INSTITUTE
OF PHARMACOVIGILANCE

Pharmacovigilance Career Framework Guideline

Jointly developed by the International Society of Pharmacovigilance Special Interest Group on PV Professional Qualification Framework and the Institute of Pharmacovigilance

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Document Objective

Define and describe roles in the pharmacovigilance profession.

The pharmacovigilance profession is an ever-evolving discipline with a rich history and an exciting future. As it encompasses multiple areas of science and a range of activities, people with various backgrounds and talents are needed to collaborate on challenging tasks. These tasks include making decisions under strict time pressure, using all sources of relevant information, reviewing the best available evidence while operating in a highly regulated environment.

ISoP Special Interest Group on Pharmacovigilance Professional Qualification Framework, in collaboration with the Institute of Pharmacovigilance, has developed this guideline as the first step while developing the Global Pharmacovigilance Professional Certification (GPPC) program. By defining roles that belong to the profession, we define the scope of the GPPC, and we can then continue with the development of the competency guidelines. These would then become the basis for testing the competency of candidates.

The roles suggested in this guideline are inspired by the pharmacovigilance job roles that exist today. The guideline was informed by the adverts and job descriptions collected. We all recognize that exact job titles may differ among organizations, however, the actual competence required for the job may be standardized and common denominators may be found between the job roles. Therefore, this guideline works with the concept of professional roles.

We do welcome your comments and input. Please, submit via email to info@pharmacovigilance.institute.

Thank you for your contribution to our pharmacovigilance profession!

On behalf of the team of authors,

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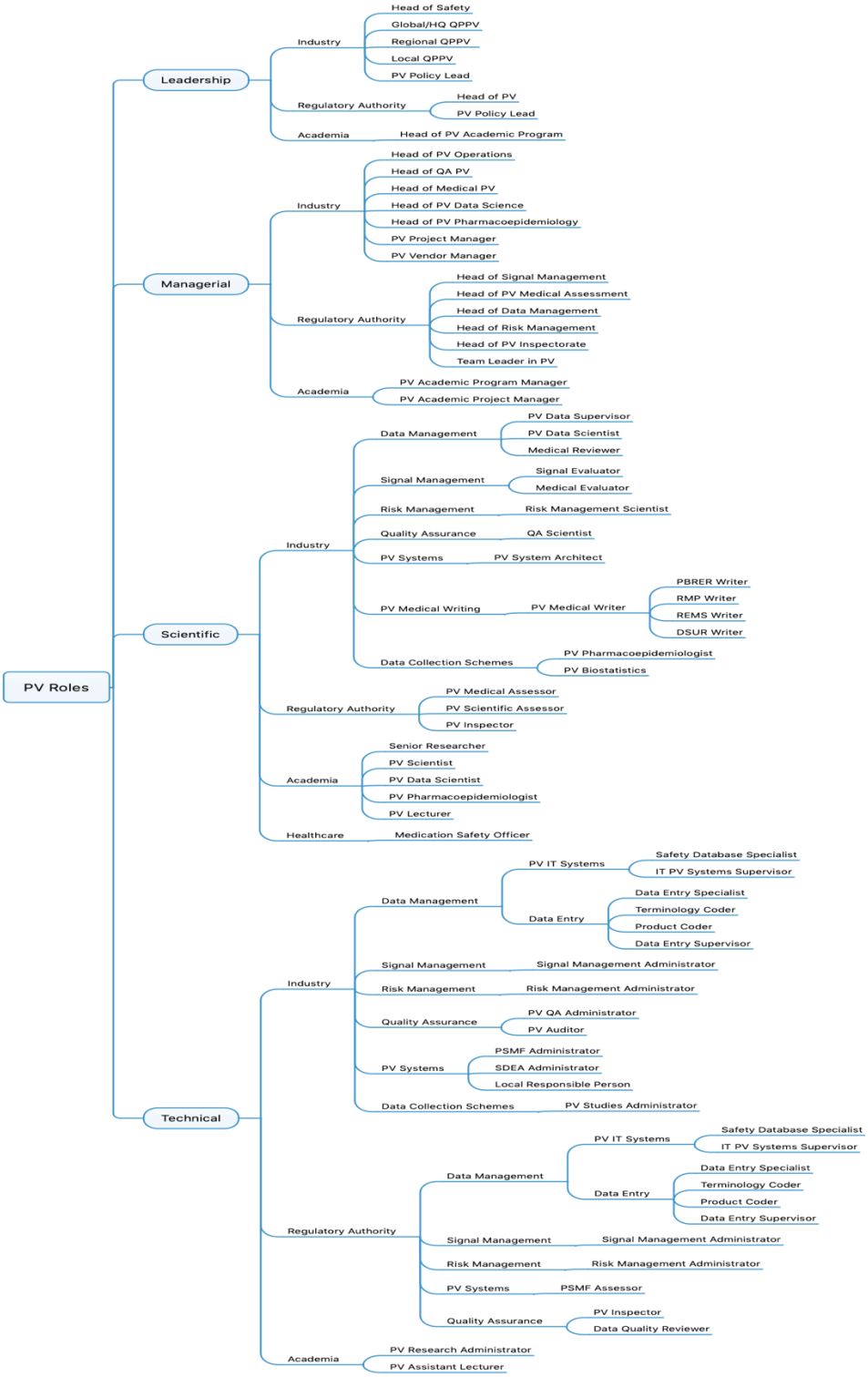
List of Abbreviations

