

Commissioning, Qualification and Validation

CQV Services

Advent Engineering provides Commissioning, Qualification and Validation services for life science facilities, utilities and equipment. ADVENT brings engineering aptitude to fast track CQV projects. ADVENT has extensive experience with practical implementation of risk-based (ASTM E-2500) verification methods.

Advent has expertise in all phases of the CQV life-cycle including Master Planning, Risk Assessments, Design Verification, System Verification, Process and Cleaning Validation, Cycle Development and Performance Qualification, Periodic Review, and Re-Qualification. ADVENT Engineering manages deliverables through a complete understanding of compliance intricacies in implementing biopharmaceutical manufacturing solutions.

Core Competencies:

- ▶ Process Equipment – Upstream, Downstream, Fill Finish & Support Systems
- ▶ Facilities and Utilities such as WFI, Clean Steam, HVAC, CTEs
- ▶ Automated Systems (DCS, PLC, SCADA, MES)
- ▶ Quality Control Labs & Analytical Instruments
- ▶ Medical Devices
- ▶ Enterprise/IT Systems

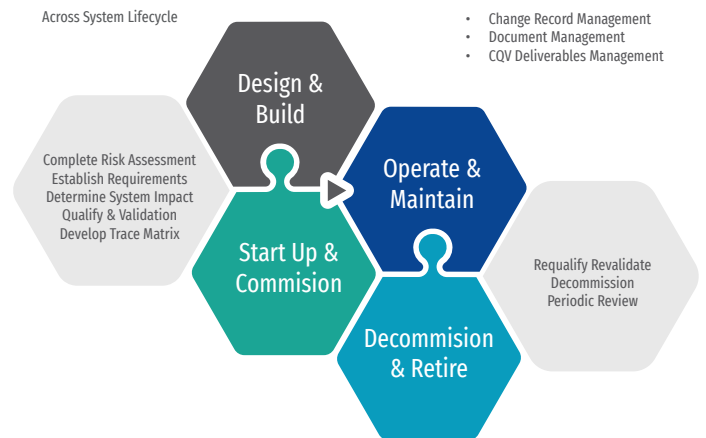
CQV Practices:

- ▶ Risk-based, Verification Programs
- ▶ CIP Cycle Development & Cleaning Verification
- ▶ Recovery Studies for Cleaning Verification
- ▶ SIP Cycle Development
- ▶ Isolator VHP Decontamination Cycle Verification
- ▶ Proactive Troubleshooting & Resolution on Verification Exceptions
- ▶ Thermal Mapping, Autoclave Sterilization Cycle Development

Areas of Expertise:

- ▶ Commissioning and Qualification Master Planning
- ▶ ASTM-E2500 Verification, FAT,SAT and Integrated CQ
- ▶ Design Qualification
- ▶ Risk Assessments, Trace Matrices, Risk Control Strategies

Advent CQV Expertise



- ▶ Re-Qualification & Re-Validation
- ▶ Cleaning & Process Validation
- ▶ Turnkey & Managed Service CQV
- ▶ Analytical Instrument Qualification and Method Validation.
- ▶ Technical Registrations Document Management
- ▶ Data Integrity Assessment
- ▶ Paperless Documentation & Approval Routing
- ▶ Custom Software for Cloud Based Deviation & Change Management

Professional Qualifications

Trinity Consultants' Advent Engineering Life Science Solutions team includes industry veterans from legacy companies Advent Engineering and Aztec Technologies, which were acquired by Trinity Consultants in 2018 and 2022, respectively. Our team has deep expertise in the commercialization of pharmaceutical/biopharmaceutical processes. The team includes highly qualified engineers and other technical specialists who work onsite at client facilities, performing engineering and design work to meet clients' development and manufacturing goals.

Advent Engineering's CQV team has subject matter experts with professional certification. Many Advent Engineering team members maintain leadership and active participation in ASQ, ISPE, ASME-BPE, PDA, and other industry organizations.

For more information, please contact us at info@adventeng.com or 919.313.7234.