APCER LIFE SCIENCES
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CASE STUDY

# Efficient Risk Management Support for Marketing Authorization Applications in LATAM Region for a Leading Pharma Company


**Therapeutic area**: Multiple therapies

**Product type**: Drugs

**Geography**: LATAM

**Product life cycle stage**: Pre-approval

## About the Client

The client is a leading generic pharma manufacturing company which has a significant presence in various indications of cardiovascular (CV), central nervous system (CNS), gastrointestinal system, diabetology and oncology. This company also has an advanced research and development (R&D) capability across the globe.

## Business Challenge

With the changes in regulations, the pharma company experienced an increase in their risk management needs for their products and clinical development programs in Mexico. Their diverse product portfolio included a treatment for hematological malignancies and gastrointestinal and psychiatric disorders. The company had only about 100 days before the new regulations became effective. They had multiple tasks pending including:

- **Submission of risk management strategies:** Any delays could have led the company to spend more time and resources on regulatory approvals resulting in delayed time to market.
- **Writing the RMPs including bringing the local influence into the risk characterization:** Many of the molecules were generic in nature with a large amount of information available on the scientific platforms.

## Overview - Risk Management Plan

**A risk management plan** (RMP) is a document that provides latest information about the safety and efficacy of a medicinal product. The RMP provides key data on plans for studies and other activities to gain more knowledge about the safety and efficacy of the medicine.

**Evolving regulatory landscape:** In mid-2017, Mexico upgraded its pharmacovigilance standards, including risk management requirements of medicines to address the safety issues and improve public health, that became effective from January 2018. The RMP became applicable for all drugs and vaccines related to their risk and post-marketing experiences. RMPs are a mandatory document and the detailed plan contents vary by country. There is broad international agreement on the need for an RMP as an important PV planning measure. COFEPRIS (The* Mexican Drug Regulatory and Health Authority Agency) categorizes RMP preparation according to the safety profile and risk assessment of each drug or vaccine (generics, new molecules, biologics/biosimilars, and orphan drugs). They focus their risk management strategy on evaluating new instruments, training, and the strengthening of human capital. They published the first-of-its-kind RMP development guide influenced by the European Union (EU) and the International Council for Harmonisation (ICH) with a template mix of different EU versions.

*Comisión Federal para la Protección contra Riesgos Sanitarios (Spanish: Federal Commission for Protection against Health Risks; Mexico).

## Solution

APCER Life Sciences, which had already been providing support to this company for its EU RMP requirements and providing consistent timely turnaround for its high-quality deliverables, was engaged to provide RMP support to this company's Mexican product and development portfolio. The intent was to develop a consistent, comprehensive and cost-effective approach. APCER moved forward to address the following areas:

- **Project Management**
  - Constitution of internal team to deal with RMPs for Mexico.
  - Kick-off meetings between APCER, the company and the Mexican affiliate.
  - Dashboard visibility of key performance indicators.
- **Trainings**
  - Country-specific trainings with support from subject matter experts (SMEs).
  - Demarcation of roles and responsibilities for each team member with an RMP subject matter expert.
- **RMP Writing**
  - Critical review of data received from the company (sponsor).
  - Identification of safety concerns.
  - Drafting of RMPs with possible risk minimization measures (RMMs) to address safety issues, thereby improving public health, which were then quality reviewed and medically evaluated to prepare a thorough document.
- **Local Influence**
  - Sharing RMPs with the Mexican affiliate of the company for review to check local relevance.
  - Translation of RMPs into the local language.
  - Strategic planning for implementation of RMMs.

## Outcome

- Successful in providing high quality RMPs within agreed timelines and per regulatory compliance requirements.
- Expedited health authority responses on the content of RMPs and implementation of RMMs.
- Provided a structure to enable strategic and expedited discussions toward RMM implementation as well as enabled the company (sponsor) to implement RMMs in the local market within regulatory timelines. Product launch timelines were also met.
- Through this work, APCER was awarded additional responsibility for end-to-end RMP preparation and implementation from the company for Mexico, Brazil, Chile, Columbia, Costa Rica and some Caribbean countries.

## Our Risk Management Capabilities

- Experience for preparing RMPs for clients, globally.
- Preparation and effectiveness assessment of additional risk minimization measures (ARMM).
- Preparation of targeted follow-up questionnaires.
- Procedure writing support for marketing authorization holder (MAH) oversight/ implementation process.
- End-to-end processes for RMP preparation.
- Expert healthcare professionals and physicians working on each RMP/Risk evaluation and mitigation strategy (REMS).

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We are an ISO 9001:2015, ISO 27001:2013, 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



For Business enquiries, please email at: marketing@apcerls.com
For General enquiries, please email at: info@apcerls.com