APCER LIFE SCIENCES
Together for better health

BROCHURE

Together for Minimizing Risk

Pharmacovigilance Services in the European Union and the United Kingdom

With increasing cost of drugs and stringent regulatory requirements, the complexity of global, end-to-end pharmacovigilance (PV) systems is also increasing. Biopharmaceutical companies are expected to adopt a proactive PV strategy as they seek market approvals for their products in the European Union (EU) and the United Kingdom (UK).

The EU and UK regions have stringent PV and regulatory requirements, such as expedited submissions of individual case safety reports (ICSRs), electronic submission of periodic safety update reports (PSURs), robust signal management processes, establishment and evaluation of risk management systems and effectiveness of risk minimisation and effective processes, to monitor the performance and effectiveness of a PV system and its quality system along with maintenance of pharmacovigilance system master file (PSMF). The companies also need to have an appropriately qualified person responsible for pharmacovigilance (QPPV) who shall reside in and operate from the EU/UK, as applicable, on a 24-hour basis, with a back-up in place in the absence of the QPPV.

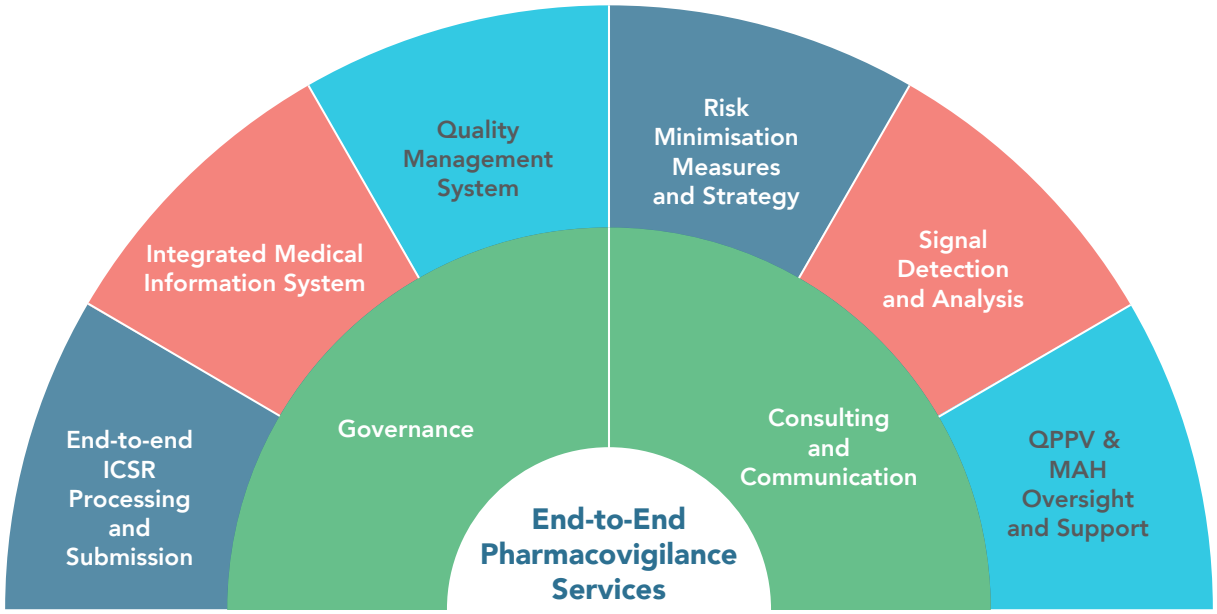
The companies will now have to comply with the UK regulations separately. The Medicines and Healthcare products Regulatory Agency (MHRA) has released guidelines on PV procedures and 'exceptions and modifications to the EU guidance on good pharmacovigilance practices that apply to UK marketing authorisation holders and the licensing authority' to reflect the status of the withdrawal of the UK from the EU. Recently, the MHRA has also released the Windsor Framework, which provides information on regulatory requirements with respect to Northern Ireland. Accordingly, the MHRA will approve all drugs for the entire UK market. This ensures a durable and long-term supply of medications to Northern Ireland. Due to certain differences with regard to the products authorised in Great Britain and Northern Ireland and overlapping the EU and UK requirements, the PV processes have become complex, leading to significant risks in ensuring regulatory compliance.

