***CONFIDENTIAL*, CATANIA, ITALY**

CASE STUDY

Full-Scale Operations for Parenteral Pharmaceuticals

Program & Project Management

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Full-Scale Operations for Parenteral Pharmaceuticals

Project Overview

CAI had the pleasure of partnering with a leading parenteral pharmaceuticals manufacturer and utilizing a OPM services approach to the Evaluation, Upgrade and Requalification of Autoclaves, Vial Washers, Depyrogenation Tunnels, Data Recorders, Vial and Syringe Fillers, Dry Heat Ovens, and Cappers.

Project

CAI led an integrated US and European project team through accelerated milestones in development, approval and execution of Equipment Evaluations, Equipment Specification Documents, Installation Qualification, and Operational Qualifications. Additionally, CAI helped drive the necessary culture changes needed for Validation, and Qualification of equipment and processes.

People

CAI led the effort to establish a culture change of the Validation Group in the approach used to perform initial and recurring qualifications for equipment and processes. The team took the lead in improvement roles and training validation personnel in new methods and principles of test writing when qualifying equipment and processes. The team generated and secured approval of multiple validation SOPs, IQ/OQ/PQ, and Equipment Specification Documents as well as document templates for future work.

Process

The CAI Team eliminated redundant documentation and qualification tasks and introduced risk based assessments to determine alarm criticalities and actions. CAI helped author and implement the Site Validation Master Plan and implemented an efficient process for verifying that manufacturing systems were suitable for their intended use. The methods used to determine the basis for acceptance criteria, product quality and patient safety risks were also established and managed. An ASTM E2500 approach to qualification was employed, to make certain that critical process and product parameters were determined and validated in thorough testing protocols.

CLIENT:
CONFIDENTIAL

LOCATION:
CATANIA, ITALY

TIME FRAME:
1 YEAR + 3 MONTHS

CONTRACT SIZE:
$615K

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Facility

The CAI team initially focused on documentation and requalification of physical equipment, providing support in areas such as alarm management, operational analysis, maintenance requirements and other tasks. CAI worked to develop Equipment Specification Documents that would be used as the basis of validation protocols. Our Team generated and executed the IQ/OQ/PQ protocols needed for selected equipment being requalified during a scheduled plant shutdown.

Quality

Quality management was critical throughout the project at all levels to meet an additional project goal of Agency Inspection readiness. Coordination with the site Quality leadership was augmented with CAI leading the effort to change the perspective of how quality attributes are viewed and approached. The new methods put in place were designed to align the site with Global Quality processes.

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