NORTHERN EUROPE

CASE STUDY

Regulatory Support and CTD Writing for Tech Transfer Project

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Regulatory Support and CTD Writing for Tech Transfer Project

Why CAI?

Following the acquisition of a range of injectable products, and in order for our client to be operationally ready for commercial production under their own Marketing Authorisation, a site transfer of two sterile injectable products (four strengths) from an already EU approved site to a new manufacturing site was being undertaken. CAI was selected as the Tech Transfer associates and Regulatory Affairs partner to support the Client.

Project Overview

CAI were engaged to provide Regulatory Affairs services, focusing on a comprehensive regulatory gap assessment and authoring of Common Technical Document (CTD) Module 3 sections for four injectable products. The purpose of this project was to support the variation package required for obtaining approval of the proposed changes.

The project commenced with an initial step of performing a regulatory gap assessment comparing the currently registered dossier to the processes utilized at the current manufacturing site. Subsequently, the information gathered was compared to the proposed manufacturing steps at the new manufacturing site. Each identified gap was categorized according to the relevant EU variation category along with conditions to be met and documentation provided.

In the next phase of the project, updated CTD sections were written based on the current and proposed manufacturing methods, analytical methods, and materials. Notably a comprehensive overhaul of the Chemistry, Manufacturing, and Controls (CMC) section of the dossier was undertaken, ensuring alignment with the proposed changes, and addressing any regulatory concerns that arose.

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Challenges

A number of challenges were faced throughout this project. The existing registered dossier did not align with the technological advancements implemented at the manufacturing site, and it fell short of compliance with certain recent regulatory requirements, such as the Annex I update and updates to pharmacopeial chapters. Additionally, certain dossiers had not undergone the necessary updates, transitioning from the Notice to Applicants format to the mandatory Common Technical Document (CTD) format.

Obstacles were also encountered during the tech transfer phase of the project and regulatory solutions were provided to these proposed challenges. The receiving site was not located in the EU and this resulted in some logistical, cultural, and GMP inspection challenges. Furthermore the sending unit did not provide full support for the transfer resulting in some knowledge gaps.

CAI Solutions

CAI's quality and regulatory experts executed the project with the following solutions:

- Strategic planning with the client team to ensure in-depth manufacturing process knowledge.
- Determine availability of current Chemistry, Manufacturing and Controls (CMC) source documentation.
- Through a science and risk-based approach, CAI understood the current product control elements, validation strategy and obtained necessary support documentation.
- CAI effectively facilitated the transfer of process knowledge from the Sending unit to the Receiving unit, effectively completing the Gap Assessments on behalf of the Sending unit.
- Authoring of CTD sections.
- Regular communication with the client's Regulatory Team.
- Alignment between the CAI Tech Transfer Team and the on-site team, guaranteeing adherence to project timelines.

Project Success

CAI's Quality Compliance and Regulatory expertise and collaborative relationship with the client allowed the Drug Product CTD documentation package to be prepared for client review on time. The CTD publishing pack released and the initial Regulatory Agency approval was received without any deficiency letter. CAI's method of seamlessly integrating all these crucial documents along with collaborating with cross functional teams on and off site, played a pivotal role in establishing an operationally ready site contributing to a successful outcome.