

# Impurities Testing

Full suite of impurity and contamination control services, from **initial profiling** to **commercial control strategy**.

HRAM technology

Structure elucidation  
experts

Highly experienced  
career scientists

Direct access to our  
scientists

**solvias**

Comprehensive impurity & contamination control services, enhancing product safety, efficacy, and quality through advanced HRAM mass spectrometry, deep expertise, and risk-based approaches.

## Comprehensive Capabilities

- ✓ Method development, transfer, and validation
- ✓ Extractables and leachables (E&L)
- ✓ Process equipment related leachables (PERLs)
- ✓ Assay and impurity testing
- ✓ Forced degradation studies
- ✓ Stability testing
- ✓ Residual solvents testing
- ✓ Genotoxic impurities testing, including nitrosamine drug substance related impurities (NDSRIs), small molecule nitrosamines, polycyclic aromatic hydrocarbons (PAHs), and alkyl halides.

## Unparalleled Expertise

The expected level of scientific rigor and technological capability has evolved and is becoming increasingly challenging. Solvias stands at the forefront of these advancements, leveraging cutting-edge technology and highly **experienced career scientists** to identify and quantify compounds with exceptional sensitivity, meeting even the most stringent analytical evaluation thresholds (AETs) and detection limits.

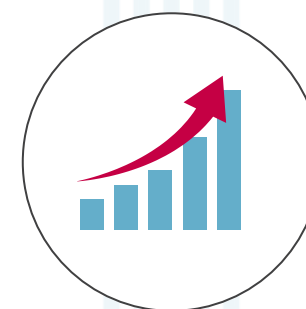
Our **risk-based approach**, grounded in years of experience and **extensive regulatory knowledge**, allows us to avoid common pitfalls and successfully manage highly complex studies using both simulated and custom design.

## Cutting-Edge Technology & Infrastructure

Solvias boasts advanced **high-resolution accurate mass (HRAM) spectrometers**, which can **detect, identify, and quantify** impurities at trace levels while providing detailed structural elucidation information. This technology eliminates the uncertainty associated with unknown peaks often generated by other analytical methods, ensuring precise and reliable impurity analysis.

- ✓ UPLC-HRAM (Orbitrap/Q-ToF)
- ✓ GC-HRAM & Headspace
- ✓ GC-HRAM (Orbitrap)
- ✓ GC/MS & GC/MS/MS
- ✓ Headspace GC/NPD & GC/FID & GC/MS
- ✓ UPLC/DAD/MS & UPLC/MS/MS
- ✓ Full stability storage
- ✓ Total Organic Carbon (TOC)
- ✓ Microwave extraction
- ✓ Reflux apparatus
- ✓ Soxhlet apparatus
- ✓ Autoclave
- ✓ Orbital rotation incubators
- ✓ High speed mill
- ✓ Hydraulic press

# Bring **your innovation** to its destination



## Start Early

Identifying impurities early allows for timely resolution of issues, which can prevent costly delays later in the development process. Early testing reduces the risk of encountering major problems during later stages, which are typically more expensive to address.



## Canton Center of Excellence

- ✓ >2,000m<sup>2</sup> of lab space
- ✓ 9 FDA inspections and multiple DEA inspections
- ✓ Over 20 client audits annually
- ✓ Controlled substance license for schedules 1-5
- ✓ 100 successful regulatory submissions



## 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.



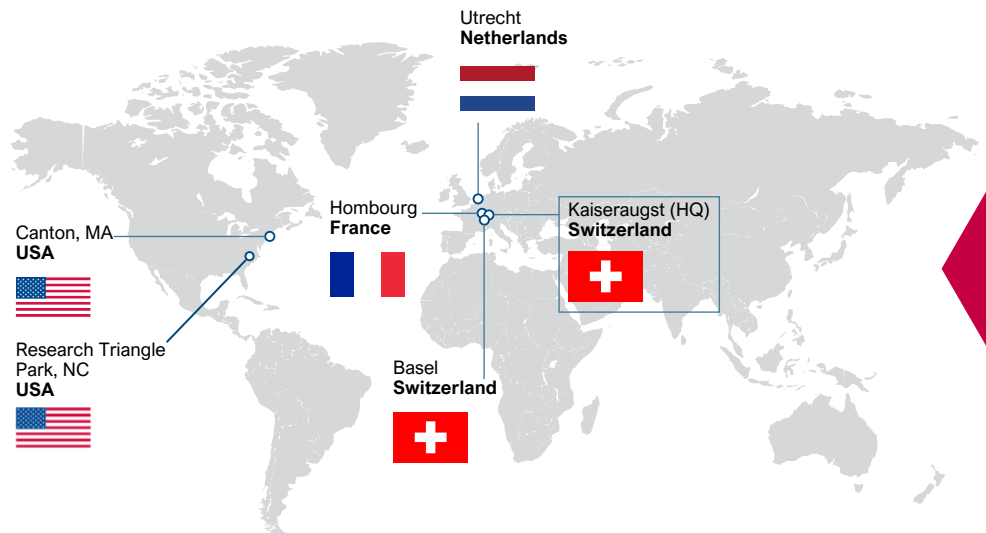
## Proven Track Record

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
- 6 centers of excellence



Contact us to speak with  
an expert: [info@solvias.com](mailto:info@solvias.com)

  [solvias.com](https://www.solvias.com)