AE	Adverse Event
AOSE	Analysis of Similar Events
APR	Annual Product Review
ATC	Anatomical-therapeutic-chemical classification
CAPA	Corrective and Preventive Actions
CCSI	Company Core Safety Information
CMD	Country Medical Directors
COP	Community of Practice
DMC	Data Management Centre
DS	Drug Safety
DSMB	Data and Safety Monitoring Board
DSUR	Development Safety Update Report
DUS	Drug Utilization Studies
EDC	Electronic Data Capture
EMA	European Medicines Agency
EOI	Expressions of Interest
EU	European Union
FAIR	Findable, Accessible, Interoperable and Re-usable principle
GCP	Good Clinical Practice
GDP	Good Documentation Practice
GM	General Manager
GMP	Good Manufacturing Practice
GVP	Good Pharmacovigilance Practice
GxP	Good x Practice
HQ	Headquarter
ICSR	Individual Case Study Report
IT	Information Technology
KPI	Key Performance Indicators
KRI	Key Risk Indicators
MA	Medical Affairs
MAA	Market Authorization Application
MAH	Market Authorization Holder
MedDRA	Medical Dictionary for Regulatory Activities
MHRA	Medicines and Healthcare Products Regulatory Agency
NCA	National Competent Authority

NDA	New Drug Application
PAES	Post-Authorization Efficacy Studies
PASS	Post-Authorization Safety Studies
PBRER	Periodic Benefit-Risk Evaluation Report
PI	Package Insert
PMR	Post-Marketing Requirements
PQR	Product Quality Review
PSMF	Pharmacovigilance System Master File
PSP	Patient Support Programs
PSUR	Periodic Safety Update Report
PV	Pharmacovigilance
QA	Quality Assurance
QC	Quality Control
QMS	Quality Management System
QPPV	Qualified Person Responsible for Pharmacovigilance
RA	Regulatory Affairs
REMS	Risk Evaluation and Mitigation Strategies
RMM	Risk Minimization Measures
RMP	Risk Management Plans
RSI	Reference Safety Information
RWE	Real-World Evidence
SAE	Serious Adverse Events
SDEA	Safety Data Exchange Agreement
SDLC	Software Development Life Cycle
SmPC	Summary of Product Characteristics
SOP	Standard Operating Procedure
TMF	Trial Master File
UAT	User Acceptance Testing
WIN	Work Instructions

Career Framework

Mind map of the roles in pharmacovigilance



1. Leadership Roles

1.1. Industry

1.1.1. Head of Safety

*Code **L.I.HS***

Job description

- 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, minimization plans and strategies, as well as the assessment of risk for drugs in development through the commercialization process.
- Ensure consistency and standardisation of roles and procedures throughout the organisation.
- Build the PV strategy and timelines.
- Plan budget for the division.
- Support and facilitate all communication, in responding and resolving safety questions from regulatory authorities, as well as audits and inspections with corrective action plans.
- Ensure oversight and management for all outsourced or insourced PV activities, including establishing and monitoring key quality and compliance metrics.
- Ensure accurate and current PV agreements, and Safety Data Exchange Agreements are in place, as well as continuously monitored for timely and accurate implementation, with all license partners, vendors and other relevant third parties.
- Support relevant management staff.
- Work with relevant staff members on safety-related deliverables, including facilitation of Safety governance meetings and Global Safety Team meetings, tracking of safety deliverables, and management of safety reports and documents.

