APCER LIFE SCIENCES
Together for better health

CASE STUDY

Establishing a regulatory roadmap for post-approval lifecycle management

Therapeutic area: Cardiovascular

Product type: Drugs

Geography: US, UK, EU, Canada

Product life cycle stage: Post-approval

About the Client

The client is a global specialty pharmaceutical company focused on acquiring prescription drugs across a broad range of therapeutic areas and different geographies, viz. the United States, the European Union, the United Kingdom, and Canada.

Business Challenge

- With the acquisition of a drug product from another pharmaceutical company, the client faced challenges with maintaining the track of post-approval life cycle changes.
- The dossiers were filed and approved in multiple geographies, which included the United States, the European Union, the United Kingdom, and Canada.
- The product was filed about a decade ago, and there were historical data with more than 200 sequences per product in the electronic common technical document (eCTD) and non-eCTD electronic submission (NeeS) formats along with various agency communications and commitments.

Overview - Regulatory Life Cycle Management

A drug product transitions from different phases throughout its life cycle. This starts from formulation of an idea, intense research and development around it, creation and compilation of a dossier, and submission of the dossier to regulatory authorities. Data with respect to quality/chemistry, manufacturing, and controls (CMC) form an integral part of the application. Only after the approval of the drug product registration, the product eventually enters the market. In due course of time, after the first launch, the pharmaceutical industries undergo different kind of scenarios wherein changes with respect to quality/CMC of the product are inevitable. The reasons could be receipt of substandard incoming materials, challenges with regulatory compliance of the raw/packaging material manufacturers, financial factors, and so on. The industry leaves no stone unturned in corroborating that the quality, safety, and efficacy of the drug product are maintained and are not affected adversely while implementing these post-approval changes. The sponsors/applicants may outsource the management of post-approval life cycle phase to the regulatory service providers and leverage their regulatory knowledge and expertise in creating high quality dossier packages with quick turnaround and in a cost-effective manner.

- The client was facing challenges with the availability of limited resources to take up the data transition from the previous owner to the client's own systems.
- These factors led the client to look out for third-party regulatory service provider who could support in managing the data transition and take up post-approval regulatory life cycle management of drug products marketed in different geographies.

Solution

To meet the regulatory obligations, APCER:

- Provided tailor-made solutions for handover.
- Mapped the project since its inception, identified milestones, and kept a check on the timelines agreed by the client.
- Provided status updates on regular basis by means of periodic calls (audio/video) with the client.
- Created client-specific SharePoint for data exchange with access controls for ease of sharing data across all verticals, keeping in mind the data security and confidentiality.
- Transferred eCTD dossiers in industry standard publishing software.
- Prepared and verified submission history sheets and reviewed them for completeness.
- Prepared summary files for quality documentation for accurate exchange of information for client's internal teams, viz. QA and Production, and
- Ensured compliance to regulatory commitments.

Outcome

- Seamless transition and handover of client's data within stringent timelines.
- Close monitoring of each action item, which was identified as part of a project plan, leading to the client's satisfaction.

Our Regulatory Affairs Capabilities

Regulatory consulting and execution services with an experienced team of CMC writers and reviewers.

Publication and submission of electronic dossiers in different countries, such as the US, the European Union, the United Kingdom, and Canada.

Regulatory and scientific team with **extensive experience** in preparing regulatory documents throughout the product life cycle.

High-quality deliverables consistently meeting or exceeding client and regulatory expectations.

Custom and fully compliant solutions to meet ever-changing regulatory requirements.

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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 27001:2013, and ISO 27701:2019 certified company.

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