***TAKEDA*, GRANGE CASTLE, DUBLIN**

CASE STUDY

Alofisel P3 Cell Therapy Facility

Commissioning, Qualification, and Validation

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Overview

After recently delivering a successful project in Regeneron and giving our strong historical relationship with Takeda, CAI was selected to support Takeda GC in rescuing a failing CQV project.

Takeda and CAI have a long-standing relationship; CAI supports Takeda at many key sites globally (Lexington, Brooklyn Park, Thousand Oaks, Osaka etc.) in commissioning, qualification, quality systems, and Operational Readiness.

Project Overview

Takeda Grange Castle constructed a new Advanced Therapy Medicinal Product (ATMP) manufacturing facility (P3) on the Takeda GC site dedicated to the manufacture of Alofisel to supply the EU, Canada, and Nordic country markets. The P3 facility is a modular constructed facility with 6 production rooms.

The project was falling behind schedule and budget and was not on course to meet its deliverables. CAI was tasked with completing the qualification effort of Production Rooms 1 and 2 and associated process equipment at the Takeda GC facility.

CLIENT:

Takeda

LOCATION:

Dublin, Ireland

TIME FRAME:

4 Years

CONTRACT SIZE:

€50 million

Client Challenges

The project team faced several challenges which directly impacted the success of the project.

CAI Challenges	CAI Solutions
Document Management System: • Missing documents • No electronic versions available • No access for CQV personnel to client DMS	• All documents generated electronically to mitigate potential loss of information. • Actively engaged with SME early in the process and creating a tracking file to establish responsibility/ accountability and understanding on document status. • Unstructured electronic document storage – reviewed online document storage filing and rearranged files into a user-friendly and coherent filing system. • Site DMS access for CQV personnel meant a more efficient document routing process and quicker approval.
Vendor Commissioning/Validation: • Tests executed incorrectly – not addressing critical acceptance criteria/testing requirements. • Inadequate GDP/paperwork	• CAI implemented a 'Perfect Pack' approach - greater assessment of vendor protocols was carried out prior to execution with QA, SME and CQV involvement. • CQV representative to witness testing and review executed paperwork to avoid unnecessary deviations. • Greater QA involvement during protocol generation to mitigate against future testing gaps/deviations. • Vendor training • Independent document reviews
Change Management System: • No access to client CMS to raise change controls/ Notification of Events (NOEs) /CAPAs. • Manual change control log in place	• Client CMS access for CQV department for quicker change resolution and implementation • Quantify change and implement engineering change management process
Communication/Lack of Key Stakeholder Involvement: • Project SharePoint not properly maintained. • Difficult to get key stakeholder involvement/input (affected by Covid/Remote working) • QA personnel only on-site 3 days a week (delay in document reviews/approvals) • Lack of Coordination between departments on schedule changes/sharing utilities	• Early and constant engagement with all key stakeholders to drive better coordination and a right-first-time scenario. • Dedicated QA staff on-site every day to sign off paperwork.

Project Success

The project was delivered on-time with the successful qualification of both Production Rooms 1 and 2. This was a notable achievement for the CAI team as it significantly contributed to the delivery of the first ATMP facility in Ireland.

Takeda recognized this and CAI won additional scope with the qualification of Production Room 4 project worth an additional €0.6m. Since then, CAI have expanded their service offerings to Takeda GC, providing QA/QP services, Regulatory Affairs support, and continuing CQV support since 2020.

Takeda GC P3 facility was Ireland's first ATMP facility and thus was a unique project with which CAI played a key role in delivering. As a result of this success, CAI has gained additional scope and expanded their service offerings in Takeda GC. CAI has become a trusted service provider for Takeda GC.

"The successes we have experienced in Cell Therapy P3 Grange Castle are a reflection of the dedication and commitment from the CAI team members, the CAI team has led by example and fundamentally displayed the knowledge and skill set required to support Takeda P3 Operations and HPRA readiness"

– Bertie Daly, Manufacturing Head, Cell Therapy Takeda P3.