- Assume leadership role in the creation of departmental SOPs, working practices, and best practices in project management.
- Have oversight of product safety deliverables, including issue identification/resolution plans, and ensure appropriate communication, tracking and reporting of such deliverables.
- Ensure that the PV Database supports the department needs, including specific workflows and reporting/querying functionalities.
- Accountable for the ongoing safety surveillance of company products.
- Contribute to and review regulatory submissions, aggregate reports, investigator communications, labelling, etc. as needed.
- Provide Safety and PV expertise in-house for products in development and marketed products.
- Liaise with other functional areas such as Clinical Development, Regulatory Affairs, Quality Assurance, Medical Affairs, Manufacturing, and Legal.
- Review and provide feedback for Safety Management Plans.
- Develop and implement relevant PV training.
- Ensure continuous improvement of resources and materials provided. Engage in continuous improvement of the processes.
- Responsible for ensuring suitable managed and up to date PV Bussiness Continuity Plans.
- Supports the implementation and following of company governance, and its policies within the PV organisation, including those related to business ethics compliance.

1.1.2. Global/HQ QPPV

*Code **L.I.GQP***

Job description

- 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.

1.1.3. Regional QPPV

A Regional QPPV role given herewith serves only as an example and can be possibly modified and developed for various regions worldwide.

1.1.3.1. EU QPPV

*Code **L.I.R.EUQP***

Job description

- Reside and operate in the EU/EAA.
- Act as a single PV contact point for competent authorities in the member states and the EMA on a 24-hour basis as well as a contact point for PV inspections.
- Responsible for the establishment and maintenance of the EU PV system in accordance with EU legislation and associated guidance documents.

- Have oversight of the functioning of the PV system in all relevant aspects including its quality system.
- Have an overview and awareness of medicinal product safety profiles.
- Have awareness of conditions or obligations adopted as part of the MA and any other commitments relating to safety or the safe use of the products.
- Have awareness of risk minimisation measures.
- Awareness of and having sufficient authority over the content of risk management plans.
- Involved in the review and sign-off of protocols of post-authorisation safety studies conducted in the EU or relevant to a risk management plan agreed in the EU.
- Awareness of post-authorisation safety studies requested by a competent authority and the results of such studies.
- Ensure submission of PV related documents in accordance with the legal requirements.
- Ensure the necessary quality, including correctness and completeness, of PV data.
- Ensure full and prompt responses to any request from competent authorities in the Member States and the EMA.
- 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).
- Have oversight of safety database, GxP status, change control, and issue management.
- Maintain a matrix of local QPPVs and equivalents (in-house and outsourced) across all EU countries
- Engage in continuous improvement of the processes and PV system.
- Involved and consulted in due diligence that may have an impact on the PV system.
- Responsible for ensuring suitable managed and up to date PV Business Continuity Plans that suitably cover the needs of the EU PSMF.
- Supports the implementation and following of company governance and its policies within the PV organisation, including those related to business ethics compliance.

1.1.4. Local QPPV

A Local QPPV role given herewith serves only as an example and can be possibly modified and developed for various countries worldwide.

1.1.4.1. UK QPPV

*Code **L.I.R.UKQP***

Job description

- 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.

1.1.5. PV Policy Lead

*Code **L.I.PVPL***

Job description

- 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.

1.2. Regulatory Authority

1.2.1. Head of PV

*Code **L.RA.HPV***

Job description

- 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.

1.2.2. PV Policy Lead

*Code **L.RA.PVPL***

Job description

- 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.

1.3. Academia

1.3.1. Head of PV Academic Program

*Code **L.A.HPVP***
Job description

- 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.

