

CONFIDENTIAL CLIENT

CALIFORNIA | USA
ONGOING SINCE 2016 | \$170,000

DRUG PROJECT ANALYSIS AND PROCESS TRENDING



 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

CAI provided consulting services to a client that is a virtual company that requested process analysis of their CMO's manufacturing for better process understanding and to identify potential improvements for each of their product lines. The client has launched three new products in three years and is currently performing scale-up activities at both existing and new CMO's requiring sterile manufacture. Two of the products use a novel polymer that is hygroscopic yet will degrade in the presence of water. CAI's work for this client included learning the processes and criticality, identifying process gaps, performing process data gathering, setting up Minitab for SPC/Process trend analysis, and summarizing information and findings.

OBJECTIVE

The objective of this project was to perform detailed process analysis and to set up statistical process control and process trending. The process data would be used to support Annual Product Reviews (APR) and regulatory filings.

SERVICES PROVIDED

- Detailed process datasets
- CPP alignment with CQAs
- Gap analysis
- SPC Analysis with summary of findings
- Process Trending
- Set up of Quality System for quarterly process reviews

VALUE DELIVERED

The process data analysis performed by CAI provided insights into process performance and potential areas of improvement. The use of CAI's experience with process consulting covered three new drug products and the novel, critical excipient. SPC analysis and process trending was used in the Annual Product Reviews and provided Continuous Process Validation (CPV) for Product Lifecycle monitoring.