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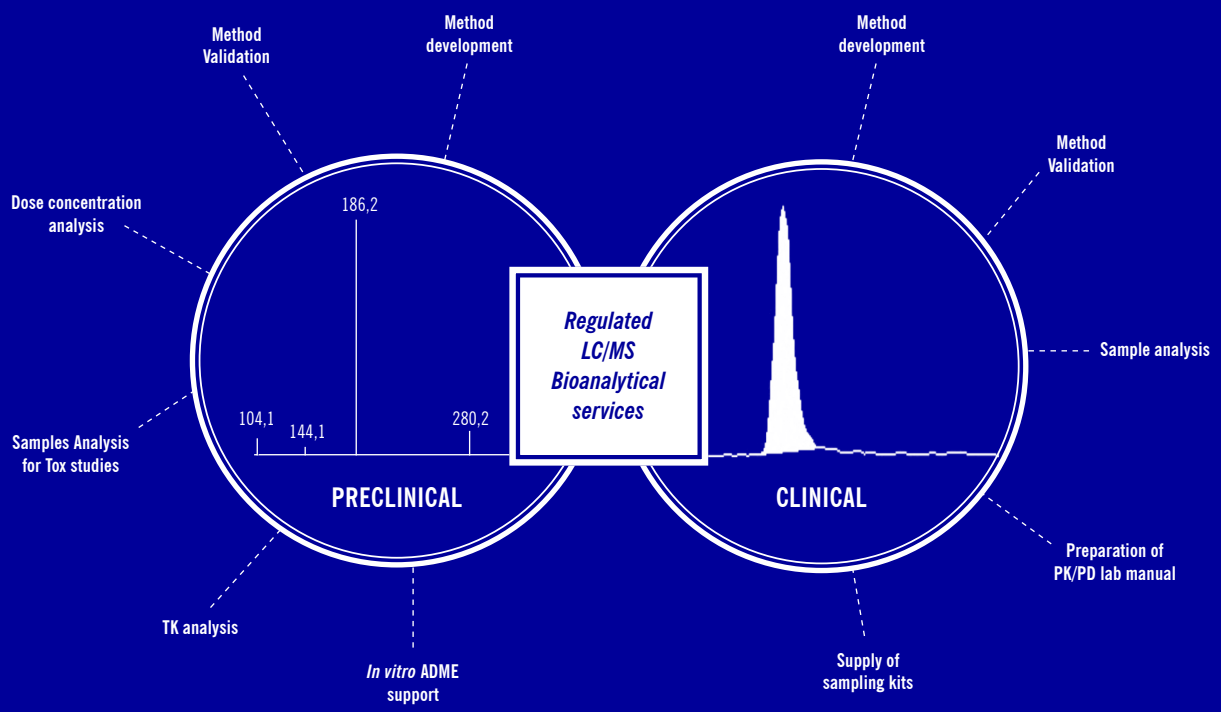
#RESEARCHNEVERSTOPS

REGULATED LC/MS BIOANALYSIS

- High quality service across all phases of pre-clinical and clinical drug development in compliance with GLP and GCP regulations
- More than 25 years of experience to perform LC/MS activities in a regulated environment
- Extensive bioanalytical method development expertise to meet the most demanding and challenging client needs
- State-of-the-art labs and technologies
- Multidisciplinary collaboration to provide an integrated solution to accelerate drug development process



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Bioanalysis plays a critical role in the assessment of drug safety and efficacy. Regulated LC/MS Bioanalysis in Evotec, with state-of-the-art instrumentation and GxP compliant laboratories, has a track record of providing bioanalytical support, for both preclinical and clinical phases of compound development, dating back over 25 years. Our teams can meet the most demanding and challenging client needs thanks to their scientific expertise, operational experience, and up-to-date knowledge of the regulatory environment. The group offers small molecules & biologics bioanalytical solutions with a high-throughput nonclinical and clinical support.

REGULATED BIOANALYSIS

- Method development
- Method transfers of existing validated methods
- Cross-validation of method performance against existing laboratories
- Bioanalytical validation following EMA/FDA guidelines
- GxP analysis in support of preclinical and clinical Phase I–III, DDI and bioequivalence studies
- Analysis of wide range of sample matrices
- Rapid turnaround times to support Phase I clinical studies
- Full quality assurance of study plan and final reports

SAMPLE MANAGEMENT

- Dedicated team
- Freezer rooms with controlled access
- Capacity to store about 300K samples at -20°C and -80°C
- Freezers connected with an alarm system and with a validated software for the temperature monitoring
- Production and supply of sampling kits, labels, study manual for the clinical trials

LC-MS BIOANALYSIS EXPERIENCE

- Antibody-drug conjugates
- Chiral compounds
- Metabolites and multi analyte methods
- Microsampling techniques (DBS, CMS, VAMS)
- New Chemical Entities (NCE)
- Liposomal products
- Oligonucleotides
- Peptides including Peptide nucleic acids (PNAs)
- Proteins (mAb)
- Small molecules biomarkers
- Tissues

ADDITIONAL ACTIVITIES

- TK data analysis (WinNonlin)
- Support to ADME *in vitro* studies (PPB, CYP inhibition, blood/plasma ratio)
- Dose formulation analysis
  – Method development and validation
  – Sample analysis to support TOX studies
- Strong collaboration with Pharmacometrics dept. for clinical PK and PD data analysis

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