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LIFE SCIENCES
Together for better health

BROCHURE

Together for Patient Safety

Clinical Safety and Pharmacovigilance

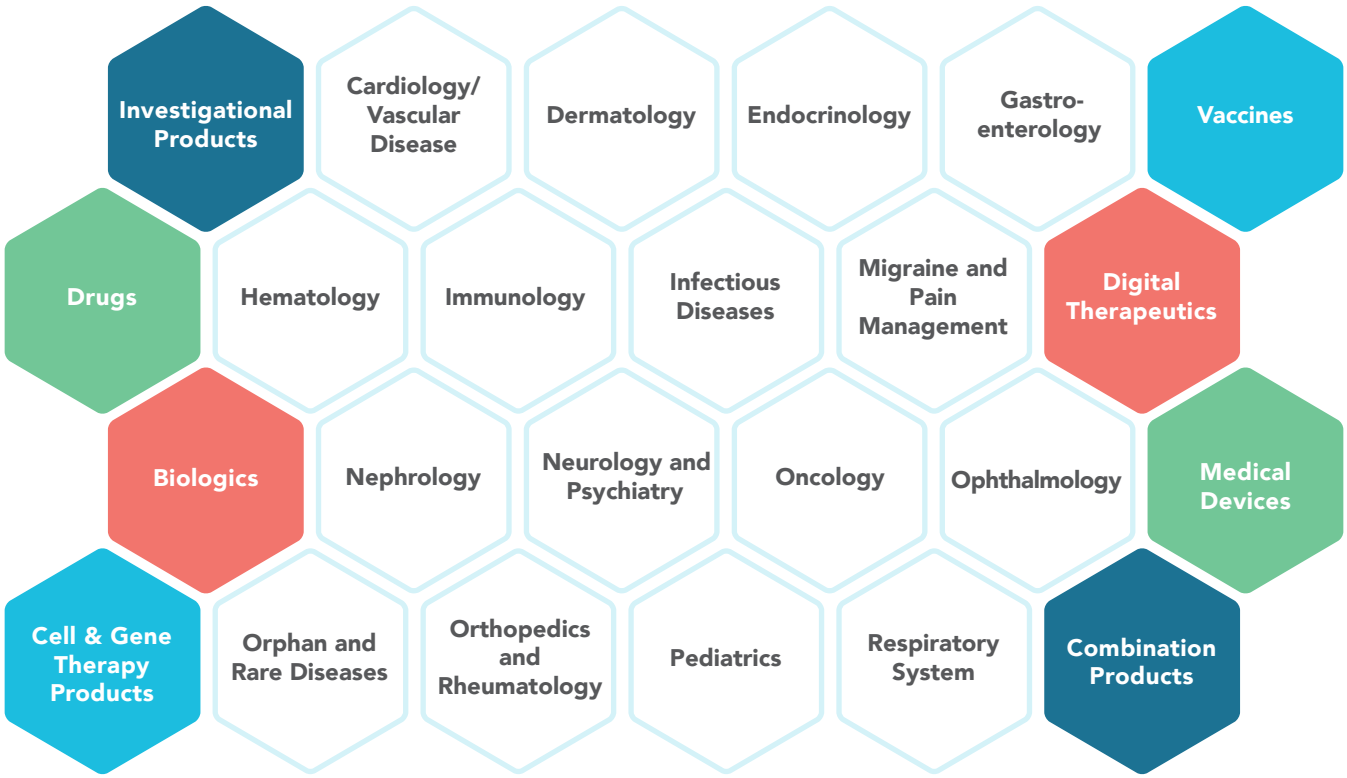
The successful development of any therapeutic product depends on numerous factors, including the safety and efficacy profile, quality of clinical data, appropriate regulatory strategies, and timely regulatory submissions. Drug development is a long and complex process, and it might take years to develop a drug from discovery to successful completion of every phase of clinical development to authorization. The primary objective of the regulatory personnel is patient safety, and their efforts are directed toward handling the growing complexity of product types. As a result, the regulatory requirements are complex and dynamic, adding to the complexity of global end-to-end Pharmacovigilance systems. Biopharmaceutical companies are expected to adopt a proactive pharmacovigilance strategy as they seek market approval for their products. Therefore, appropriate risk mitigation strategies and pharmacovigilance processes should be in place as early as possible.

Why APCER as a Strategic Partner?

The successful development of any product depends on various factors, such as safety and efficacy portfolio, quality of clinical and product development data, appropriate regulatory strategies, and timely submission at each step of approval.