2. Managerial Roles

2.1. Industry

2.1.1. Head of PV Operations

*Code **M.I.HPVO***
Job description

- Responsible for providing guidance, advice, direction to ensure compliance at the regional/country level.
- Interact with CMDs, GMs, and Commercial as needed, and periodically, to ensure strong PV connectivity, proactively identifying new programs, initiatives, strategies, or risks that may impact the PV system.
- Interact with local Safety Contacts to ensure PV compliance in the regions/countries.

- Partner with senior local/regional and global roles outside of the PV organisation and membership at Regional Lead team forums and governance boards to develop strategies to reduce risk to the PV system.
- Escalate non-compliance in the region as appropriate.
- Accountable for the implementation of new regulations in their region by liaising with central/regional teams and third parties.
- Attend relevant regional PV meetings.
- Lead network activities.
- 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.

2.1.2. Head of Quality Assurance PV

Code **M.I.HQA**

Job description

- 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.

2.1.3. Head of Medical PV

*Code **M.I.HMPV***

Job description

- 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.

2.1.4. Head of PV Data Science

*Code **M.I.HPVDS***

Job description

- 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.

2.1.5. Head of PV Pharmacoepidemiology

*Code **M.I.HPVPE***

Job description

- 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.

2.1.6. PV Project Manager

*Code **M.I.PVPM***

Job description

- 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.

2.1.7. PV Vendor Manager

*Code **M.I.PVVM***

Job description

- 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.

2.2. Regulatory Authority

2.2.1. Head of Signal Management

*Code **M.RA.HSM***

Job description

- 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.

2.2.2. Head of PV Medical Assessment

Code M.RA.HPVMA

Job description

- 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.

2.2.3. Head of Data Management

*Code **M.RA.HDM***

Job description

- 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.

2.2.4. Head of Risk Management

Code M.RA.HRM

Job description

- 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.

2.2.5. Head of PV Inspectorate

*Code **M.RA.HPVI***

Job description

- 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.

2.2.6. Team Leader in PV

*Code **M.RA.TLPV***

Job description

- 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.

2.3. Academia

2.3.1. PV Academic Program Manager

*Code **M.A.PVPM***
Job description

- 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.

2.3.2. PV Academic Project Manager

*Code **M.A.PVPM***
Job description

- 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.

3. Scientific Roles

3.1. Industry

3.1.1. Data Management

3.1.1.1. PV Data Supervisor

*Code **S.I.DM.DS***
Job description

- 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.

3.1.1.2. PV Data Scientist

*Code **S.I.DM.DSC***

Job description

- 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.

3.1.1.3. Medical Reviewer

*Code **S.I.DM.MR***

Job description

- 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 the 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 the medical input and guidance for ad-hoc queries for ICSRs.
- Lead and direct medical oversight and guidance to vendors performing case processing including required training.
- Lead and implement with alliance partners harmonization and industry-standard medical review and case assessment standards.
- Liaise with the marketing team(s) to evaluate safety impact and provide input into program design (e.g., social media, market research, patient support programs).
- Participate in inspection/audit related readiness activities and provide support for internal and external PV audits.
- Develop and deliver relevant training.

3.1.2. Signal Management

3.1.2.1. Signal Evaluator

*Code **S.I.SM.SE***

Job description

- Responsible for educating stakeholders on the use of 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 the Signal Management component of activities and work in close collaboration with other client's/company's divisions.
- Develop and conduct signal detection activities, adverse event trending analysis and prepare signal detection and trending reports.

- Perform and oversee routine signal detection activities (literature review, individual case awareness and aggregate data review) to identify, assess and escalate signals appropriately.
- Author and contribute to relevant regulatory documents (e.g., PSURs, renewal documents, RMPs, submission documents) according to agreed timelines and processes.
- Develop and deliver relevant training.

3.1.2.2. Medical Evaluator

*Code **S.I.SM.ME***

Job description

- 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.

3.1.3. Risk Management

3.1.3.1. Risk Management Scientist

*Code **S.I.RM.RMS***

Job description

- 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.

3.1.4. Quality Assurance

3.1.4.1. Quality Assurance Scientist

*Code **S.I.QA.QAS***
Job description

- 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.

3.1.5. PV Systems

3.1.5.1. PV Systems Architect

*Code **S.I.PVS.SA***
Job description

- 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.

