



MascoLab

Certified Laboratory for Pharmaceutical *Process Services*





Your Trusted Partner for Pharmaceutical Process Services

At MascoLab, we specialize in delivering reliable and high-quality validation and analytical services to support your pharmaceutical manufacturing processes.

As **part of Masco Group**, we draw on over a century of engineering excellence, cutting edge technologies for clean utilities and upstream liquid processing, and global manufacturing capacity to ensure rapid scaling, safety and performance in every project.

MascoLab is a spin off of DOC, Masco Group's Commissioning, Qualification and Validation (CQV) & Product Process Validation (PPV) expert, **created to deliver fully integrated validation, analytics and compliance.** Backed by over 25 years of industry expertise and cutting edge technical know how, DOC

has guided many pharmaceutical and biotech companies through qualification, validation and compliance challenges with confidence.

Partnering with DOC and other Masco Group companies, **MascoLab merges precision validation services with DOC's process validation and regulatory guidance.** The result is a fully integrated solution that accelerates your time to market, lowers risk and inspires confidence at every stage. Together, we deliver the best of Masco Group for smarter, faster and more reliable outcomes.

Facts & Figures



+750

Validation Project
concluded



+10

Years of
experience



+100

International
clients



UNI EN ISO 9001
Certified



From concept to compliance, MascoLab supports every step of your validation journey.

MascoLab Services

We provide specialized validation services to support GMP compliance and pharmaceutical development.

With a deep understanding of the life science sector and a strong commitment to regulatory excellence, MascoLab offers a full suite of validation services.

We support our clients throughout the product lifecycle, ensuring operational efficiency, and full regulatory adherence.

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

- Process Validation
- Cleaning validation
- Annex 1 - Contamination Control Strategy
- On-site support
- Training

Documentation

- Gap analysis
- Quality Risk Management (QRM)
- Extractables assessment
- Toxicological assessment
- Risk Assessment

Filter Validation Testing

We support the validation of filtration systems with end-to-end project coordination, analytical testing, and compliance strategies aligned with current regulatory expectations.

In compliance with the main regulatory and technical references: Annex 1, PDA TR No. 26, FDA Guideline Aseptic Processing, ASTM F838, USP <1663>, USP <1665>



Filter Validation

- Compatibility
- Extractables and Leachables
- Adsorption
- Bacterial Viability
- Bacterial Retention Studies (including PUPSIT procedure)

Activities supporting filtration systems

- Filterability test
- Rinsing Study
- Integrity tests (Bubble Point, Diffusive/Forward Flow, Pressure Hold)
- Product-Wetted Integrity tests

In-Process Materials and SUS Qualification

Our team conducts risk assessments, documentation audits, and targeted analyses to qualify in-process materials and Single Use Systems (SUS) used during manufacturing, ensuring process integrity and product safety.

Performed in compliance with the last regulatory and technical references: Annex 1, USP <87>, USP <88>, USP <1665>



Material Qualification

- Compatibility
- Adsorption
- Extractables and Leachables

Complementary activities

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

Primary Packaging Validation & Qualification



We evaluate the compatibility and suitability of primary packaging components through scientific studies and compliance-focused protocols, helping ensure product protection and regulatory alignment.

Performed in compliance with the latest regulatory and technical references: USP <87>, USP <88>, USP <381>, USP <1207>, USP <1660>, USP <1663> and USP <1664>

Packaging Validation & Qualification

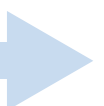
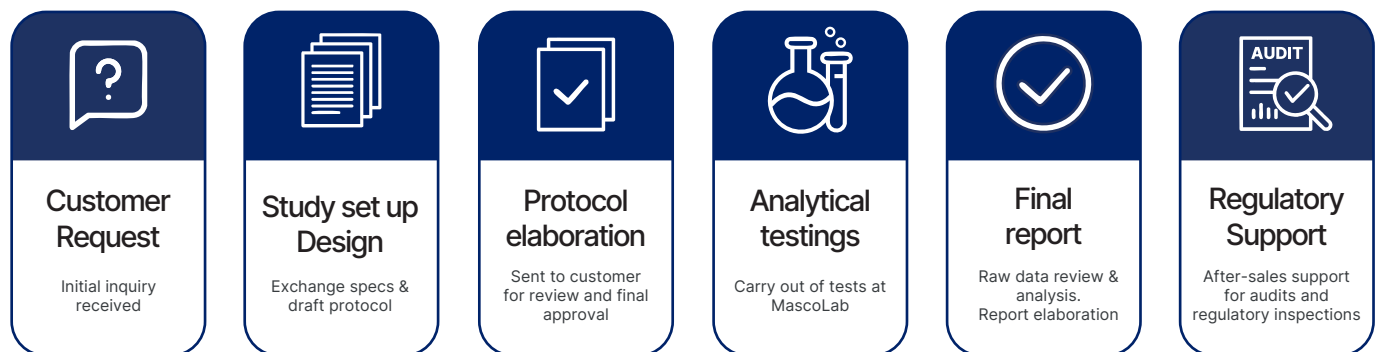
- Compatibility
- Adsorption
- Extractables and Leachables
- Container Closure Integrity Test
- Functionality assessment
- Biological test
- Inner surface durability of Glass Containers
- Antimicrobial Effectiveness Test





Our Workflow

Each project follows a structured workflow. From the initial request to the final report, every phase is overseen by dedicated project managers to ensure clarity, compliance, and efficiency.





From concept to compliance, MascoLab supports every step of your validation journey.

Meet the Experts

We're scientists, specialists, and problem-solvers — but most of all, we're people who care deeply about the work we do and the impact it has.



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D.O.C. srl - Documentation
Organization and Consultancy