Partnering with a provider that ensures impeccable quality and regulatory compliance is imperative to ensure safe and effective use of therapeutic products as well as anytime inspection readiness. APCER is an end-to-end Pharmacovigilance service provider with the expertise to monitor the regulatory landscape and assess the impact on pharmacovigilance processes to ensure compliance to global and regional regulatory requirements.

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



Clinical Safety and Pharmacovigilance Capabilities

Pharmacovigilance System Setup and End-to-End Integrated Support

- Setting up of safety database and management (e.g., ARISg and ARGUS)
- Safety data exchange agreement support with business partners and third parties
- Pharmacovigilance consulting that involves standard operating procedure (SOP) development, quality systems, and strategic consulting
- Precision and specialized product vigilance activities for cell and gene therapy products, medical devices, and combination products

Serious Adverse Event (SAE) Case Processing

- Integrated pharmacovigilance (PV) and medical information (MI) response centers
- Multi-lingual, multi-therapeutic MI contact centers running 24x7 for medical inquiries and adverse event(s) follow-up
- End-to-end ICSR processing, including medical review and electronic transmission, as required.
- Clinical trial case processing and medical review across all phases
- Data collection support, safety mailbox management, and local safety submission

Literature Surveillance

- Literature searches for products in the investigational stage (in clinical trial phase), pre-authorization stages, and post-marketing phase
- End-to-end literature search and review, including support in defining search strategy
- Global literature screening on various literature search databases such as Embase, PubMed, and customer-specified databases
- Local literature screening as per local regulations, including translation by certified translators
- Procurement and review of full-text articles, where applicable
- Medical literature monitoring

Aggregate Reporting

Our team can support in compilation of aggregate reports as per the regulatory requirements on a global basis, publishing of reports and preparation of submission packages (electronic common technical document [eCTD] format), and electronic submissions to various regulatory authorities via submission portals.

We can support various types of aggregate reports such as:

- Periodic benefit-risk evaluation report (PBRER)
- Periodic safety update report (PSUR)
- Periodic adverse drug experience report (PADER)
- Addendum to clinical overview (ADCO) for renewal
- Clinical expert statement (CES)
- Summary bridging reports (SBR)
- PSUR addendum report (AR)
- Development safety update report (DSUR)
- Annual safety report (ASR)
- Annual investigational new drug (IND) safety report
- Expert report for renewal
- Safety assessment report
- Post market surveillance report (PMSR) for medical devices

Safety Surveillance and Risk Management Activities

- End-to-end signal management, including submission of validated signals and standalone signal notification through various channels, as applicable
- Handling of regulatory recommendations and responses for requests/queries received from the healthcare authorities
- Creation and review of signal management procedures
- Stakeholder/local affiliate workshop/training on signal and risk management process
- Routine risk monitoring activities, including preparation and periodic review of risk management plan
- Implementation of additional risk minimization 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 REMS and aRMM

Global and Local Pharmacovigilance System Master File (PSMF) Management

- Effective set up of modular global PSMF integrating all applicable territorial requirements for PSMFs
- Single PSMFs for applicable territorial requirements
- Risk-based maintenance of PSMF modules/Annexes
- 7-day ad hoc updates for authority requests
- PSMF locations at the country of operation of QPPV, if required
- Expert review and gap analysis of the PSMF procedures and templates

Qualified Person for Pharmacovigilance (QPPV)/Local Responsible Person for Pharmacovigilance (LRP)/National contact person for pharmacovigilance (NCP)

- Global QPPV
- EU QPPV and Responsible Person (RP) for EudraVigilance for clinical trials
- Graduated plan officer (GPO)/Information officer (IO) in Germany
- UK QPPV and NCP in the UK, as applicable
- Well-established network of Local QPPV/LRP in 120+ countries, including all EU countries
- Local QPPV management and oversight support
- Local regulatory intelligence, end-to-end regional PV and risk management activities with translation capabilities
- Direct interaction with local regulatory authorities on PV and regulatory matters
- QPPV office providing oversight and support to QPPVs

APCER's extensive global partner network across 120+ countries ensures that you get 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 Pharmacovigilance services

Experienced team of 100+ physicians, >90% healthcare professionals

Expertise in multiple therapeutic areas for various product types across all phases of the drug life cycle

Experience working for multiple regulatory authorities with Safety Reporting capabilities in 100+ countries

Anytime inspection readiness and experience supporting successful 70+ Regulatory Inspections in last 3 years

Robust processes and accreditations in ISO 9001:2015 (QMS), ISO 27001:2022 (ISMS), and ISO 27701:2019 (PIMS)

Cloud managed ARISg and ARGUS safety databases and other newer technologies in pipeline

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) 11 4650 0802

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