3.1.6. PV Medical Writing

3.1.6.1. PV Medical Writer

3.1.6.1.1. PBRER Writer

*Code **S.I.MW.PBRER***
Job description

- 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.

3.1.6.1.2. RMP Writer

*Code **S.I.MW.RMP***
Job description

- 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.

3.1.6.1.3. REMS Writer

*Code **S.I.MW.REMS***

Job description

- 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.

3.1.6.1.4. DSUR Writer

*Code **S.I.MW.DSUR***

Job description

- 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.

3.1.7. Data Collection Schemes

3.1.7.1. PV Pharmacoepidemiologist

*Code **S.I.DCS.PVP***

Job description

- 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.

3.1.7.2. PV Biostatistician

*Code **S.I.DCSB***

Job description

- 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.

3.2. Regulatory Authority

3.2.1. PV Medical Assessor

*Code **S.RA.MA***

Job description

- Provide administrative oversight of medical review activities.
- Perform review and evaluation of causality assessment of adverse events in individual case safety reports.
- Author scientific publications on behalf of the regulatory authority.
- 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.
- Participate at all levels (internally and externally) in the formulation and preparation of regulatory policies, guidelines, legislation, and opinions.
- Develop and deliver relevant training.

3.2.2. PV Scientific Assessor

*Code **S.RA.SA***

Job description

- 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.

3.2.3. PV Inspector

*Code **S.RA.PVI***

Job description

- 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.

3.3. Academia

3.3.1. Senior Researcher

*Code **S.A.SR***

Job description

- 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.

3.3.2. PV Scientist

*Code **S.A.PVS***

Job description

- 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.

3.3.3. PV Data Scientist

*Code **S.A.PVDS***

Job description

- 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.

3.3.4. PV Pharmacoepidemiologist

*Code **S.A.PVPE***

Job description

- 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.

3.3.5. PV Lecturer

*Code **S.A.PVL***

Job description

- Teach and instruct university students in the theory and practice of a PV to enrich their knowledge.
- Interpret and analyse 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.
- Interpret and analyse data collected during testing to formulate conclusions, new insights, or solutions.
- Employ various teaching approaches, learning styles, and channels to instruct students.
- PV training and capacity building.
- Monitor developments in the PV. Keep up with new research and regulations.
- Cooperate with other PV education professionals.
- Contribute, participate, and support team meetings, including materials preparation, meeting minutes writing, and action item tracking.

3.4. Healthcare

3.4.1. Medication Safety Officer

*Code **S.H.MSO***

Job description

- Work with medical staff, pharmacy staff, nursing staff, and other pertinent health care providers.
- Responsible for guiding the design, implementation, maintenance, and evaluation of safe medication systems within a hospital.
- Work collaboratively with all members of the healthcare team, pharmacists, nursing staff, medical staff leadership, and patient safety.
- Assess medication use system processes, identify opportunities to improve medication use safety and review, design solutions for system failures, and institute practice changes.
- Serve as a subject matter expert for all medication safety initiatives and efforts, and work collaboratively to investigate, implement and monitor medication safety initiatives.
- Actively participate in outstanding customer service and accept responsibility in maintaining relationships that are equally respectful to all.
- Develop and deliver relevant training.

4. Technical Roles

4.1. Industry

4.1.1. Data Management

4.1.1.1. PV IT Systems

4.1.1.1.1. Safety Database Specialist

*Code **T.I.DM.ITS.SDS***
Job description

- 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 clinical 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 including database configuration, data entry, data collection, dictionary values, application packages, event reporting procedures, and troubleshooting.
- Work closely with the division lead to ensure standardization and accuracy of all data entered and retrieved from the safety databases.
- Track and process assigned pharmaceutical and DMC queries.
- 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.

4.1.1.1.2. IT PV Systems Supervisor

*Code **T.I.DM.ITS.ITSS***

Job description

- 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.

4.1.1.2. Data Entry

4.1.1.2.1. Data Entry Specialist

*Code **T.I.DM.DE.DES***

Job description

- 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.

