BIOLOGICS CLIENT, *LIAONING PROVINCE, CHINA* **CASE STUDY**

QMS Remediation to Comply With FDA / EU / Industry Best Practices

Quality, Compliance & Regulatory

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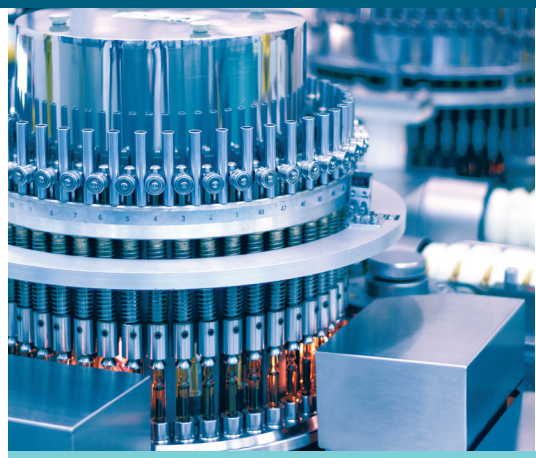
QMS Remediation to Comply With FDA/EU/Industry Best Practices



Overview

- Map the existing QMS to the CAI ICHQ12 based model
- Perform high level initial review
- Perform detailed GAP Analysis
- Develop 35 integrated risk-based Quality Systems Manual / Policies / Procedures

Challenge

The client's QMS was fragmented and siloed, and the facility was not yet operational.

Solutions

CAI used in-house tools to map the existing to an in-house best in class ICHQ10 based model.

CAI brought together a panel of 6 US and EU based Consultants that were able to flex in and out of this project while inputting on their specific areas of expertise.

CAI were able to redefine the QMS to focus on Quality Systems as distinct from GMP operational procedures.

CAI integrated many different informal QRM tools into the QMS to help differentiate Quality from Business attributes.

The CAI team worked in a collaborative manner to ensure that the overall QMS was based on a standard set of risk and science-based principles and deployed common terminology.

WHY CAI?

We were brought in because of our Global reach. CAI has a panel of EU- and US-based Consultants and Qualified Persons available that are experts on EU/FDA GMP requirements. CAI could execute this project remotely with an onsite presence of our China-based Project Manager. We were also able to provide translation services from our China Office.

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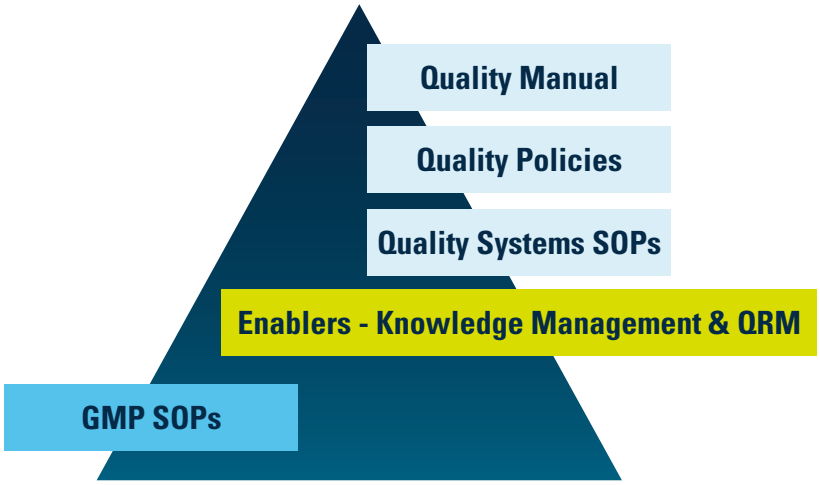
Solutions (continued)



Result

Clients QMS redesigned to align with industry standards, principles of QRM were embedded in the Client QMS to ensure ongoing efficiencies and to minimize the size of the Quality footprint.

Client well positioned to apply for EU or US product marketing authorizations.