***CLIENT*, NEW ENGLAND REGION, USA**

CASE STUDY

Company X Quality Systems Integration

Quality, Compliance, & Regulatory

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Company X Quality Systems Integration

Project Overview

A team of six CAI personnel worked as the liaison between the parent company's external quality assurance and the purchased company X to integrate quality systems and ensure a smooth transition for five global product lines. In addition, the CAI personnel were charged to support ongoing remediation efforts from previous FDA inspections and meet timelines previously provided to the FDA for corrective actions.

Quality Systems

- Quality Agreements
- Inspection Readiness
- Change Control
- SOP Development
- cGMP Training
- Deviation Investigation

Challenges

- All products and their components from the purchased company were externally manufactured.
- Defining clear supply chain requirements including markets to be served by each product.
- Supporting of regulatory filing changes including on-going market launches and new external partners during the integration activities.
- Supporting of six mock inspections and three internal audits performed in a two year period throughout the transition.
- Supporting of FDA inspections with all external partners.
- Managing knowledge transfer of product lines and quality history during personnel changes.
- Leading movement from a manual document control system to an electronic system.

CLIENT:
CONFIDENTIAL

LOCATION:
NEW ENGLAND REGION, USA

TIME FRAME:
2 YEARS

CONTRACT SIZE:
$2.5 MM

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Solutions (Continued)

- Negotiated quality system requirements with external partners for cell bank, API, Drug Product, Packaging, and Distribution resulting in 23 executed quality agreements.
- Worked cross-functionally with the parent company's purchasing, legal, and external manufacturing to align requirements with external partners.
- Handled knowledge transfer/development for all FDA observations.
- Closed all open change controls from the purchased company within 9 months, allowing smooth transition to the parent company's change control system.
- Defined training requirements and set up training plans.
- Each CAI resource performed as the project manager detailing the work flows and progress for each affected quality system.
- Participated as scribes, planners, and Subject Matter Experts for mock inspections and internal audits.
- Executed six quality agreements between global internal parent company sites and the purchased company X, providing clear guidance on roles and responsibilities.

Value Delivered

All five product lines not only remained viable to the parent company but also were expanded into new markets for future revenues. External partners were streamlined for improved CMO management. All external partners passed FDA inspections during the transition period ensuring patients that they would continue to receive safe and effective products.