APCER LIFE SCIENCES
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CASE STUDY

Strategies for Extending Drug Substance Shelf Life

During the Post-Approval Phase

Therapeutic area: Cardiovascular

Product type: Medicinal Product

Geography: US

Product life cycle stage: Post-approval

About the Client

The client is a global pharmaceutical company that covers drug products and devices focusing on major therapeutic areas like cardiology, central nervous system, and internal medicines.

It currently markets drug products in different regions across the globe, including the United States of America (US), the United Kingdom (UK), Europe, ASEAN, the Middle East, and other rest of the world markets.

Business Challenge

The client was facing the challenges given below.

- **Limited resources:** Managing the vast drug and device portfolio with a small team of regulatory affairs professionals was a difficult task for the client.
- **Limited experience:** The existing team, which mostly **relied on consultants, had limited experience** in strategizing, authoring, and compiling the chemistry, manufacturing, and controls (CMC)/quality changes for drug products.
- **Identification of alternate drug substance source:** After acquiring a new drug product, the client started facing issues with the availability of an alternate drug substance source, leading to drug product supply disruptions in the US market.

Overview

This case study describes an instance wherein because of constraints in the supply of a drug substance, the drug product applicant insisted on the feasibility of extending the shelf life of the drug substance so that the available lots can be used for extended period for producing the drug product batches. This was a typical case involving deep knowledge of regulatory nuances, extensive coordination with industry as well as regulatory stakeholders, ensuring business continuity for the drug product owner until an alternate source of drug substance could be identified and onboarded.

Extending the shelf life of a drug product has the following benefits:

- Financial benefits: minimized waste and associated costs
- Operational benefits: improved supply chain management and enhanced business continuity
- Patient and healthcare benefits: increased product availability and patient access

Strategies to support the extended shelf life of a drug product include the following:

- Conducting stability studies for a longer period
- Implementing improved manufacturing processes and packaging designs
- Using more stable and robust formulations
- Enhancing storage and handling procedures to minimize degradation

To help the pharmaceutical industry in managing such changes, the regulatory authorities have laid down clear guidance on how the applicants can meet the current regulatory expectations while ensuring product quality, efficacy, and safety. Keeping oneself abreast with the current regulatory expectations, complying with which incurs huge amounts of cost, hiring trained regulatory professionals can help the industry deal with reducing the cost yet making their life easier especially when the product portfolio to be managed is quite vast and across different markets.

- **Limited stock of drug substance:** Only **a small number of drug substance** lots were available at the drug product manufacturing site, which were also approaching the established expiration date, posing a risk of stock depletion.

The only way to avoid a stockout was to check feasibility of extending the shelf life of a drug substance until an alternate source could be identified and onboarded for manufacturing drug product batches.

Solution

APCER's team of experienced and trained regulatory affairs professionals provided support in **strategizing this post-approval change** for extending the shelf life of a drug substance.

- Support in strategizing the post-approval change included:
  - » **Evaluation of the long-term stability data** generated by the existing drug substance manufacturer for an extended period.
  - » **Assessing the impact of the drug substance quality data** with extended shelf life on the already approved application in the US market.
  - » **Utilizing the knowledge of the regulatory guidelines** and our extensive experience in pharmaceutical industrial practices, the post approval change was categorized as Changes Being Effected – 30 days (CBE-30).
  - » **Shared the requirements to be fulfilled** with the applicant and the contract manufacturing organizations (CMOs) (for drug substance and drug product) including the documentation and data to support the change.
  - » **Identified gaps and provided recommendations**, on supporting data, for the CMO (which included stability protocols and data for drug product batches) to comply with current agency expectations.
- APCER's regulatory team **authored the required CBE-30 supplement package** followed by the **review** and **electronic publishing**.
- APCER's regulatory team was in **constant touch with the client** to promptly address the requirements by means of frequent meetings to ensure timely submission of the package within a short span of 2 weeks from receipt of the proposal.

Outcome

APCER's experienced regulatory affairs team helped the applicant to achieve the following outcomes to facilitate the approval for extending the shelf life of the drug substance.

With the collaborative effort from all the stakeholders involved in the project, a **comprehensive submission package** adhering to the relevant regulatory guidance had been prepared.

The supplemental application was submitted successfully to the US FDA, focusing on the quality of the deliverables since its approval had a direct impact on the drug product supply chain.

The well-prepared, high-quality package facilitated **timely approval from the US FDA without any deficiencies** for extending the shelf life of the drug substance.

The risk of disruption to the supply chain was mitigated on time as the available inventory of the drug substance batches was used to manufacture the drug product until identification of the alternate source of the drug substance.

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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