NORTHERN EUROPE

CASE STUDY

# QCR: Operational Readiness

## Regulatory Support for Site Technology Transfer



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# QCR: Operational Readiness

## Regulatory Support for Site Technology Transfer

**CLIENT:**
CONFIDENTIAL

**LOCATION:**
NORTHERN EUROPE

**TIME FRAME:**
17 WEEKS

**CONTRACT SIZE:**
$160,000

## Why CAI?

In order for our client to be operationally ready for commercial production, a site transfer of an Advanced Therapy Medicinal Product (ATMP) from an already EU approved site to a purpose-built European site was being undertaken by the client. CAI was selected as the Operational Readiness partner to support them with the regulatory aspects of the site transfer.

Quality, Compliance & Regulatory

**CASE STUDY**

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## Project Overview

CAI were engaged to provide QCR services to author CTD (Common Technical Document) Module 3 Sections for an ATMP (Stem Cell product) to allow the regulatory change.

The regulatory change was managed under a Post-Approval Change Management Protocol (PACMP). A Post-Approval Change Management Protocol, as described in ICH Q12 (Technical and Regulatory Considerations for Pharmaceutical Product Lifecycle Management), details specific changes that a Marketing Authorization Holder would like to implement during the lifecycle of the product and how these would be prepared and verified. This approach supports more agility in lifecycle management and lends itself to operational readiness as it affords opportunity for streamlined change implementation. The PACMP provides a framework and checklist of sorts, for the activities that are required for compliant preparation and verification of the changes proposed. It is also a tool that, where used well, can reduce the complexity of a proposed change (by having transparency around the requirements and studies needed to verify the change and prospective agreements with the regulator) and thus positively impact the reporting category (lower) and health authority approval lead time.

As part of the pre-defined PACMP, CAI were engaged to create updated CTD sections containing information that was streamlined and simplified with the level of detail designed to provide future flexibility.

## Client Challenges

PACMPs require, by their nature, a comprehensive product and process understanding and diligence in risk analysis. This allows the MAH (Marketing Authorization Holder) to understand and predict the impact of a change on the active substance or finished product quality providing assurance the safety, quality and efficacy of the impacted product is not compromised.  Companies are expected to effectively leverage the complex concepts of Quality Risk Management and ICH Q9, and CAI provided support with these intricate subjects.

As this project involved a product transfer between sister sites in different countries, readily available historic (original validations for example) and accurate data were, at times, difficult to obtain from the new manufacturing site.  A gap assessment of the available documents was also conducted to ensure the completed submission package was available for the PACMP.

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## CAI Solutions

**CAI's QCR experts executed the project with the following solutions:**

- Review and familiarization with the approved PACMP commitment with European Medicines Agency.
- 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 andobtained necessary support documentation.
- Author CTD sections.
- Adherence to agreed documentation timelines, understanding responsibilities and report back regularly to the Global Regulatory Team.
- Management of the content within the Regulatory Repository.
- Act as liaison between new manufacturing site and the Global Regulatory Team.

## Project Success

CAI's Quality Compliance and Regulatory expertise allowed the Drug Product CTD documentation package to be prepared for client review one week ahead of schedule. The client review process was completed without incident and the CTD publishing pack released.

Regulatory Agency approval was received without any deficiency two weeks ahead of the expected date. CAI's approach in weaving together all these critical documents helped in achieving an operationally ready site with a successful outcome within an accelerated timeline.

*Client Reference is for internal use only.*