- Proactively drive quality and efficiency to meet timelines and milestones for data management, ensuring scientific and operational excellence in support of strategic imperatives and collaboration with the cross-functional team(s).
- Entry data of SAEs under strict regulatory and internal timelines.
- Perform monthly maintenance and reconciliation of trackers for safety data exchanged.
- Perform standard database searches/output in support of clinical-safety database reconciliation, as well for routine recurring monthly requests safety data.
- May assist with regular maintenance and reconciliation of departmental submissions trackers, such as expedited regulatory submissions and Safety Notification Letters.
- Develop escalation plan and execute issues with site non-compliance related to adverse events.
- Support the identification of corrections and creation of updates in the safety database following medical review.
- Interact with clinicians, nurses, pharmacists, and marketing partners externally, as well as internal staff at company headquarters, to get necessary missing information.
- 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.

4.1.1.2.2. Terminology Coder

*Code **T.I.DM.DE.TC***
Job description

- 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.

4.1.1.2.3. Product Coder

*Code **T.I.DM.DE.PC***

Job description

- 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.

4.1.1.2.4. Data Entry Supervisor

*Code **T.I.DM.DE.DES***
Job description

- 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.

4.1.2. Signal Management

4.1.2.1. Signal Management Administrator

*Code **T.I.SM.SMA***

Job description

- 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.

4.1.3. Risk Management

4.1.3.1. Risk Management Administrator

*Code **T.I.RM.RMA***
Job description

- 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.

4.1.4. Quality Assurance

4.1.4.1. PV Quality Assurance Administrator

*Code **T.I.QA.QAA***

Job description

- 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.

4.1.4.2. PV Auditor

*Code **T.I.QA.PVA***

Job description

- 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.

4.1.5. PV Systems

4.1.5.1. PSMF Administrator

*Code **T.I.PVS.PSMF***

Job description

- 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.

4.1.5.2. SDEA Administrator

*Code **T.I.PVS.SDEA***

Job description

- 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.

4.1.5.3. Local Responsible Person

*Code **T.I.PVS.LRP***

Job description

- 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.

4.1.6. Data Collection Schemes

4.1.6.1. PV Studies Administrator

*Code **T.I.DCS.PVSA***

Job description

- 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.

4.2. Regulatory Authority

4.2.1. Data Management

4.2.1.1. PV IT Systems

4.2.1.1.1. Safety Database Specialist

*Code **T.RA.DM.ITS.SDS***

Job description

- 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.

4.2.1.1.2. IT PV Systems Supervisor

*Code **T.RA.DM.ITS.ITSS***

Job description

- 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.

4.2.1.2. Data Entry

4.2.1.2.1. Data Entry Specialist

*Code **T.RA.DM.DES***

Job description

- 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.

4.2.1.2.2. Terminology Coder

*Code **T.RA.DM.TC***

Job description

- 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.

4.2.1.2.3. Product Coder

*Code **T.RA.DM.PC***
Job description

4.2.1.2.4. Data Entry Supervisor

*Code **T.RA.DM.DESV***
Job description

- 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.

4.2.2. Signal Management

4.2.2.1. Signal Management Administrator

*Code **T.RA.SM.SMA***

Job description

- 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.

4.2.3. Risk Management

4.2.3.1. Risk Management Administrator

*Code **T.RA.RM.RMA***

Job description

- 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.

4.2.4. PV Systems

4.2.4.1. PSMF Assessor

*Code **T.RA.PVS.PSMF***

Job description

- 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.

4.2.5. Quality Assurance

4.2.5.1. PV Inspector

*Code **T.RA.QA.PVI***
Job description

- 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.

4.2.5.2. Data Quality Reviewer

*Code **T.RA.QA.DQR***
Job description

- 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.

4.3. Academia

4.3.1. PV Research Administrator

*Code **T.A.PVRA***

Job description

- 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.

4.3.2. PV Assistant Lecturer

*Code **T.A.PVAL***

Job description

- 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.

