APCER LIFE SCIENCES
Together for better health

CASE STUDY

Enabling compliance through strong PSMF management & QPPV oversight

Therapeutic area: Multiple therapies

Product type: Drugs, devices, and vaccines

Geography: EU

Product life cycle stage: Pre-approval and post-approval lifecycle

About the Client

The client is a leading generics manufacturing pharma company having a significant presence in various therapeutic segments of cardiovascular (CV), central nervous system (CNS), gastrointestinal system, diabetology, pediatric, as well as complex areas such as oncology with advanced research and development (R&D) capabilities and presence in over 40 countries.

Business Challenge

This global pharmaceutical company was preparing and submitting PSMFs through their in-house team. During an MHRA inspection, multiple significant findings were observed which included the following:

- A "major" finding related to the PSMF content and marketing authorization holder (MAH) oversight, which impacted the planning and conduct of the inspection.
- Further analysis highlighted lack of adequate knowledge of GVP Module II, which deals with the structure and content of the PSMF. There was a deficiency in clarity in PSMF-related procedure.
- Due to the lack of PSMF expertise, maintenance of the PSMF documents in-house was challenging for the MAH.

Overview - Pharmacovigilance System Master File

A Pharmacovigilance System Master File (PSMF) is an essential comprehensive document which is mandatory for any marketing authorization holder (MAH) marketing their product within the European Union. This is a dynamic document with Annexures and needs to be updated periodically based on the GVP Module II.

The PSMF contains all the important details pertaining to pharmacovigilance (PV) system, drug safety operations for the MAH and their products. It is an important tool for providing:

- An oversight of the entire PV system.
- Key PV personnel involved.
- Details of the PV databases used.
- Quality oversight and the listing of all related standard operating procedures (SOPs).

This is used as a reference in implementing the various activities, setting up PV processes and is also required at the time of any new submissions.

Solution

The client approached APCER team, which was their existing PV services provider, to provide support for PSMF within 30 days.

- **Established Processes:** Under an experienced project management team by PSMF vertical, consisting of an expert PV manager and a QPPV, our efforts led to a robust risk proportionate PSMF process. The templates and checklists ensured data accuracy per the requirements mentioned in the GVP module II.
- **Gap Analysis:** A governance meeting with the PSMF subject matter experts (SMEs) at APCER and the global client team was conducted to analyze gaps in current PSMF process. There were several deficiencies observed in PSMF content. Based upon the analysis, it was suggested to transcribe the PSMF as per standard operating procedure (SOP) driven APCER templates for data accuracy and data completeness.
- **Kick-off Meeting:** Post analysis, the project team coordinated in transcribing the global data and analysed details from more than 40 worldwide affiliates of the client within a week's time.

Routine PSMF Services

- PSMF/SPS Preparation & Maintenance
  - EU
  - Non-EU (PvMF/PSSF)
- PSMF/SPS Review

Specialized PSMF Services

- Master File Gap Analysis
- RFI Response
- Core and Local PSMF Handling
- MAH oversight Process Set-up and Workshop

Outcome

With an experienced team under the guidance and oversight of its QPPV, APCER was able to:

- Implement appropriate PSMF strategy.
- Address all PSMF-related gaps and concerns related to non-compliance.
- No critical/major concerns for PSMF issues in audit.
- Deliver highest levels of accuracy and helped achieve the regulatory compliance.
- Continuously collaborate with the MAH to maintain EU PSMFs.
- Collaborate on non-EU PSMFs for other semi-regulated markets.

Our PSMF Capabilities

Support 20 global clients on EU/Non-EU PSMF requirements; with over 150 PSMFs and 2600 annexures prepared.

Experience in working with different PSMF templates based on client processes.

Experienced HCPs as PSMF writers/ reviewers led by expert PV manager.

Direct EUQPPVs oversight - as an industry expert.

Core vs Local filling the gap flexible approach for Global PSMFs.

A **robust risk-proportionate PSMF process** with templates and checklists ensuring data accuracy.

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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.

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