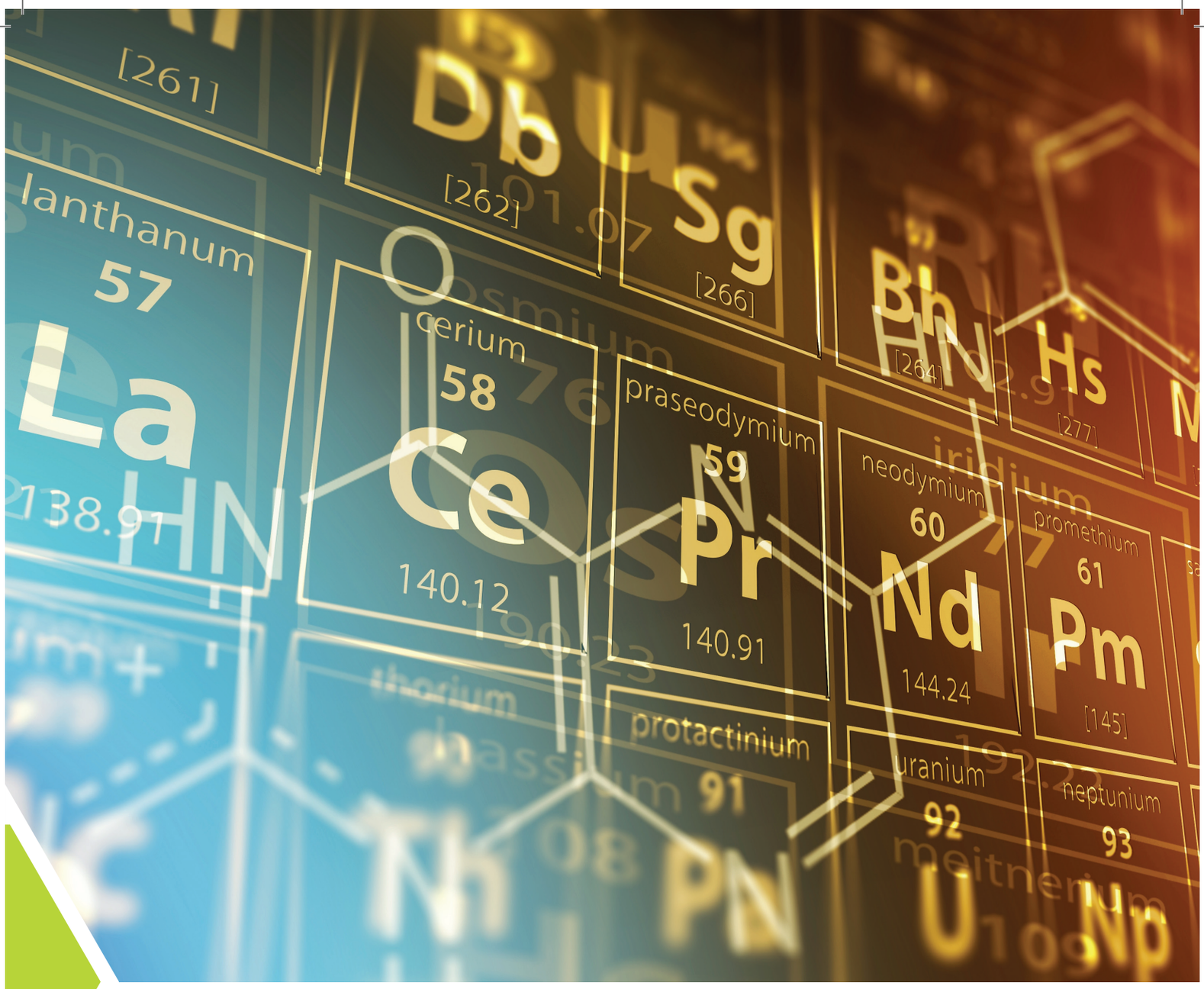


Elemental Impurities Testing

In pharmaceutical products, elemental impurities can originate from various sources. They may be residual catalysts that were added intentionally during synthesis, or already present (e.g., processing equipment, container/closure systems, impurities in the drug product). Since elemental impurities can impact patients' health and interfere with a drug's efficacy, it is essential to tightly regulate their levels within acceptable limits in active pharmaceutical ingredients (APIs), medicinal products and raw materials. **Our highly competent and experienced team of experts facilitate a risk-based control strategy ensuring adherence to current regulatory guidance.**

