# Bioanalysis

right solutions.
right partner.

## Method validation and study sample analysis according to ICH M10

*Bioanalysis is an important part of the safety and efficacy assessment of drug products that are under development. ALS offers method development, validation and study sample analysis of about 70 elements. Adherence to ICH M10 Guideline in the method validation stage will ensure the quality of bioanalytical laboratory data in support for development and market approval of drug product.*

### Quality at our core

Our bioanalytical operations by ICP-SFMS undergo all validation steps to ensure that each test meets the relevant validation parameters. Quality is at our core and the laboratory complies with relevant international regulatory standards including:

- EN-ISO 17025
- GLP statement of compliance
- GCLP
- GMP
- FDA certificate of registration
- ISO 14001

### The Laboratory

By operating the most sensitive analytical instrumentation (ICP-SFMS) in a controlled environment, ALS offers trace- and ultra-trace element testing with LOQs matched by few labs worldwide. We have validated and accredited analytical methods for determining 67 elements in body fluids such as blood, serum, plasma and urine.

Robust contamination control, thorough remediation strategies and method development allows measurements of wide ranges in concentrations. This is of particular importance in pharmacokinetics studies where concentrations can vary from low ppt to percentage levels.

With decades of experience in analytical testing of drug products and as part of clinical and pre-clinical studies, we have successfully developed and validated over 350 analytical methods for determining metals and elemental impurities for our clients.

### Research

ALS conducts research in the fields of analysis of metals, element speciation and isotope ratios. This has resulted in nearly 200 scientific articles and conference papers with thousands of citations. Our research has put us in the forefront, and we intend to hold that position into the future.

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