CONFIDENTIAL CLIENT

US AND EUROPE
5 YEARS | $1.3 MILLION

PHASE 3 STERILE DRUG PRODUCT AND API

- Commissioning & Qualification
- Building Commissioning
- Asset Management & Reliability
- Quality, Compliance, & Regulatory
- Human Performance
- Process & Manufacturing Technology
- Program & Project Management
- Automation & Information Technology
- The Chemistry of Full-Scale Operations™
- Data Centers

WHEN YOU NEED TO MEET A HIGHER STANDARD™

PROJECT OVERVIEW

Two CAI senior manufacturing consultants, representing a virtual pharmaceutical company, directed process and analytical method development at three CMOs to accomplish the production of Phase 2 and Phase 3 clinical supplies of API and sterile drug product. CAI authored IND CMC submittals to the FDA that gained approval of manufacturing and testing programs as pre-requisites to Phase 3 clinical trials. Additional CAI subject matter experts supported the project as-needed in areas of Quality Compliance, Risk Assessment, Process Technology, and Regulatory Affairs.

OBJECTIVE

Project objectives were multi-faceted: selected a new US-based CMO for sterile drug product for scaled-up Phase 2/3 manufacturing and accomplished the transfer of process technology and analytical test methods; coordinated the API process and analytical improvements to perform Phase 3 manufacturing at a European CMO; oversaw the manufacturing and testing of two formulations of sterile drug product to support Phase 3 clinical trials; complied with FDA regulatory requirements for Phase 2/3 IND CMC submittals and gained agreement that the manufacturing program was satisfactory to support Phase 3 clinical trials.

SERVICES PROVIDED

- CMO selection using risk-based approach for sterile drug product.
- Technology transfer risk assessment with risk mitigation programs for drug product.
- Quality compliance audits for three CMOs, (API, DP, Packing/Distrubting) and the supplier of a critical excipient.
- Program management for the successful technical transfer of the sterile drug product process and analytical test methods, including lab-to-lab equivalency challenge.
- Process development for two sterile drug product formulations and an improved API process. Development included process capability using QbD techniques.
- Product specification and retest increments defined for Phase 2 and 3 drug product.
- Oversaw and approved the design, selection, and testing of all labels and packaging components.

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- Wrote and approved all process related MBRs, SOPs, and study protocols at CMOs.
- On-site supervision at CMOs for all production runs during Phase 2 and 3 drug product batches and the Phase 3 API batch.
- Approved long term stability studies for all products. Initiated and directed implementation of alternative sterility-indicating test for vials.
- Directed bulk placebo process development and production to support FDA required non-clinical toxicology studies.
- Secured "specialty" contract services such as: elemental impurity analysis, toxicology assessment of process change, and sterile filter validation.
- Authored IND CMC sections for submittals of two new INDs.
- Owner-representative services covered: MS Agreements (3), Quality Agreements (4), Confidentiality Agreements (9), Contracts (27 with 9 vendors), Scope Changes (16).

VALUE DELIVERED

Under CAI project leadership, the Client had sufficient supply of sterile drug product in time to support planned Phase 3 clinical trials and future Phase 2/3 studies of new indications. CAI applied experience in Quality Compliance, Regulatory Affairs, Process and Analytical Technology, Manufacturing, and Technology Transfer to advance the project from CMO selection through "product in the warehouse," with FDA alignment. The project met all schedule and budget requirements.