



## Bioanalytical lab for clinical services (GCLP)

Pharmacelsus is a bioanalytical laboratory providing customized analytical services for clinical studies.

We support safety-relevant clinical phase I/II studies using LC-MS for the quantification of drugs, drug candidates and their metabolites under regulated conditions (GCLP).

For identification and structure elucidation of metabolites in human clinical material, Pharmacelsus owns software supported procedures operated by highly trained experts.

Technological platforms based on high-through-put immunologic detection expand the analytes of interest to large molecule biomarkers and biologics.

All applications comply with the current guidances of the EMA/FDA, the ICH and the German national law.



### Phase I/II pharmacokinetic sample analysis (GCLP)

- Analysis performed under regulated conditions (EMA/ FDA/ICH, European Guidance 2001/20/EG, German GCP-Verordnung, OECD guidances on GLP and the German Chemical Law)
- 7 qualified high end LC-MS systems for quantification and metabolite analysis

(Thermo- Fisher: **Q-Exactive, Q-Exactive Plus, TSQ Quantum**. Sciex: **Q-TOF X500 B**)

- Application of fully validated bioanalytical methods in plasma, urine or other matrix
- Validated computerized systems and software (21CFR Part 11)
- Data transfer to clinical databases according agreed data transfer specifications
- Participation as PK- and analytical experts at Safety Monitoring Committees

### Metabolite identification and structural elucidation

- Detection of metabolites formed in human study samples (liquid matrices i.e. plasma, urine, CSF or tissues and faeces)
- Software supported (**Compound Discoverer 2.1 and 3.1, Metabolite Pilot**) analysis of LC-MS data for detection of metabolites derived from a drug candidate
- Structural proposal based on MS/MS fragment analysis with high mass resolution
- Quantification or semi-quantification of new metabolites formed
- All study phases are performed under full regulated conditions using validated or research grade analytical methods

### Biomarker quantification

- Technological platforms:  
**Luminex X Map** (Immunofluorescence) **Mesoscale MSD** (Electrochemiluminescence-Immunoassay)
- Types of biomarkers: Immune, Metabolic, Cancer, Neuro e.g. Interleukines, Lymphokines, Hormones, Enzymes
- Types of samples: Plasma, Serum, Blood, Tissue, Tissue lysates
- Validated computerized systems and software (21CFR Part 11)
- All study phases are performed under regulated conditions using validated or research grade analytical methods