legislation and guideline development	**Intermediate**	Dir 2001/83/EC (as amended by Dir 2010/84/EU); Reg (EC) 726/2004 (as amended by Reg (EU) 1235/2010)

73. Data Quality Reviewer

Code **T.RA.QA.DQR** *Technical · Regulatory Authority · Quality Assurance* **DRAFT** competency standard

Also known as: Quality Assurance Technical Data Reviewer; Quality Control Data Reviewer; ICSR Data Reviewer

v2: Proposed citation mapping: each topic is paired with a source drawn from the verified base (all sources checked against their issuing body, 2026-07-12) and refreshed to the in-force version — confirm each topic→source fit on review. Blank-note gaps are filled and misfit template topics flagged. Job description and proficiency levels are unchanged from v0.3 for this role.

Job description (v0.3 wording retained)

- Audit safety data entries and relevant protocols/reports.
- Prepare, collaborate, and review reports regarding findings.
- Coordinate review to ensure that all safety data are collected and archived correctly and according to applicable regulatory requirements.
- Ensure compliance with all relevant regulatory requirements.
- Contribute to transparency and communication initiatives through the provision of scientifically rigorous and consistent information to promote the safe and effective use of medicines.
- Liaise with and provide technical information, advice, and guidance on PV matters to other regulatory colleagues, pharmaceutical companies, relevant national and international bodies, healthcare professionals and members of the public.
- Support external compliance monitoring with PV obligations.
- Participate at all levels (internally and externally) in the formulation and preparation of regulatory policies, guidelines, legislation, and opinions.
- Contribute, participate, and support team meetings, including materials preparation, meeting minutes writing, and action item tracking.

Competency claims with verified sources

General Knowledge

Competency claim (knowledge topic)	Level	Verified source
Pharmacovigilance principles and Good Pharmacovigilance Practices (GVP) overview	**Basic**	EMA GVP Module I (2012); Dir 2001/83/EC (as amended by Dir 2010/84/EU); Reg (EC) 726/2004 (as amended by Reg (EU) 1235/2010)
The pharmacovigilance system and Pharmacovigilance System Master File (PSMF)	**Intermediate**	EMA GVP Module II (Rev 2, 2017); Comm. Impl. Reg (EU) 520/2012, as amended
Individual case safety report (ICSR) management and regulatory reporting timelines	**Intermediate**	EMA GVP Module VI (Rev 2, 2017); ICH E2D(R1) (in force EU 18 Mar 2026); ICH E2B(R3) (v5.02, 2016)

Role-Specific Knowledge *Includes topics derived from this role's job description.*

Competency claim (knowledge topic)	Level	Verified source
PV quality management system (GVP Module I)	**Expert**	EMA GVP Module I (2012); Comm. Impl. Reg (EU) 520/2012, as amended
Audits and regulatory inspections	**Expert**	EMA GVP Module IV (Rev 1, 2015); EMA GVP Module III (Rev 1, 2014)
CAPA (corrective and preventive action) management	**Intermediate**	EMA GVP Module IV (Rev 1, 2015)

Competency claim (knowledge topic)	Level	Verified source
Deviation and non-compliance handling	**Intermediate**	EMA GVP Module I (2012)
PV policy, legislation and guideline development	**Intermediate**	Dir 2001/83/EC (as amended by Dir 2010/84/EU); Reg (EC) 726/2004 (as amended by Reg (EU) 1235/2010)

74. PV Research Administrator

Code **T.A.RA** *Technical · Academia* **DRAFT** competency standard

Also known as: Health Scientist Administrator

> *v2: Proposed citation mapping: each topic is paired with a source drawn from the verified base (all sources checked against their issuing body, 2026-07-12) and refreshed to the in-force version — confirm each topic→source fit on review. Blank-note gaps are filled and misfit template topics flagged. Job description and proficiency levels are unchanged from v0.3 for this role.*

Job description (v0.3 wording retained)

- Responsible for the administrative aspects of EC and CA submissions and subsequent communications and updates.
- Set up and maintain the TMF.
- Manage study material distribution and receipt at appropriate stages of the study.
- Liaise with other relevant departments.
- Preparation of scientific materials and reports as required.
- Assist in the management of PV projects in compliance with ICH-GCP, relevant SOPs, local regulations, and guidelines.
- Contribute, participate, and support team meetings, including materials preparation, meeting minutes writing, and action item tracking.

