Product & Process
Validation services

From process validation and material qualification to consultancy and training.

DOC
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A dedicated team offering a wide range of services

At DOC, our team of skilled project managers, biologists, and biotechnologists leverages deep industry experience to provide comprehensive services in the development and validation of sterile processes, culminating in the qualification of pharmaceutical and cosmetic finished products.

We adeptly handle a broad array of product formulations, including Active Pharmaceutical Ingredients (APIs), cytotoxic substances, controlled drug substances, and their precursors.

We perform validations for both newly developed and existing processes, adapting to any improvements or modifications. Our methodical approach to process validation aligns with international regulatory compliance, with each validation tailored to the specific demands, significance, and complexity of the process and equipment.

Our validation services

Focusing on pharmaceutical and cosmetic liquid applications, DOC is able to offer the following validation services:

- **Consultancy** and **Documentation** support
- **Filter** Validation and Ancillary Tests
- **Packaging** Qualification
- **In-process Material** Qualification

We ensure personalized guidance every step of the way.

Our team, composed of seasoned project managers, trainers accredited by AIFA, and members of premier pharmaceutical associations like AFI and PDA, provides expert support throughout your entire project.

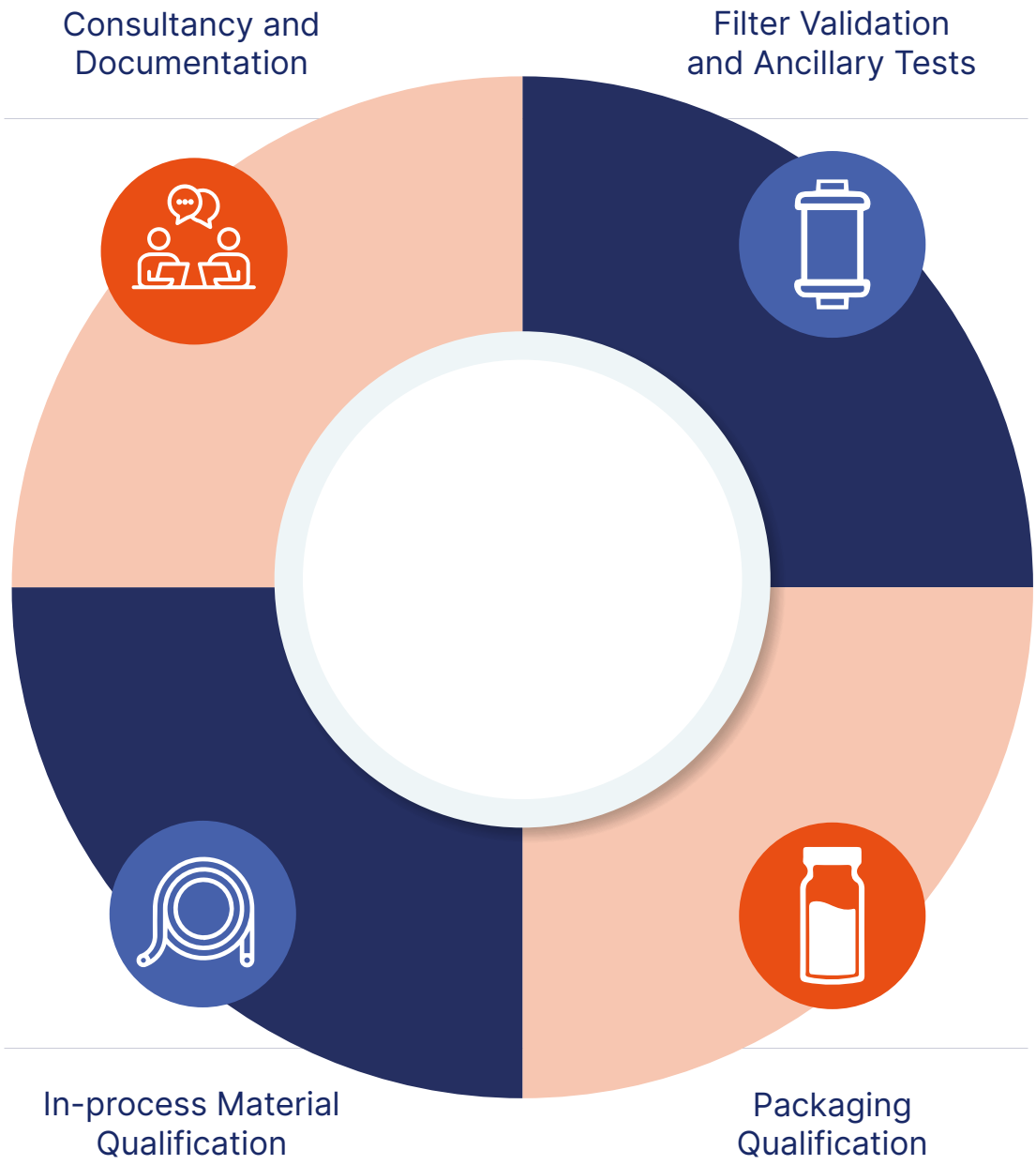
From the initial design of study definitions to the discussion and interpretation of results, we ensure **personalized guidance** every step of the way.

A dedicated point of contact will assist you, guaranteeing **tailored support** and streamlined project execution.

An expert team of laboratory technicians perform tests in GMP-oriented regime in our own **MascoLab.**

Main services

Validation and qualification services focused in the *following areas*



Consultancy and Documentation

Full client support for process and validation documentation in compliance with the last regulatory guidelines.
An unique team of project managers is able to evaluates process data available, issues the documentation and supports clients until regulatory submission and audit.

Consultancy

- Cleaning validation
- Process Validation
- Annex 1 - Contamination Control Strategy
- APS (Aseptic Process Simulation)

Documentation

- Gap analysis
- Risk assessment (Extractables and Leachables, Nitrosamines, Elemental Impurities)
- Extractables assessment
- Toxicological assessment

Filter Validation and Ancillary Tests

Filter validation activities in compliance with the main regulatory and technical references: **Annex 1, PDA TR No. 26, FDA Guideline Aseptic Processing, ASTM F838-15, USP <1663>, USP <1665>**

Filter Validation

- Compatibility
- Extractables and Leachables
- Adsorption
- Bacterial Viability
- Bacterial Retention Studies

Activities supporting filtration systems

- Filterability test
- Rinsing Study (Bubble Point and Forward Flow)
- Product-Wetted Integrity tests (Bubble Point and Forward Flow)

In-process Material Qualification

In-process materials qualification and ancillary tests performed in compliance with the last regulatory and technical references: **Annex 1, USP <87>, USP <88>, USP <381>, USP <661.2>, USP <1663>, USP <1665>**

Material Qualification

- Compatibility
- Adsorption
- Extractables and Leachables

Activities supporting the Material Qualification:

- Biological Tests for Plastics and Elastomers
- Physic-chemical Tests for Plastics and Elastomers

Packaging Qualification

Packaging components (Elastomeric closures, Glass and Plastic Materials) qualification performed in compliance with the last regulatory and technical references: **USP <1663>, USP <1664>, USP <1207>, USP <381>** and **USP <1660>**

Packaging Qualification

- Compatibility
- Adsorption
- Extractables and Leachables
- Container Closure Integrity Test
- Functionality assessment
- Biological test
- Inner surface durability of Glass Containers
- Antimicrobial Effectiveness Test

Guidance for regulatory challenges

Product & Process Validation services

DOC
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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.

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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