Key Safety Challenges Faced by Pharmaceutical Companies

- Complexity in health authority regulations and risk of non-compliance to local regulations
- Ineffective risk minimisation
- Difficulty in deployment of local PV contact personnel in multiple countries
- Lack of appropriate QPPV oversight
- Complexity in compliance to post-Brexit regulations
- Major or critical inspection findings
- Lack of an integrated PV system
- Lack of effective quality system processes

APCER's team of highly qualified, dedicated and experienced experts consults, implements and helps minimise risks while ensuring compliance to regulatory requirements throughout the drug life-cycle phases and across multiple therapeutic areas.

Pharmacovigilance Services in the European Union and United Kingdom Throughout the Drug Development Life Cycle



APCER's End-to-End Pharmacovigilance Services

Pharmacovigilance System Setup and End-to-End Integrated Support

- Creation and maintenance of PSMF/summary of pharmacovigilance systems (SPS).
- Setting up and hosting of safety database and management (e.g. ArisG and Argus).
- Safety data exchange agreement support with business partners and third parties.
- Pharmacovigilance consulting involving standard operating procedure (SOP) development, quality systems and strategic consulting.

Expedited and Periodic Safety Reporting

- Integrated PV and medical information (MI) response centres.
- Multi-lingual, multi-therapeutic MI contact centres running 24x7 for medical inquiries and adverse event(s) follow-up.
- In-house local translation capabilities.
- End-to-end ICSR case processing, including electronic transmission as required.
- Experience in clinical trials case processing across all phases.
- Data collection support, safety mailbox management and local safety submission.
- Medical review case assessment.
- End-to-end global literature screening and review.
- Local literature screening as per local regulations.
- Aggregate report compilation and submissions of PSURs, periodic benefit–risk evaluation reports (PBRERs), development safety update reports (DSURs), addendum to clinical overview (ACO), etc.

Safety Surveillance and Risk Management Activities

- Robust signal management processes to meet global and local regulatory requirements.
- Routine risk monitoring activities, including periodic review.
- Preparation and review of risk management plan.
- Implementation of additional risk minimisation measures (aRMM), including drafting of educational materials, educating/training healthcare professionals (HCPs) and setting up drug and/or patient registries (e.g. pregnancy registry) on a web-based HCP and patient registration portal.
- Tracking and effectiveness assessment of aRMM.
- Addressing health authority questions.
- Tracking regulatory intelligence for potential signals and risk management updates.

Qualified Person Responsible for Pharmacovigilance (QPPV), Local QPPVs and QPPV Oversight and Support

- QPPV and back-up QPPV for the EU.
- QPPV and back-up QPPV for the UK.
- Medically qualified person where applicable.
- National contact person for pharmacovigilance (NCP) in the UK.
- Local qualified person for pharmacovigilance (LQPPV) in the EU and Rest of World (RoW).
- Responsible person for EudraVigilance for clinical trials.
- Graduated plan officer (GPO)/Information officer (IO) in Germany.
- Dedicated QPPV office to facilitate QPPVs in tracking and maintenance of effective PV oversight activities, and thus ensuring regulatory compliance.
- Direct interaction with local regulators on PV and regulatory matters.
- A set-up of integrated local PV systems.

Our extensive and well-established global strategic partner network across 120+ countries and actively serving in 30+ countries for various clients. This ensures that you get an efficient, high quality and completely tailored Local PV solutions to meet your requirements.

The APCER Advantage

Over 15 years of experience in managing end-to-end PV services

Experienced team of subject matter experts (SMEs) and physicians with extensive expertise in therapeutics and strong medical knowledge

Robust planning and processes in place to ensure effective marketing authorisation holder (MAH) oversight

Strong expertise in handling ever-changing regulatory requirements

Audit-ready quality processes, anytime inspection readiness (AIR)

Highly adaptable, with proven collaboration across the functional areas

Wide-ranging experience with the European Medicines Agency (EMA), MHRA, United States Food and Drug Administration (US FDA), Therapeutic Goods Administration (TGA), Medsafe, Gulf Cooperation Council (GCC), Association of Southeast Asian Nations (ASEAN), etc.

Excellent risk mitigation strategies, with a strong business continuity plan

Currently providing Local PV and QPPV support in 30+ countries for various clients, including partner network

APCER LIFE SCIENCES | Together for better health
Part of APC Group

APCER Life Sciences is committed to improving health in partnership with its clients. We bring together safety, medical, regulatory and technology resources to ensure that patients receive the safest, most effective therapies possible.

We are an ISO 9001:2015, ISO 27001:2022, and ISO 27701:2019 certified company.

Learn more at www.apcerls.com or contact us at one of our global offices: Americas: (+1) 609 455 1600 • Europe: (+49) 2409 725 6120 • UK: (+44) 208 326 3220 • Asia: (+91) 79 6677 8600

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