- Development of Phase-Appropriate Solutions
- State-of-the-Art Instrumentation
- Decades of Expertise
- Validated Multi Element Method
- Lowest LOQs Achievable

solvias

Demonstrating Regulatory Compliance

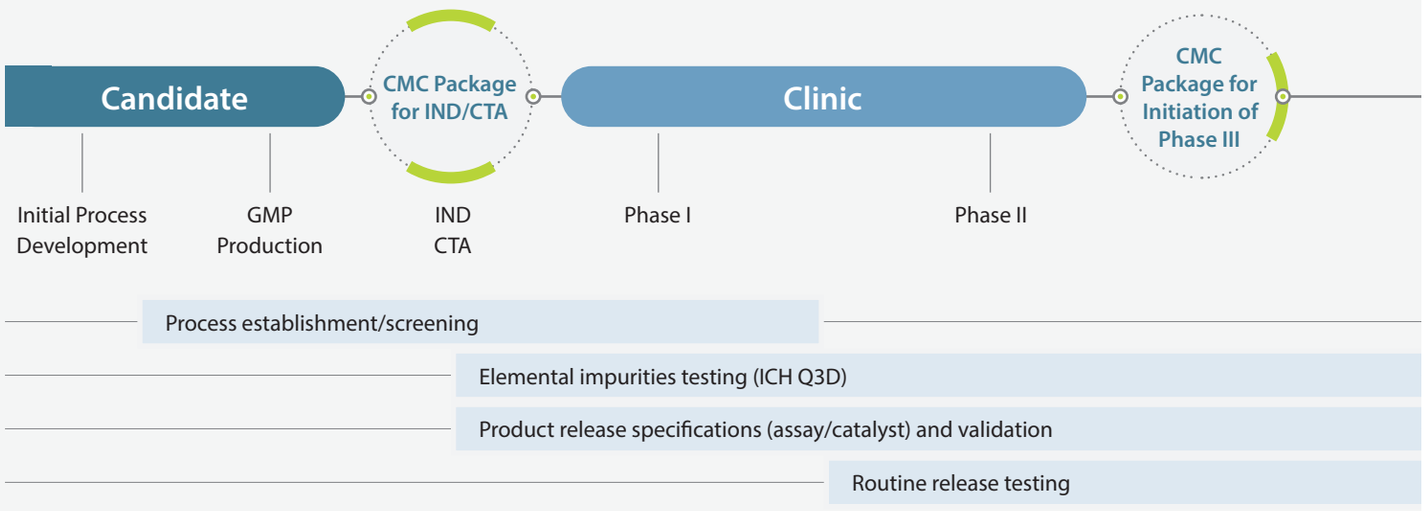
Key considerations

Since 2018, the ICH Q3D guideline has been globally adopted for pharmaceutical products to limit patient exposure to potentially toxic elements above specified limits during their course of treatment. In this guideline, **24 elemental impurities are defined and further categorized into 3 major classes based on their toxicity and probability of their presence in drug products**. Therefore, it is imperative to incorporate all the listed elements into the risk assessment process for every drug product to ensure that the detected element remains within the permitted daily exposure (PDE) limit.

Regulatory authorities strongly advise the control of elemental impurities to be consistent with ICH Q3D,Ph. Eur. 5.20 and USP 232 guidelines. Our experts comply with these regulatory guidelines and requirements to ensure that your products meet the highest quality standards.

Monitoring elemental impurities at the lowest concentration levels is a key challenge in providing drug safety and regulatory compliance. Our expertise with state-of-the-art instrumentation (e.g. ICP-MS, ICP-OES) allows us to detect elemental impurities at the lowest possible levels.

