

Your ideal partner
to validate your
pharmaceutical
drug production

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Thanks to an experienced team of Project Managers and Laboratory Technicians, our mission is to **help you by delivering high quality standard validation and analytical services, in compliance with the latest GMP regulations.**

LabAnalysis Process Pharma qualified laboratories, located near Milan (**Italy**), are fully equipped for any kind of **validation activities** and **process development** such as filtration patterns, single use components and systems, in-process materials and primary packaging qualification. The synergy with LabAnalysis Group ensures a **360° support** for any type of other analytical assessments for validation, quality control and investigational purpose.

OVERVIEW



+3.000

Validation Project
concluded



+50

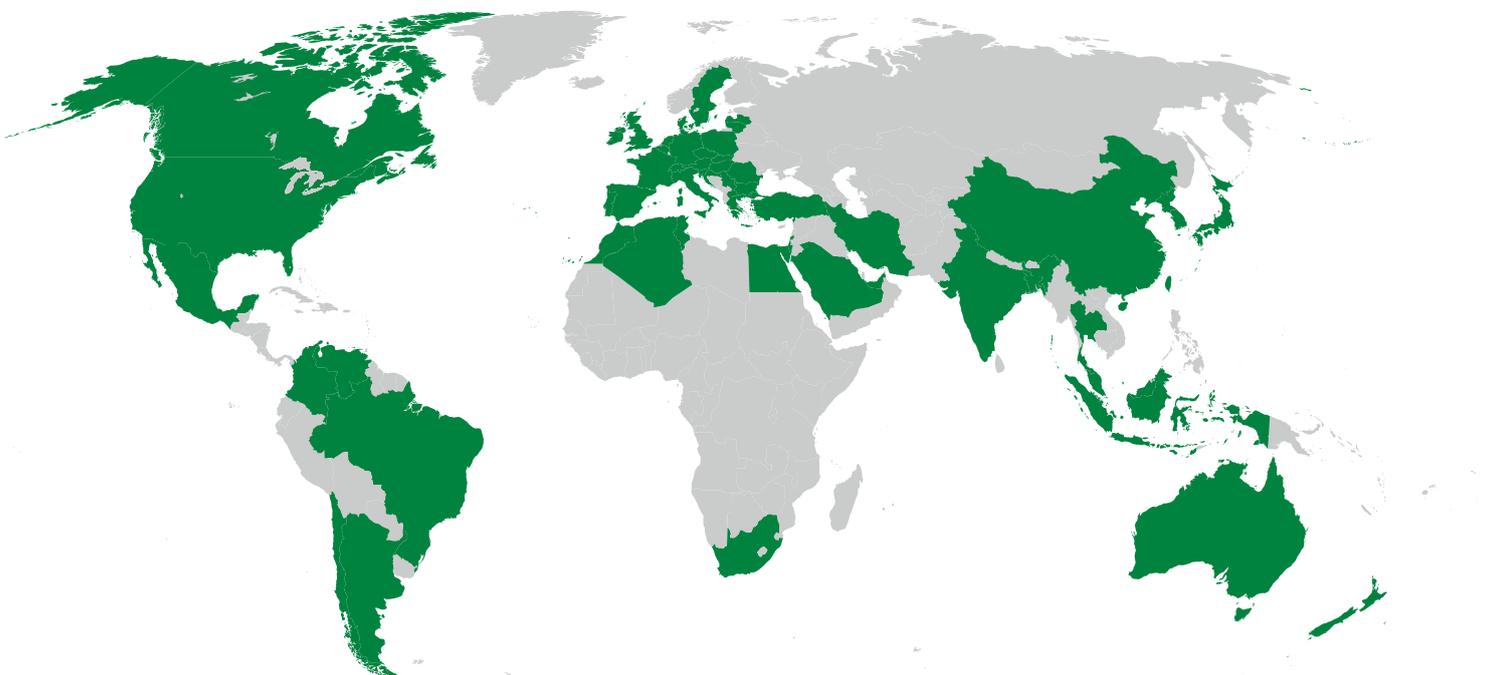
Years of experience in
filter and SUS validation



+14.000

Lab & offices
dedicated sqm

LOCAL REACH GLOBAL EXPERTISE



LABANALYSIS PROCESS PHARMA AUTHORIZATION



UNI EN ISO 9001

LABANALYSIS LIFE SCIENCE AUTHORIZATIONS



GMP Certificate
by AIFA Italian
Medicines Agency



FDA Approved by
US Food & Drug
Administration



GLP Certificate
by Italian Ministry
of Health



UNI EN ISO 9001



UNI ISO 45001



UNI EN ISO 14001

SERVICES

Product and Process Filter Validation

- Compatibility Studies
- Extractables and Leachables Studies
- Adsorption Studies
- Viability Studies
- Bacterial Retention Studies
- Product wet integrity test

Extractables and Leachables Studies in Elastomeric closures, Glass and Plastics

- Qualifications and Quantifications
of organic and inorganic compounds
applying several analytical techniques

Inner surface durability of Glass Containers (USP 1660)

Compatibility Studies of material in contact with drug product

Adsorption Studies of material in contact with drug product

Toxicological Evaluation and Assessment

Cleaning Validation

- Validation Master Plan
- S.O.P. Development and Review
- Cleaning Validation Protocols and Reports
- Grouping & Bracketing Approach
- Toxicological Assessment (PDE)

In process qualification studies for

- Tubing
- Connection
- Biocontainer
- Process equipment or material in contact
with the pharmaceutical formulation

Single Use System Validation

Process Optimization Study

- Screening
- Filterability
- Feasibility
- Scale-up studies

LabAnalysis Process Pharma experts are **operative members within pharma regulatory recognized association (PDA)**, **qualified trainers for regulatory agencies (AIFA; ANM; EOF)** and **educational programs (university master)**.

PRODUCT TYPES



Pharmaceutical
Products



Biotech/Biologics



API



Vaccines

CUSTOMER TYPES



CMO/CDMO



Medical device
manufacturers



Technology Vendors



Consultancy
companies



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Head quarter

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