Appendix 1: List of Role Synonyms

		Job Title	Synonym/Equivalent
LEADERSHIP	Industry	Head of Safety	Head of Group Health and Safety
			Head of Patient Safety
			Director of Drug Safety
		Global/Headquarter QPPV	Global Safety Leader
		EU QPPV	-
		UK QPPV	-
		PV Policy Lead	-
	Regulatory Authority	Head of PV	Head of Safety Surveillance
		PV Policy Lead	-
	Academia	Head of PV Program	-
MANAGERIAL	Industry	Head of PV Operations	Global PV Operations Manager
			Director of PV Management and Operations
		Head of QA PV	Director of Quality Management
			Director of Quality Assurance
			Director of PV Quality
		Head of Medical PV	Medical Director PV
			Director Medical Writing
		Head of PV Data Science	PV Data Science Leader
		Head of PV Pharmacoepidemiology	-

		PV Project Manager	PV Project Director
			Head of Project Management
		PV Vendor Manager	-
	Regulatory Authority	Head of Signal Management	Head of Signal Detection
			Signal Management Lead
		Head of PV Medical Assessment	Medical Director
			Medical Lead
		Head of Data Management	Head of Statistics
			Head of Data Science
		Head of Risk Management	Safety Risk Lead
			Director of Risk Operations
			Head of Risk And Compliance
		Head of PV Inspectorate	Head of PV Audits & Inspections
		PV Team Lead	PV Systems Team Leader
	Academia	PV Program Manager	-
		PV Project Manager	Project Coordinator
SCIENTIFIC	**Industry**	PV Data Supervisor	Data Entry Supervisor
		PV Data Scientist	Process Data Scientist
		Medical Reviewer	Medical Record Reviewer
			Medical Document Reviewer
			Clinical Reviewer
		Signal Evaluator	Signal Scientist Safety Signal Assessor

			Safety Signal Accessor
		Medical Evaluator	Medical Review Evaluator
			Clinical Evaluator
			Medical Care Evaluator
			Medical Liason
		Risk Management Scientist	PV and Risk Management Scientist
		QA Scientist	QA Assurance Specialist
			Quality Control Scientist
		PV System Architect	Clinical System Architect
			PV Solution Architect
		PBRER Writer	PSUR Writer
		RMP Writer	-
		REMS Writer	-
		DSUR Writer	-
		PV Pharmacoepidemiologist	PV Epidemiologist Researcher
			PV Research Fellow
		PV Biostatistics	Biostatistician
	Regulatory Authority	PV Medical Assessor	PV Medical Officer
			Pharmaceutical Assessor
		PV Scientific Assessor	PV Scientific Officer
	Academia	Senior Researcher	Senior Research Specialist
			Research Associate
		PV Scientist	Drug Safety Scientist

			Safety Scientist
		PV Data Scientist	-
		PV Pharmacoepidemiologist	PV Research Fellow
		PV Lecturer	Regulatory Science Instructor
			PV Instructor
	Healthcare	Medication Safety Officer	Drug Safety Officer
			PV Clinical Officer
TECHNICAL	**Industry**	Safety Database Specialist	-
		IT PV Systems Supervisor	-
		Data Entry Specialist	Medical Data Entry Specialist
			Data Control Specialist
		Terminology Coder	Medical Coder
			Clinical Coder
		Product Coder	-
		Data Entry Supervisor	-
		Signal Management Administrator	-
		Risk Management Administrator	Risk System Administrator
			Risk Operation Administrator
		PV Auditor	-
		PV QA Administrator	PV Regulatory Compliance
			Clinical QA Associate
			Quality Auditor
		PSMF Administrator	PSMF Specialist

			PMSF Associate
		SDEA Administrator	-
		Local Responsible Person	LSR – Local Safety Responsible
			LPPV – Local Contact Person for PV
		PV Studies Administrator	PV Officer
	Regulatory Authority	Safety Database Specialist	-
		IT PV Systems Supervisor	-
		Data Entry Specialist	Medical Data Entry Specialist
			Data Control Specialist
		Terminology Coder	Medical Coder
			Clinical Coder
		Product Coder	-
		Data Entry Supervisor	-
		Signal Management Administrator	-
		Risk Management Administrator	Risk System Administrator
			Risk Operation Administrator
		PSMF Assessor	-
		PV Inspector	PV Auditor
		Data Quality Reviewer	Quality Assurance Technical Data Reviewer
			Quality Control Data Reviewer
			ICSR Data Reviewer
	Academia	PV Research Administrator	Health Scientist Administrator
		PV Assistant Lecturer	Regulatory Science Instructor

			PV Instructor