PRA Health Sciences

Pharmacokinetics with Ligand Binding Assays at PRA's Laboratories for Drug Development

Introduction

The PRA Bioanalytical Laboratory has over 15 years of experience in pharmacokinetic analysis of biological therapeutics in support of pre-clinical and clinical studies in all phases of drug development. The PRA bioanalytical laboratory is a GLP certified lab that works according to GLP and GCP principles and EMA 2011, FDA 2018, and ICH M10 2019 (draft) guidances for performing pharmacokinetic analysis.

Innovation

With the aim of further improving assay reproducibility, PRA offers the capability of pharmacokinetic assessments by automated liquid handling using the Hamilton Starlet robot. This is specifically important in cases of pharmacokinetic support for biosimilar/bioequivalence trials in which all assay variability needs to be kept to a minimum to enable reliable comparison of the pharmacokinetic profiles of multiple compounds.

In case a highly sensitive pharmacokinetic assay is required, for instance, in the case of highly potent biological therapeutics, PRA offers pharmacokinetic assessment on the SMCIA platform. With this assay platform, an assay sensitivity in the picogram or even femtogram range can be reached.

Capabilities and Equipment

- ELISA (SpectraMax M5), ECLIA (MSD SQ120), SMCIA (SMC Erenna, SMCxPro), MSD S-plex, Sample Management and Data Analysis (Watson LIMS) and Automation and Liquid Handling (ViaFlo, Hamilton StarLet)
- At our laboratories, we can develop and validate a method within 20 working days, with sample analysis turnaround time of five days and draft reports available within four weeks after the last sample analyzed
- Capablility of dealing with common assay challenges, such as matrix effects, target interference, drift, and PK support for Biosimilar/Bioequivalence trials

Capacity and People

Project Manager (12)
Single point of contact for the sponsor

Scientist or Supervising Analyst (16)
In direct contact with PM and Analyst

Analysts (40)
Performing Method Development, Validation, or Sample Analysis

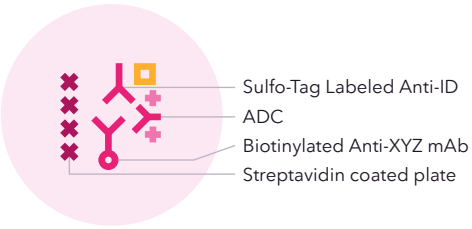
Experience

Experienced in the transfer, development, and validation of PK assays for many types of biotherapeutics:

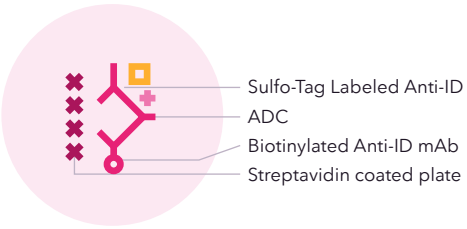
- Antibodies, pegylated compounds, bispecific antibodies, fusion proteins
- Biotherapeutics with soluble targets: total/bound/free assays
- Antibody drug conjugates (ADC's); total/conjugated/free assays

PK Analysis on ADC's (Antibody Drug Conjugate)

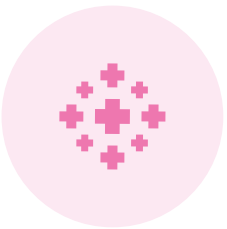
CONJUGATED ASSAY



TOTAL ASSAY
(conjugated and unconjugated)



FREE ASSAY
LC-MS/MS assay for the warhead



Contact Our Experts

MARTINE BROEKEMA
broekemamartine@prahs.com | +31 624 820 630

Associate Director of Bioanalytical Science in the Assen, NL, Bioanalytical Laboratory. Over 10 years of experience in regulated bioanalysis for pharmacokinetic, pharmacodynamic, and immunogenicity analysis for large molecule therapeutics.

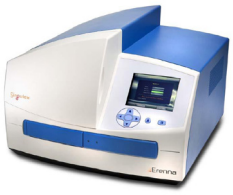
AMANDA HAYS
haysamanda@prahs.com | +1 913 345 5718

Director of Bioanalytical Science in the Lenexa, Kansas, Bioanalytical Laboratory. Over 8 years of experience in bioanalytical assay development and optimization of PK immunoassays, immunogenicity (ADA and cell-based NAbs) for large molecule therapeutics.

Equipment

ELISA – SpectraMax M5

ECLIA - MSD SQ120, S-Plex



SMCIA – Erenna, SMCxPRO