Drug Development Process



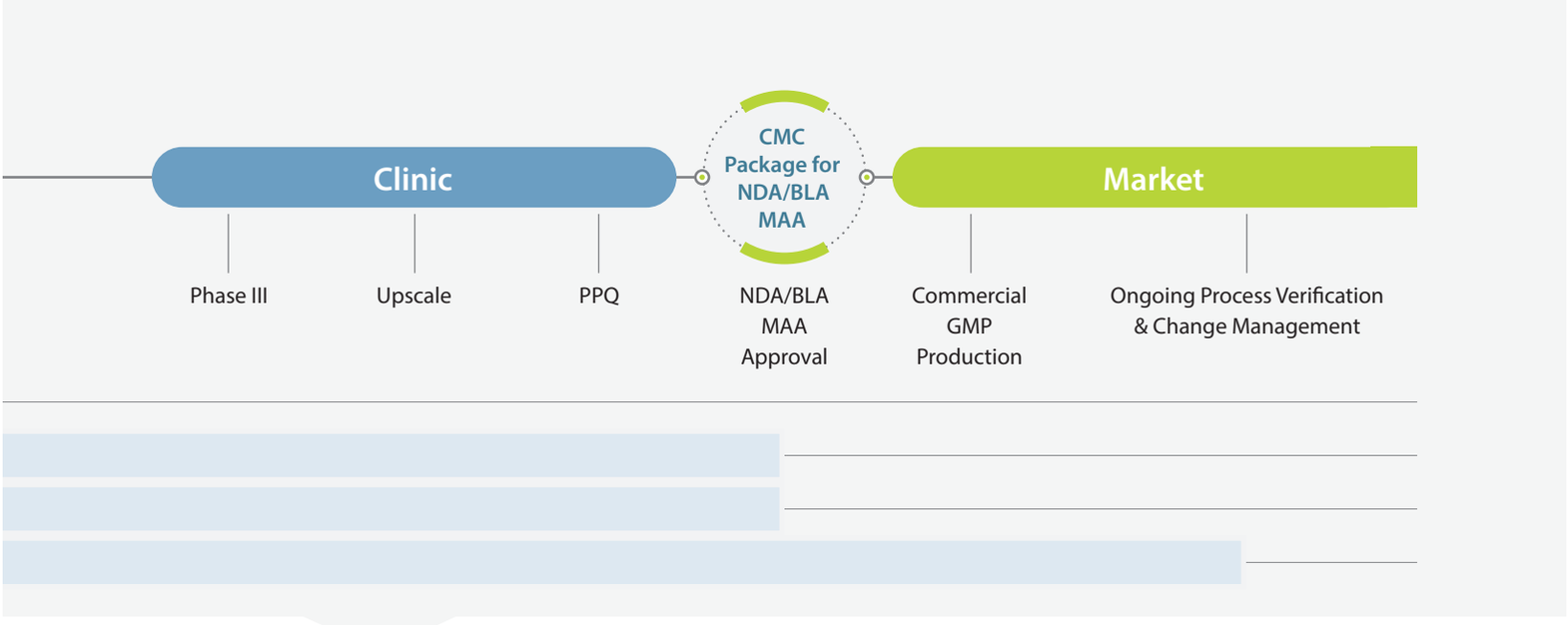
Our experts strongly recommend early screening to ensure that your products meet the highest standards of compliance and safety. From a QBD standpoint, determining levels and sources of elemental impurities early on will allow you to establish an adequate elemental impurity control strategy. Furthermore, this risk-mitigation approach enables you to base your risk assessment and control strategy on actual data vs. a purely theoretical-based risk assessment. As such, **we commit to helping you identify subtle changes in elemental impurity patterns over time to flag changes before they become an issue. At Solvias, we provide a comprehensive range of testing services with a standard timeline of 10 days.**

Our offerings include:

Process establishment and screening	**We test to the highest standards.** Our expert team is here to assist you in navigating the complex regulatory landscape and our testing complies with current regulatory guidance.
Elemental impurities testing (in accordance with ICH Q3D)	
Product release testing and validation	
Routine release testing	

Core capabilities ..... and the **value we bring**

Validated multi element method (>30 elements in a single experiment)	**Enables fast decision-making** towards maintaining product quality
Solutions tailored to your needs	**Phase-appropriate solutions:** from product specific method applicability studies to full method validation for GMP release analyses
Access to state-of-the-art instrumentation and dedicated lab infrastructure	**Lowest LOQs achievable** **Capable of handling large volumes** with fast turnaround times
Your extended lab	We can easily **manage non-standard and toxic samples** (e.g. hard to digest materials, HIPOs, etc.)
Metal-free sample preparation	**Mitigates risk of contamination** during sample prep