Competency claims with verified sources

General Knowledge

Competency claim (knowledge topic)	Level	Verified source
Pharmacovigilance principles and Good Pharmacovigilance Practices (GVP) overview	**Basic**	EMA GVP Module I (2012); Dir 2001/83/EC (as amended by Dir 2010/84/EU); Reg (EC) 726/2004 (as amended by Reg (EU) 1235/2010)
The pharmacovigilance system and Pharmacovigilance System Master File (PSMF)	**Intermediate**	EMA GVP Module II (Rev 2, 2017); Comm. Impl. Reg (EU) 520/2012, as amended
Individual case safety report (ICSR) management and regulatory reporting timelines	**Intermediate**	EMA GVP Module VI (Rev 2, 2017); ICH E2D(R1) (in force EU 18 Mar 2026); ICH E2B(R3) (v5.02, 2016)

Role-Specific Knowledge *Includes topics derived from this role's job description.*

Competency claim (knowledge topic)	Level	Verified source
PV curriculum and educational methods **VERIFY FIT**	**Expert**	WHO PV Core Curriculum for University Teaching (van Eekeren et al., Drug Saf 2018)
Pharmacovigilance science and research methodology **NEW CITATION**	**Intermediate**	ENCePP Guide on Methodological Standards (Rev 11, 2023); STROBE Statement (von Elm et al., 2007)
Regulatory framework and GVP overview	**Intermediate**	EMA GVP Module I (2012)
Scientific writing and publication **NEW CITATION**	**Intermediate**	ICMJE Recommendations (Jan 2026)
PV policy, legislation and guideline development	**Intermediate**	Dir 2001/83/EC (as amended by Dir 2010/84/EU); Reg (EC) 726/2004 (as amended by Reg (EU) 1235/2010)

75. PV Assistant Lecturer

Code **T.A.AL** *Technical · Academia* **DRAFT** competency standard

Also known as: Regulatory Science Instructor; PV Instructor

v2: Proposed citation mapping: each topic is paired with a source drawn from the verified base (all sources checked against their issuing body, 2026-07-12) and refreshed to the in-force version — confirm each topic→source fit on review. Blank-note gaps are filled and misfit template topics flagged. Job description and proficiency levels are unchanged from v0.3 for this role.

Job description (v0.3 wording retained)

- Teach and instruct university students in the theory and practice of a PV to enrich their knowledge.
- Support interpretation and analysis of current data gathered from sources such as market data, scientific papers, customer requirements and questionnaires which are current and up to date to assess development and innovation in areas of expertise.
- Support interpretation and analysis of data that may help with formulating conclusions, new insights, or solutions.
- Support PV training and capacity building.
- Keep well informed with new/upgraded PV regulations.
- Cooperate with other PV education professionals.
- Contribute, participate, and support team meetings, including materials preparation, meeting minutes writing, and action item tracking.

Competency claims with verified sources

General Knowledge

Competency claim (knowledge topic)	Level	Verified source
Pharmacovigilance principles and Good Pharmacovigilance Practices (GVP) overview	**Basic**	EMA GVP Module I (2012); Dir 2001/83/EC (as amended by Dir 2010/84/EU); Reg (EC) 726/2004 (as amended by Reg (EU) 1235/2010)
The pharmacovigilance system and Pharmacovigilance System Master File (PSMF)	**Intermediate**	EMA GVP Module II (Rev 2, 2017); Comm. Impl. Reg (EU) 520/2012, as amended
Individual case safety report (ICSR) management and regulatory reporting timelines	**Intermediate**	EMA GVP Module VI (Rev 2, 2017); ICH E2D(R1) (in force EU 18 Mar 2026); ICH E2B(R3) (v5.02, 2016)

Role-Specific Knowledge

Includes topics derived from this role's job description.

Competency claim (knowledge topic)	Level	Verified source
PV curriculum and educational methods **VERIFY FIT**	**Expert**	WHO PV Core Curriculum for University Teaching (van Eekeren et al., Drug Saf 2018)
Pharmacovigilance science and research methodology **NEW CITATION**	**Intermediate**	ENCePP Guide on Methodological Standards (Rev 11, 2023); STROBE Statement (von Elm et al., 2007)
Regulatory framework and GVP overview	**Intermediate**	EMA GVP Module I (2012)
Scientific writing and publication **NEW CITATION**	**Intermediate**	ICMJE Recommendations (Jan 2026)
Training, education and capacity building	**Basic**	WHO PV Core Curriculum for University Teaching (van Eekeren et al., Drug Saf 2018)

Bibliography (verified sources)

Sources cited across the framework's competency claims, each verified against the issuing body on 12 July 2026 (see guideline/v2-citations-verified.md for the verification record). Version and revision numbers are the current in-force editions; where a source is updated on a fixed cycle (e.g., MedDRA), the citation notes the cadence so it does not silently go stale.

