APCER LIFE SCIENCES
Together for better health

CASE STUDY

Successfully Managed Alternative Drug Substance Approval
for Business Continuity

Therapeutic area: Ophthalmology

Product type: Medicinal Product

Geography: US

Product life cycle stage: Post-approval

About the Client

The client is a global innovator company that focuses on the development and acquisition of a range of innovative products, including ophthalmology drugs and devices. The company has been investing significantly in customer-focused research and development, thereby ensuring that products and treatment therapies are designed as per users' requirements and suitability.

Business Challenge

A leading pharmaceutical company needed support on post-approval change for the introduction of an alternate source of the drug substance for one of their products. Their specific challenges included:

- **Managing the vast drug and device portfolio** with a small team of regulatory affairs professionals was difficult for the client.
- **The existing team had limited experience** in strategizing, authoring, and compiling the chemistry, manufacturing and controls (CMC)/quality changes for drug products.
- The client works with different contract organizations for manufacturing and analytical testing of raw materials and packaging materials and drug product. Thus, **liaising with multiple stakeholders** with its small team of regulatory professionals **posed a challenge**.
- **The risk associated with supplies of the existing drug substance** from the supplier was one of the issues the client was dealing with, which had a direct impact on business continuity.

Overview

The pharmaceutical industry is expected to comply with regulatory requirements that are continuously evolving during all phases of drug product life cycle. All companies seek to maintain market authorization and ensure product quality and safety. Therefore, understanding the nuances of post-approval life-cycle management is crucial. Post-approval changes are required for business continuity, which are triggered by process improvisation, rationalizing the cost of raw materials, to address market complaints, etc.

Keeping abreast of the current regulatory requirements incurs enormous cost. Hiring trained regulatory professionals helps the industry to reduce the cost, especially when the product portfolio to be managed is quite vast and across different markets.

A change in the drug substance during the post-approval phase could be due to many reasons, including issues related to the quality of the drug substance, supply chain, and cost. The regulatory authorities across the globe have clearly listed down the conditions to be met and the requirements to be addressed so as to ensure that the drug product meets its intended quality, safety, and efficacy.

Solution

APCER's highly skilled and trained professionals provided a tailor-made solution aligned with client's expectations and scope of work. The team assisted in strategizing the post-approval change to introduce an alternate source of drug substance.

The strategy for handling the change

- **Evaluation of change controls:** The quality documentation from the proposed vendor was reviewed.
- **Assessed the impact of the quality data:** A further review of the implication of the alternate vendor's data on the already approved application in the US market was conducted.
- **Applying knowledge of the regulatory guidelines:** After evaluating the change data, the post-approval change was categorized as Changes Being Effected in 30 days (CBE-30) submission.
- **Communicating the necessary criteria and requirements:** APCER's Regulatory Team shared the clear requirements to be fulfilled with the applicant and the contract organization, which included documentation and data requirements to support the change.

Document authoring and review

- **Prepared the required CBE-30 supplement package**, which was reviewed and electronically published.

Client communications

- **Frequent communication** with the client and the contract organizations to compile the supplemental package within the stipulated timeframe.
- **Timely addressal** of the requirements through frequent meetings.

Outcome

With all the efforts from APCER's Regulatory Affairs team and support from the client, a **comprehensive package** for the introduction of an alternate source of the drug substance with quality data from the alternate vendor was prepared.

The compiled package along with the supplement was **timely submitted** to the US FDA, ensuring compliance with the current regulatory requirements.

The CBE-30 supplement was approved by the US FDA as per the established timelines without any queries.

Upon receipt of timely approval, the risk to drug substance **supply issues was handled**, and the risk to business continuity for the drug product was effectively mitigated.

Our Regulatory Affairs Capabilities

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

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

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