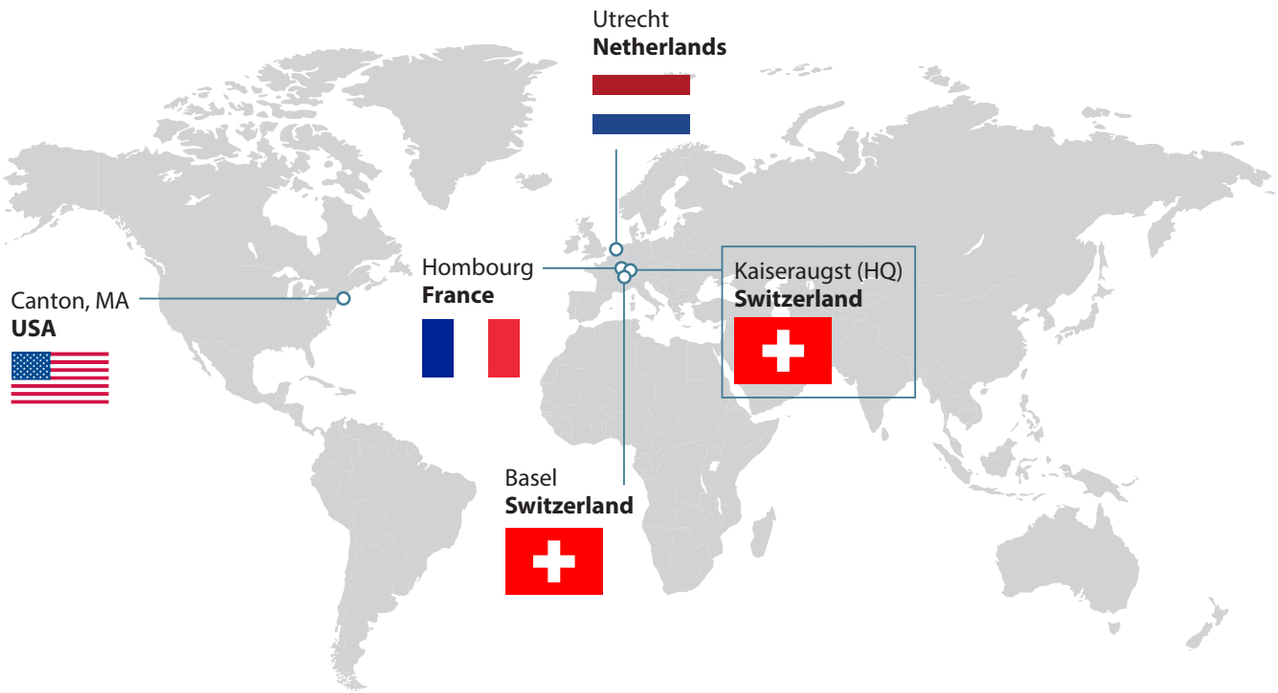
Equipment & Infrastructure

- Inductively Coupled Plasma-Mass Spectrometers (ICP-MS), single and triple quad
- Inductively Coupled Plasma-Optical Emission Spectrometers (ICP-OES)
- Combustion methods
- Inductively coupled plasma-optical Emission spectrometry (ICP-OES)
- X-Ray fluorescence spectrometer (XRF)
- Atomic Absorption Spectrometers (AAS), with Flame(F-AAS), Cold Vapour (CV-AAS) or Electrothermal (ET-AAS) Atomization Setup
- Microwave digestion units
- Ovens and electric heaters
- Metal-free lab capability
- Laminar flow hoods (incl. possibility to handle tox material down to OEL of 50 ng/m^3)
- High tox kit to handle samples with OEL below 50 ng/m^3
- Option for Schöniger combustion, Carius and Wurzschmitt digestion

Why Partner with Us?

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

Solvias Group



Contact us to speak with an expert

inquiries@solvias.com

Tel. +41 61 845 60 00
Römerpark 2
4303
Kaiseraugst Switzerland

solvias.com