LabAnalysis
PROCESS PHARMA

Process Validation

Your ideal partner

to validate your pharmaceutical drug production

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.

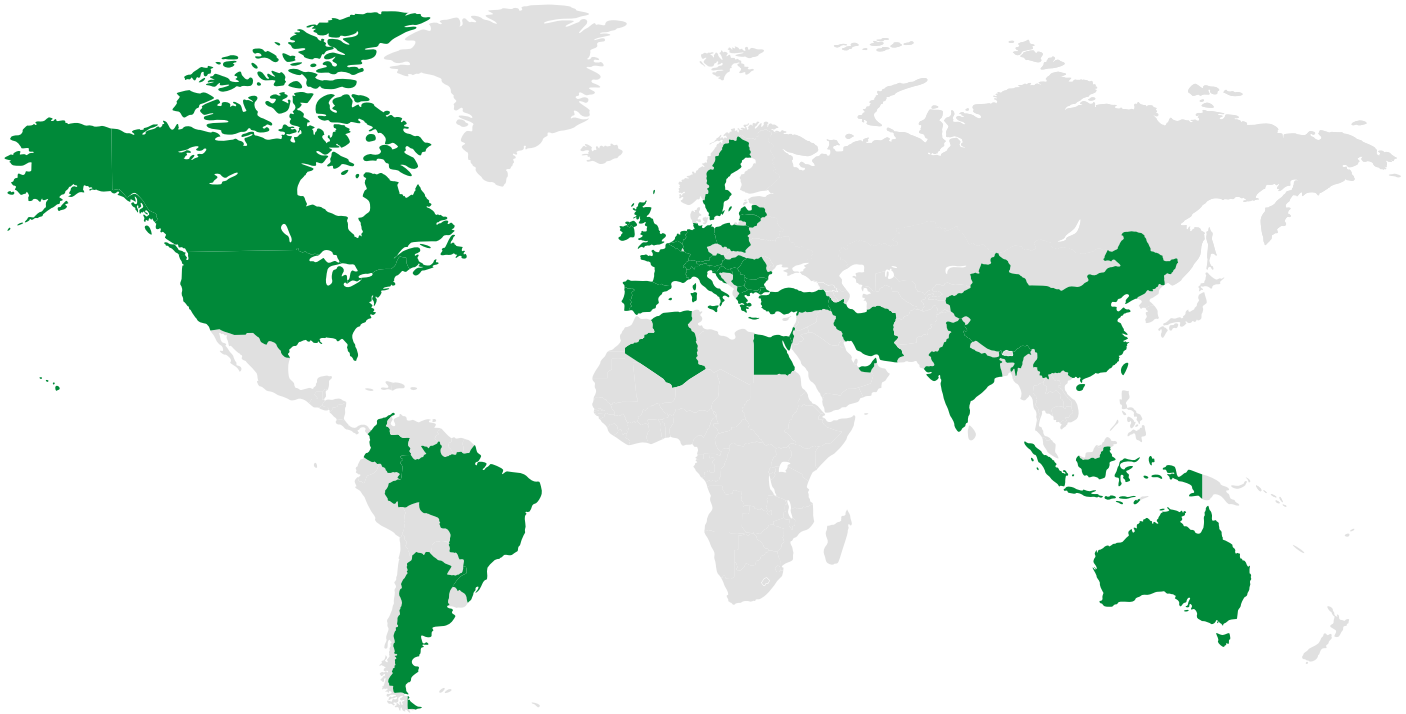
OVERVIEW

+3.000
Validation Project concluded

+25
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

LabAnalysis
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