ARE YOU READY?

MEDICAL MANUFACTURER, *TBILISI, GEORGIA*

MDR COMPLIANCE PROJECT

CASE STUDY: COMPLIANCE & REGULATORY ISSUES

MDR Compliance Project

CAI started its collaboration with the client in 2019 originating from personal contacts of CAI agents. During this time, CAI delivered more than 350k€ of projects focused mainly on quality, compliance, and regulatory affairs. The MDR compliance project cost about 200k€.

In the vicinity, there were limited service providers which allowed CAI to step in with their worldwide scale to bring EMA/FDA level quality and compliance to the regional life sciences industry. CAI's reputation, technical expertise, and skillset delivered a successful project.

CLIENT:
Confidential

LOCATION:
Tbilisi, Georgia

TIME FRAME:
~1.5 years

CONTRACT SIZE:
200K€

PROJECT OVERVIEW

The Medical Device Regulation (MDR) project lasted approximately 1,5 years with up to four Senior CAI agents involved with numerous tasks throughout the project. An initial gap assessment against the new MDR requirements was conducted by CAI. A project road map was then designed with the client's management to address the identified gaps. Workstreams (several working teams) were created to follow up and close the gaps on the MDR requirements. The QMS (Quality Management System) was adapted to the new MDR model originating from a historical approach where the previous EU medical devices regulation and client CE certificate was based. All the company processes were reviewed and updated with reference to clinical studies, biocompatibility, batch release, and sterilization validation. New aging studies were also started to extend the products expiry date from 3 to 5 years.

The road map included the following:

- Perform high level initial review.
- Map the existing QMS to the CAI MDR based model.
- Perform detailed QMS gap analysis vs MDR 745/2017 requirements.
- Develop 19 MDR based quality system new procedures. Update 15 existing procedures.
- Develop 45 MDR compliance templates aligned with new QMS procedures.
- Develop 3 technical files with product information
- Regulatory strategy revision and advisory for Notified Body application.

CLIENT CHALLENGES

A project charter was developed to monitor project status, however sub-charters requested for client sub-teams to monitor the project advancements were never developed.

Steering Committee Meetings were organized quarterly to provide update on the project progresses. Up to now 28% of the action plans were not started due to regulatory postponements. 72% closed or in final draft review. The project closure date has been postponed due to the regulatory filing postponement.

CAI SOLUTIONS

Several highly technical skilled CAI agents guided the client through the Notified Body application. All the client's processes were reviewed and updated in reference to clinical studies, biocompatibility, batch release, and sterilization validation. New aging studies were also initiated, to extend product life from 3 to 5 years.

PROJECT SUCCESS

Numerous projects have been running in parallel at the client's site however the MDR project, coordinated by CAI has been the biggest from the company's perspective and one their most successful. CAI supported creation of a new quality culture, with a modern and lean approach to medical devices, including Class IIb and III compliance and quality. During CAI's collaboration and support, many new markets opened. New products were launched with process improvements and enhancements to existing products and the introduction of the operational excellence model to the client. Several Notified bodies audits confirmed the new CAI approach was best in class. Client resources knowledge increased and their compliance skills set was on par with the new MDR guidance.

ARE YOU READY?

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