System Qualification Division (CQV)

From Commissioning & Qualification to Validation Maintenance

SQ Division, part of D.O.C. s.r.l, MASCO Group, offers a wide range of services from Commissioning & Qualification of new or in use Systems to re-Validation of equipment and Systems used in pharmaceutical Manufacturing Processes, including Training on GMP related topics.

DOC
MascoGroup

Our experience

SQ Division can offer to its clients more than 25 years of experience in the CQV of pharmaceutical process equipment and critical utility systems following the international cGMP requirements.

Project Organization

SQ Division is organized in several project teams equipped with the most sophisticated validation instrumentations to face the different pharmaceutical manufacturing technologies during the CQV phases and following periodical re-qualification and re-calibration activities.

Main services

Consultancy Services

DOC can offer a wide range of consultancy services focused on GAP Analysis and Recovery plan for existing facility to comply with current regulatory requirements (e.g. New Annex 1 for manufacturing sterile products).

cGMP General support

- System GMP Design Review
- RTM & Quality Risk Analysis
- Existing Facility GMP Audit
- Validation Master Plan
- SOPs preparation support
- Qualification Documentation Gap Analysis & recovery
- Data Integrity Compliance assessment
- cGMP inspections preparation

Commissioning Support & Qualification (CQV)

At DOC, our team has in-depth, hands-on experience in the qualification of pharmaceutical equipment and systems, following the requirements of Regulatory Agencies (e.g. US-FDA, EMA, PIC/S, WHO, etc).
Our qualification methods follow the EU-GMP Annex 15, WHO, PDA and ISPE Guidelines for CQV.

Commisioning Support

- VIT Support
- FAT
- SAT
- Instruments Calibration

Qualification:

- Design Qualification
- Installation qualification
- Operational qualification
- Performance Qualification
- Change Control Qualification

Validation Maintenance

DOC can support its clients in the Validation Maintenance activities by providing Re-Calibration services, Process and System Re-validation both as periodical activity and in case of system modification and revamping.

Validation Maintenance services

- GMP Impact Assessment in case of system modification
- Instrument Re - Calibration
- Periodical Process and System Re-Validation
- Change Control & Re-Validation

CSV & Data Integrity

DOC can provide its clients the Computerized System Validation and Data Integrity compliance Verification for GMP direct impact System Controllers following the relevant GMP requirements from EMA, US-FDA and international guidelines (e.g. GAMP).

Data Integrity

- Data Governance
- Process & Data Flow focused on Data Integrity
- Data Integrity requirements verification (ALCOA+)
- GAP Analysis, Risk Assessment (DIRA) & Remediation Plan

CSV

- VMP & URS Review
- Inventory List
- RTM
- FDS & HDS review
- FAT/SAT witnessing
- IQ/OQ support