

# Trusted Expertise in Pharmaceutical Analysis

Regulatory driven, phase appropriate analysis to support your CMC programs **from development to release** 

Complete Drug Development Support

In Depth Regulatory Knowledge Proven Track Record

Raw Materials, Excipients, APIs, DS, DP, and Packaging



# Your single, trusted analytical partner for your entire product development journey

# Characterization

Our deep expertise in all major physico-chemical analytical technologies ensures robust molecule characterization. By assessing the attributes that impact your product's stability, potency, purity, and safety, we reduce the risk of unexpected hurdles and guide your analytical testing strategy for later clinical phases.

# cGMP DS & DP Testing & Release

Complete portfolio of drug substance and drug product testing and release services **in accordance with ICH Q2A/Q2B**, with rapid turnaround to eliminate supply chain bottlenecks.

### Excipients and Raw Materials Testing & Release

With just-in-time analysis and a large portfolio of verified methods, we support your production plan and inventory management. From sample release to receipt in 10 business days.

# **Stability Studies**

We offer a **comprehensive storage and testing portfolio** at every phase of the development cycle, with 600+ stability programs under our belt, all in accordance with ICH guidelines for drug development.

## Impurities and Extractables & Leachables

From initial profiling to commercial control strategy, we provide a full suite of impurity and contamination control services. With state-of-the-art equipment, HRAM technology, and our proprietary database with 6,000+ E&L compounds, we identify tracelevel impurities even in the most difficult matrices and delivery systems.

GMP-compliant services performed in accordance with FDA/EMA, BPSA, PQRI, and ISO 10993, USP 1663/1664, 665/1665.

#### Impurities

- ✓ Nitrosamines and genotoxic impurities (ICH M7)
- Elemental impurities (ICH Q3D)
- Process-related impurities (PRI)
- Residual solvents (ICH Q3C)
- Unknown organic impurities (ICH Q3A/B)
- Particulate matter

#### **Delivery Systems**

- OINDP
- ✓ Parenteral
- ✓ Oral
- ✓ Topical & transdermal
- ✓ Single-use products

### **Biosafety Testing**

Our microbiology labs offer compendial and alternative rapid methods that fast-track your product development, with **results in 5 days**.

# Bring your innovation to its destination



# **One-Stop Analytical Solution**

We cater to all your analytical needs with our unparalleled expertise.



# Complete Drug Development Support

From early characterization to commercial release, we guide you through each step of the drug development process.



# In Depth Regulatory Knowledge

Our expertise blends scientific and regulatory knowledge, allowing us to offer solutions from development to troubleshooting to over 700 global customers.

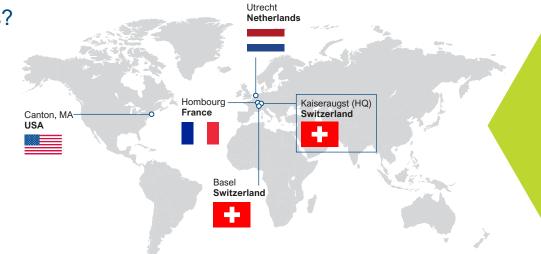


# Proven Track Record

Our dedication to quality, timely delivery, and customer satisfaction, reinforced by our industry contributions and high satisfaction ratings, sets us apart.

# Why partner with us?

- CDMO/CRO
- Founded in 1999
- 800+ team members
- 175+ PhD-level scientists
- GMP, GLP, ISO9001 certified
- 22.5K sqm of lab capacity
- 700+ customers worldwide
- 5 centers of excellence



Contact us to speak with an expert: info@solvias.com



