

Product & Process Validation services

From process validation and material qualification to consultancy and training.

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.

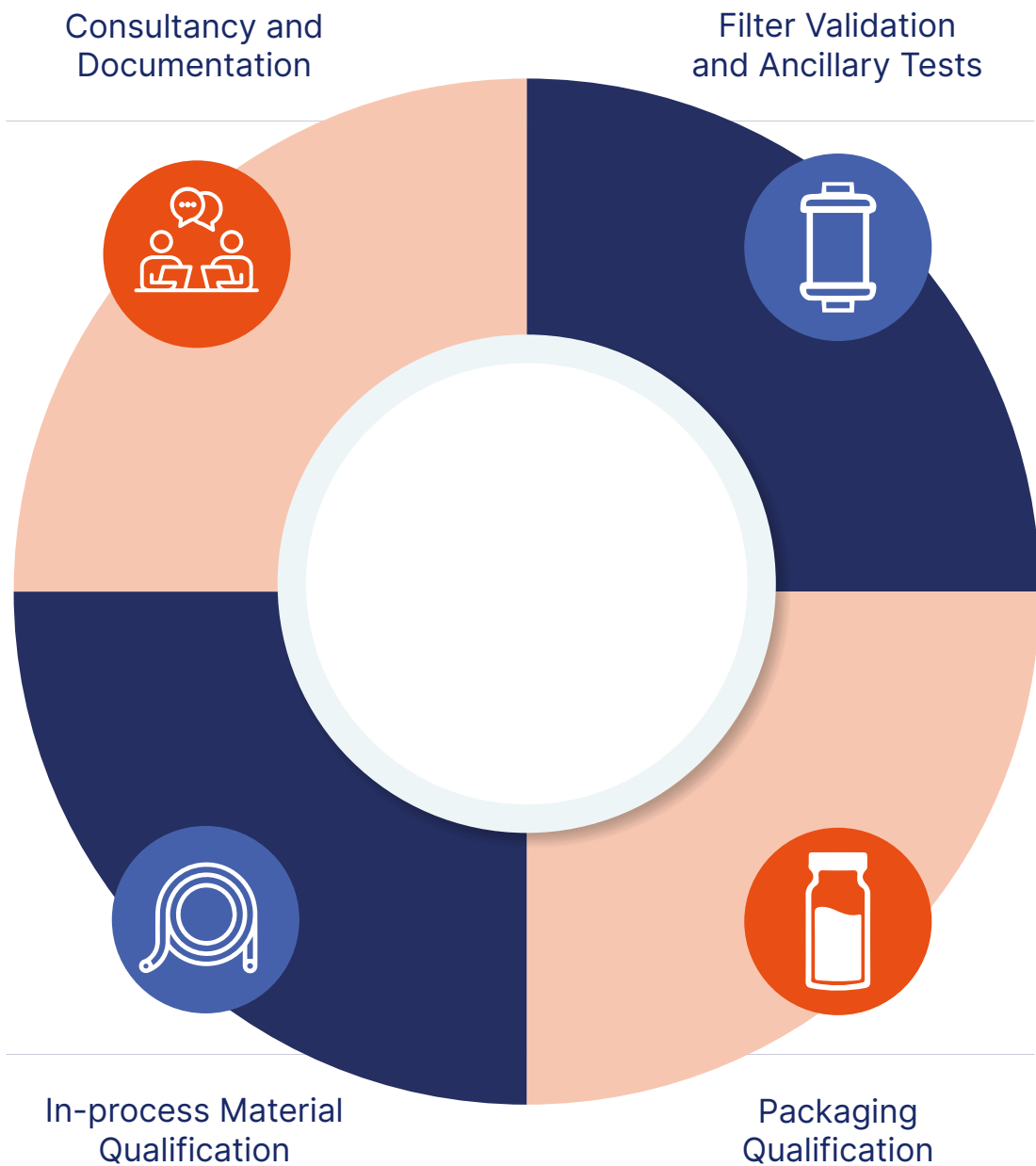
Our team, composed of seasoned project managers, trainers accredited by AIFA, and members of premier pharmaceutical associations like AFI and PDA, provides expert support throughout your entire project.

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**.

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 evaluate 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

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