

## Manufacturing Process and Equipment Validation Review, Approval and Implementation

### OVERVIEW

Compliance Implementation Services (CIS) was retained in 2010 by a mid-sized global pharmaceutical company to aid the Quality Assurance (QA) department with validating and commissioning a new start-up (ISO 5, 7, and 8) biologics-based, multi-product, disposable, perfusion-based manufacturing suite. This involved CIS consultant engagement with validation document review and approval to ensure compliance during the Installation Commissioning Validation (ICV) activities.

### SCOPE

Assistance with the validation documents surrounding the manufacturing site required an understanding of the client company's existing quality systems, as well as federal and international manufacturing regulations and guidances. CIS worked with cross-functional groups to facilitate on-time closure of protocols and discrepancies. When CIS arrived, both validation and document timelines were behind schedule. However, but with the assistance of CIS consultants, the speed of the documentation workstream was promptly increased to start meeting deadlines. CIS also helped create, review, and approve facilities, cell culture, purification, stand-alone equipment, and manufacturing support Standard Operating Procedures (SOPs). As this was a start-up facility, all processes were new and had to be written and implemented from the beginning.

### METHODOLOGY

CIS Subject Matter Experts (SMEs) referenced 21 CFR 210 and 211, as well as ICH Q7, to ensure that the documentation being reviewed and approved conformed to all necessary industry regulations. In addition, CIS ensured that the validation work was in line with American Society for Testing and Materials (ASTM) standards. Using their professional SME experience, combined with industry regulations, CIS was able to deliver results that were both compliant and effective.



### PROVEN EXPERTISE

Compliance Implementation Services (CIS) is a consulting firm specializing in compliance strategies for pharmaceutical companies. Our experts can quickly identify your exposure to compliance risks, help you develop a strategic plan and ensure its implementation, and assist you in on-going adherence to legal and regulatory requirements.

CIS' experts have a deep understanding of the following areas:

- Supplier and Vendor Audits
- Inspection Readiness
- Key Performance Indicators (KPIs) Development
- Quality Systems Development and Enhancement
- Global Quality Process Harmonization
- Root Cause Analysis and CAPA Effectiveness
- Document Control System Development and Enhancement

## DELIVERABLES

CIS used best-practices from the pharmaceutical industry, leveraging ASTM guidelines, to ensure that all ICV documentation was driven through to completion with minimal discrepancies. With the successful roll-out of validation documents and protocols, the pharmaceutical company will be able to ensure that they meet market demand for their new drug product.

Documents reviewed and updated by CIS during this project included:

- Commissioning Test Plans (CTPs)
- Installation Operational Qualification (IOQ)
- Performance Qualifications (PQs) and Process Validation (PV)
- Design Reviews (DRs)
- Process and Identification Diagram (P&ID)
- Deviations
- cGMP Investigations
- Change Controls
- Metrology System Requests (MSRs)
- Standard Operating Procedures (SOPs)
- System-level and Component Criticality Assessments
- Validation Discrepancies

## BENEFITS

The client benefited from CIS’ consultants project work in the following ways:

- Competent SMEs mined existing documentation in relation to QA questions and potential issues.
- CIS consultants were able to leverage existing documentation from suppliers, commissioning and technology transfers to reduce the number of required testing and documents for the overall project.
- Assurance that SOP and validation documents met current industry best-practice standards and compliance regulations (21 CFR 210 and 211, ICH Q7 and ASME).



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- The client company’s validation documents, system-level, and component criticality assessments, IOPQs, process validation, and SOPs now contain vast improvements that can be leveraged for future validation documentation projects.
- The client company is now positioned for a positive outcome and successful completion of future FDA inspections.
- CIS was able to help the project move forward and increase the ability of the QA department to meet the established timelines.