



Joe Holland

CQV Engineering Manager

Joe serves as the CQV Engineering Manager for TCS, where he is responsible for oversight of CQV Engineers and generation / management of commissioning and qualification services. He is well versed in the fields of facilities/utilities/equipment commissioning and qualification, process validation, and project management within the pharmaceutical and medical device manufacturing industry (USDA/FDA/EU regulated). He is skilled at developing proficient qualification strategies and has a strong ability to execute validation or commissioning plans within the client's timelines and requirements for regulatory compliance.

Education

University of Georgia,
B.S. Biochemical
Engineering

Certifications

Engineer-in-Training
(EIT): Georgia

OSHA 30-Hour

Areas of Experience

Project Management

FUE Commissioning &
Qualification

Sterilization Process
Validation

Aseptic Process
Validation

Factory and Site
Acceptance Testing

Quality Assurance

Risk-Based
Qualification

Aseptic Gowning

Root Cause Analysis

Failure
Troubleshooting

Audit Response /
Support

Risk Assessing

Plant Chiller System Commissioning Agent

TCS is currently serving as the Commissioning Agent providing testing and documentation for the phased replacement and upgrade of a large, multibuilding process chilled water system supplying three chilled water loops delivering -25 °C, -10 °C, and 6 °C glycol solution. Two existing chillers and assorted pumps, controls, and safety systems will be replaced with new 200-ton ammonia chillers and new pumps with variable frequency drives. An additional chiller, pumps, and cooling tower is also being added to allow for an N+1 redundancy to the system. Joe is acting as the Lead CxA for the project.

Global Innovation Center of Excellence Laboratory and Office Expansion

TCS managed the construction and commissioning of a ±65,000 GSF laboratory and office expansion project. The BSL2 laboratories support a range of activities from both bio-development and research functions. Joe serves as the Quality Assurance Project Manager, having joined the project at the start of the Implementation/Construction phase to oversee commissioning and qualification activities. Systems include HVAC (AHUs, FCUs, VAVs, CAVs, Energy Recovery Unit, Glycol Skid), lab gases / process utilities (CO₂/N₂/LN₂/O₂/CDA, RO/DI water, waste), vacuum systems, building automation system (BAS), walk-in cold storage, architectural finishes, boilers/pumps, chillers, electrical, generators, fire alarms/protection, lighting and controls, lightning protection, laboratory equipment, and more. The team created and executed over 120 CQV protocols within the 20-month project construction and turnover schedule.

ABSL₃ Avian Isolator Facility Sterilization System

Joe provided CQV / QA management oversight for the design, installation, and qualification of a fully automated vaporized hydrogen peroxide (VHP) decontamination system for an animal research facility. The project scope includes upgrades to an existing BSL2-level facility, installation, and start-up of a full-facility VHP system, and construction of a utility building to house the VHP generation skid. Joe's role includes direct management of TCS's CQV Engineers during generation and execution of all commissioning and validation activities related to the project.

Filling and Freeze-Drying Production Facility

Joe was a member of the quality assurance and CQV team for the implementation, commissioning, and qualification of a project for ~47,000 ft² GMP CLA sterile aseptic blending, 600vpm filling, automated freeze drying, refrigerated storage and ancillary support areas. The team tackled over 150 CQV protocols within the 24-month project schedule.

Small-Volume API Manufacturing Department Upgrades

Joe served as the Quality Assurance Project Manager on a project for design and implementation of various process upgrades to an active pharmaceutical ingredient manufacturing plant. The project included: design and buildout of a custom 400L antigen concentration skid; onboarding of a 300L single-use fermentation system with portable chillers and computerized control panels; and buildout of necessary facility / utility upgrades required for delivering clean steam, lab gases, and electrical for support of the new systems. The modifications and implementation of the upgrades were managed within a GMP environment, around ongoing and active site operations, and the project was completed on time to support onboarding of new product lines for the client.