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CASE STUDY

From Challenge to Compliance:
Streamlining Complex Drug Product Manufacturing Site Changes

Therapeutic area: Ophthalmology

Product type: Medicinal Product

Geography: EU

Product life cycle stage: Post-approval

About the Client

The client is a leading global innovator company that focuses on the development and acquisition of a range of innovative products, including drugs and devices for ophthalmic use. It 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 global pharmaceutical company needed support for introducing an alternate manufacturing site for a drug product to ensure consistent product quality and uninterrupted availability for patients. The specific challenges included:

- **Limited Resources:** Managing the diverse portfolio of drugs and devices with a small team of regulatory affairs professionals was a challenge.
- **Limited expertise:** The existing team had limited experience in strategising, authoring and compiling the CMC/quality changes for drug products.
- **Product quality:** Issues with product quality necessitated decommissioning the existing manufacturing site and introducing a new site to ensure quality.
- **Business continuity and continuous supply:** The planned decommissioning of the existing drug product manufacturing site could affect business continuity.
- **Multiple stakeholders:** Communicating with multiple stakeholders, including contract manufacturing organization (CMO) and testing laboratories (for raw materials, packaging materials and drug product) was a challenge.

Overview

This case study elaborates a new drug product manufacturing site approval requirement for a drug product application in the European Union. Marketing Authorisation Holders (MAHs) may encounter such requirements for many reasons, such as:

- Business reasons: to address increasing market demands, reduce the burden on the primary manufacturing site, etc.
- Quality and compliance reasons: to mitigate risks associated with the quality of drug products, issues related to quality compliance and good manufacturing practices (GMP) at the existing facility, etc. and
- Cost effectiveness and profitability

Thus, for the pharmaceutical industry, the regulatory authorities have established clear guidance on how MAHs can meet the regulatory requirements while ensuring product quality, efficacy and safety. 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.

Solution

Based on applicant's expectations and scope of work, a tailor-made solution was provided.

- **A structured strategy for handling the change:**
  - » **Evaluation of change controls:** A thorough review of the administrative and quality documentation available from the proposed site.
  - » **Assessing the impact of the change:** Evaluating the impact of change on the approved application to prevent negative effects on product quality and compliance.
  - » **Liaising with regulatory authority:** Early engagement with the European authority to sought clarity on the extent of drug product batch data to be generated to facilitate timely submission and approval.
  - » **Change categorisation:** Based on the data and information gathered, the variation to address this change was categorised as Type IB.
  - » **Requirements to be fulfilled:** Identified and communicated the necessary requirements to the applicant and other stakeholders to support the change.
  - » **Recommendations to improve quality:** Recommended measures to the existing CMO for the ongoing product quality issues. Kept regulatory authority well informed about the required investigation(s) at each milestone.
- **Authoring submission package:** Prepared a required Type IB variation package which was followed by its review and electronic publishing.
- **Seamless coordination:** Frequent meetings with the client and other stakeholders to timely address the requirements and compile the package within the stipulated time frame.

Outcome

Complete quality package: The team successfully prepared a comprehensive submission package for Type IB variation to support the site change process.

Timely submission: The variation was timely submitted to the European Medicines Agency (EMA), ensuring regulatory compliance.

Client satisfaction: APCER's regulatory affairs professionals monitored each action item closely, resulting in MAH satisfaction.

Regulatory approval: The variation was approved by the EMA as per the established timelines without any additional request for supplemental information.

Implementing enhanced precautions: Identification of the quality and procedural challenges at the existing site helped in establishing additional precautions at the new site.

Maintaining business continuity: Upon receipt of timely approval of the variation procedure, the risk to business continuity of 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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We are an ISO 9001:2015, ISO 27001:2022, and ISO 27701:2019 certified company.

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