An interdisciplinary teamwork consisting of engineers and technicians with focused expertise in process engineering, commissioning, qualification, information technology, quality and used to operate in regulated environments, will provide you a full service, including the use of our in house measurement instruments park.

Our qualification solutions are based on the latest regulatory requirements and guidelines maintaining the focus on minimizing cost and compliance related risks.
SERVICES
PORTFOLIO

- Validation Plan / Master Plan
- Commissioning Plan
- Support in issuing/improvement of procedures to enhance lean qualification streamline
- Process Equipment and Utilities Inventory
- User Requirement Specifications
- GMP Compliance Assessment / GAP Analysis
- Remediation activities to cover assessment gaps
- Design Qualification (DQ)
- Risk Analysis / Impact Assessment
- Supplier Testing Activities Witnessing (FAT/SAT Support)
- Qualification Protocols (IQ, OQ and PQ)
- Clean Room Qualification
- Temperature Mapping Services
- Transport Validation
- Sterilization Process Validation (ETO, Gamma, Steam, Overheated Water)
- Technology Transfer
- Calibration Services

Input to C&Q Process

Product Risk Assessment / Control Strategy (ICH Q8)

CQAs

CPPs

Regulatory, Organization / Site, Operational, Health and Safety / Environmental Requirements

Requirements

Design Specify

Build / Verify

Accept and release

Continued improvement

Operation

Periodic Review

Traceability

C&Q Planning

C&Q Testing and Documentation

Acceptance and Release

DR/DQ

System Risk Assessment

System Classification

URS