1. European Commission. Directive 2001/83/EC on the Community code relating to medicinal products for human use, as amended by Directive 2010/84/EU. Consolidated version (01/01/2025). EUR-Lex.
2. European Commission. Regulation (EC) No 726/2004 laying down Community procedures for the authorisation and supervision of medicinal products and establishing a European Medicines Agency, as amended by Regulation (EU) No 1235/2010. Consolidated version (28/01/2022). EUR-Lex.
3. European Commission. Commission Implementing Regulation (EU) No 520/2012 on the performance of pharmacovigilance activities, as amended by Reg (EU) 2025/1466. Consolidated version (12/08/2025). EUR-Lex.
4. European Parliament and Council. Regulation (EU) 2016/679 — General Data Protection Regulation (GDPR).
5. EMA. Guideline on good pharmacovigilance practices (GVP) — Module I: Pharmacovigilance systems and their quality systems (2012).
6. EMA. GVP Module II: Pharmacovigilance system master file (Rev 2, 2017).
7. EMA. GVP Module III: Pharmacovigilance inspections (Rev 1, 2014).
8. EMA. GVP Module IV: Pharmacovigilance audits (Rev 1, 2015).
9. EMA. GVP Module V: Risk management systems (Rev 2, 2017).
10. EMA. GVP Module VI: Collection, management and submission of reports of suspected adverse reactions to medicinal products (Rev 2, 2017), and Addendum II: Masking of protected personal data (2025).
11. EMA. GVP Module VII: Periodic safety update report (Rev 1, 2013).
12. EMA. GVP Module VIII: Post-authorisation safety studies (Rev 3, 2017).
13. EMA. GVP Module IX: Signal management (Rev 1, 2017), and Addendum I: Methodological aspects of signal detection from spontaneous reports.
14. EMA. GVP Module X: Additional monitoring (2013).
15. EMA. GVP Module XV: Safety communication (Rev 1, 2017).
16. EMA. GVP Module XVI: Risk minimisation measures (Rev 3, 2024).
17. EMA. GVP Annex I: Definitions (Rev 5, 2024).
18. EMA. Good practice guide on recording, coding, reporting and assessment of medication errors (EMA/762563/2014, 2015).
19. ICH. E2A: Clinical Safety Data Management — Definitions and Standards for Expedited Reporting (Step 4, 1994).
20. ICH. E2B(R3): Electronic Transmission of Individual Case Safety Reports — Implementation Guide, Data Elements and Message Specification (v5.02, Step 4, 2016).
21. ICH. E2C(R2): Periodic Benefit-Risk Evaluation Report (PBRER) (Step 4, 17 Dec 2012).
22. ICH. E2D(R1): Post-Approval Safety Data — Definitions and Standards for Management and Reporting of Individual Case Safety Reports (Step 4, 2025; EU in force 18 Mar 2026).
23. ICH. E2F: Development Safety Update Report (DSUR) (Step 4, 2010).
24. ICH. E9: Statistical Principles for Clinical Trials (1998), and E9(R1) Addendum: Estimands and Sensitivity Analysis in Clinical Trials (2019).
25. CIOMS. Practical Aspects of Signal Detection in Pharmacovigilance: Report of CIOMS Working Group VIII. Geneva, 2010. ISBN 978-92-9036-082-7.
26. Evans SJW, Waller PC, Davis S. Use of proportional reporting ratios (PRRs) for signal generation from spontaneous adverse drug reaction reports. Pharmacoepidemiol Drug Saf. 2001;10(6):483–486. PMID 11828828.

27. ENCePP. Guide on Methodological Standards in Pharmacoepidemiology (Rev 11, 2023).
28. von Elm E, Altman DG, Egger M, Pocock SJ, Gøtzsche PC, Vandenbroucke JP. The Strengthening the Reporting of Observational Studies in Epidemiology (STROBE) statement: guidelines for reporting observational studies (2007).
29. ICMJE. Recommendations for the Conduct, Reporting, Editing, and Publication of Scholarly Work in Medical Journals (January 2026).
30. Wilkinson MD, et al. The FAIR Guiding Principles for scientific data management and stewardship. Sci Data. 2016;3:160018.
31. MHRA. 'GXP' Data Integrity Guidance and Definitions (Rev 1, March 2018).
32. FDA. Data Integrity and Compliance With Drug CGMP: Questions and Answers — Guidance for Industry (December 2018).
33. FDA. Risk Evaluation and Mitigation Strategies (REMS) — Food and Drug Administration Amendments Act 2007, FD&C Act §505-1.
34. ISPE. GAMP 5: A Risk-Based Approach to Compliant GxP Computerized Systems, 2nd Edition (2022).
35. European Commission. EudraLex Volume 4, Annex 11: Computerised Systems (2011).
36. ISO. Identification of Medicinal Products (IDMP) standards: ISO 11615, 11616, 11238, 11239, 11240.
37. MedDRA (Medical Dictionary for Regulatory Activities), maintained by the MSSO; current v29.0 (2026), released twice yearly.
38. Uppsala Monitoring Centre (WHO-UMC). WHODrug Global.
39. van Eekeren R, et al. What Future Healthcare Professionals Need to Know About Pharmacovigilance — the WHO PV core curriculum for university teaching. Drug Saf. 2018;41:1003–1011.
40. WHO. The importance of pharmacovigilance: safety monitoring of medicinal products. Geneva, 2002. ISBN 92-4-159015-7.
41. WHO / Uppsala Monitoring Centre. Safety Monitoring of Medicinal Products: Guidelines for setting up and running a Pharmacovigilance Centre. 2000. ISBN 91-630-9004-X.
42. WHO. Medication Without Harm — WHO Global Patient Safety Challenge (WHO/HIS/SDS/2017.6, 2017).