APCER LIFE SCIENCES
Together for better health

CASE STUDY

Partnering for CMC Writing in New Drug Application

Therapeutic area: Cardiovascular

Product type: Small molecule drug-device combination

Geography: US

Product life cycle stage: Product development and New Drug Application submission

About the Client

An innovator pharmaceutical company developing and providing treatment for cardiovascular disorders for ease of "self-administration" of the medication and in turn preventing emergency visits.

Business Challenge

- The client had a small team of drug formulation and clinical experts who developed a robust drug product and administration regimen. However, they had difficulty putting together a structured chemical development report (CDR) and product development report (PDR).
- Further challenges were posed by the involvement of multiple sites in the development of drug substance and drug product.
- The client was looking for product development experts who could assist their internal teams with gap assessments of their drug substance and drug product development, provide development strategies to bridge identified gaps, and write and/or review a CDR and a PDR according to regulatory requirements.

Overview - Chemistry, Manufacturing, and Controls

The pharmaceutical industry invests heavily, which includes financial aspects and knowledge and experience of some bright and strong-willed minds devoted to patient care, in developing a medicinal product to help the end user (a patient) alleviate their ailment.

Much data are generated in inventing a drug molecule and discovering an appropriate administration route ensuring quality, efficacy, and safety.

Health authorities have enacted clear compliance for the industry relating to the extent of data, data type, and data presentation structurally formatted for seamless review and approval. In the ever-evolving healthcare sector, the industry must keep abreast with current regulatory expectations.

To keep track of upcoming updates and ensure complete and compliant submission, sponsors may outsource drafting, review, and compilation of drug product dossiers to regulatory service providers who can leverage their expertise in creating a regulatory-compliant, cost-effective, high-quality dossier package within quick turnaround. The dossier package includes sections on quality requiring expert CMC inputs to understand data, evaluate observations and extrapolate their impact, and compile data in a structured output –

Solution

In order to meet our client's expectations and regulatory requirements, APCER's seasoned CMC reviewers and writers:

- Reviewed initial drafts and collated data supporting the CDR and the PDR.
- Provided guidance on what data to be captured and their representation in a specified format.
- Instituted processes to get controlled access to the client's data repositories for data exchange and writing the reports.
- Evaluated the data and associated documents generated during the development to streamline the CDR and PDR drafting approach. The strategies for developing drug substances and products were defined by highlighting the gaps and establishing the need for additional data required to be generated.
- Worked collaboratively with client's formulation and analytical scientists and provided potential solutions to challenges in the development journey as the project progressed.
- Institutionalized strong governance between APCER and client teams along with monitoring real-time project progress and addressing requirements for regulatory compliance, course correction, and/or identified gap fulfilment.
- Reviewed the initial drafts of CDR and PDR, and updated these reports with newly generated data until report finalization.

Outcome

- Timely completion of the CDR and PDR as per client's project plan.
- High-quality output with the development reports led to increased client confidence and an opportunity to extend business engagement for other CMC sections.
- The finalized CDR and PDR to be used for drafting New Drug Application sections, which would then be submitted to the United States (US) Food and Drug Administration.

Our Regulatory Affairs Capabilities

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

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

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

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 27001:2022, and ISO 27701:2019 certified company.

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