

# Commissioning, Qualification, and Validation SMEs

PSC is one of the largest providers for Commissioning, Qualification, and Validation services for the life science industry. Our team consists of seasoned experts in the validation of equipment, facilities, utilities, computer systems, processes, and cleaning validation. We provide end to end solutions with expertise in Validation Master Plans, Requirement Specifications (URS/FRS/DS), Risk Assessments, Traceability Matrices, IQ/OQ/PQ Protocols, Summary Reports, and Turnover Packages.

## Our Expertise

### Equipment Validation

- Lab Instruments & Analytical Methods
  - HPLC, GC, Centrifuge, Pipettes, Freezers, Incubators, Lyophilizers, Depyrogenation, Autoclave
- Manufacturing Equipment
  - Fill lines, Packaging Equipment, S&R
- CQV, FAT/SAT Support, Documentation

### Facilities Validation

- Cleanrooms, Filling, Packaging, Labeling, and Warehousing Facilities, Safety Requirements
- CQV, Decommissioning, P&IDs, Design Engineering, Project Engineering, Training, Maintenance, 21 CFR 210/211

### Utilities Validation

- Critical Utilities, Black Utilities, Water Systems, Pure Steam, Compressed Air, Medical Gases, HVAC, CIP, SIP
- CQV, Piping Layouts, Critical Utility Inspection, Audit Preparations

### Computer Systems Validation

- Software Validation, Automation and IT
  - BMS, CDMS, CRM, CTMS, DMS, EBR, EDC, eDHR, eMDR eQMS, ERP, eTMF, LIMS, LMS, MES, PLC, PLM, RIM
- 21 CFR Part 11, GAMP 5, Risk Based CSV, Manual and Automated Testing, Data Migration, Qualification, Quality Assurance

### Process Validation

- Prospective Validation, Retrospective Validation, Concurrent Validation, Revalidation
- Process Design, Process Qualification, Continued Process Verification, 21 CFR 210/211, 21 CFR 820, Product & Manufacturing Process Transfer, Product & Process Specs

### Cleaning Validation

- Sampling (Direct Surface Sampling/ Swab Sampling, Rinse Sampling), Routine Production In-Process Control, Analytical Methods
- Documentation, Cleaning Process Design, Equipment Design, Establishment of Limits

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