Yanan Zang

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Education

2015 - 2018 MS in Pharmaceutical Analysis
(Research Area, Drug Metabolism and Pharmacokinetics)
Shenyang Pharmaceutical University

2011 - 2015 BS in Pharmacy
Shenyang Pharmaceutical University

Working Experience

Oct 2023 – Present Research Technician, PTR Department, College of Pharmacy
University of Florida

Jul 2021 – Sep 2023 Scientist/Study Director, DMPK Department,
Dizal Pharmaceutical Co., Ltd. (previously known as AstraZeneca's Innovation Center China)

Non-clinical DMPK (small molecule)

- As a sponsor representative, design, outsource and manage non-GLP DMPK and GLP toxic-kinetic (TK) studies in support of IND and/or NDA submission, including absorption, distribution, metabolism, excretion (ADME), *in vitro* drug-drug interactions (DDI) studies under non-GLP, and LC-MS/MS method validation or transfer, bioanalysis (BA), TK parameter analysis and report supporting for toxicology studies under GLP.
  - ✓ DMPK IND studies include *in vitro* permeability with a validated Caco-2 BCS cells and P-gp/BCRP substrate, rat and dog PK; plasma protein binding and blood-to-plasma ratio; CYP enzymes phenotyping, inhibition and induction; SLC transporters substrate and inhibition. Rat PK, QWBA, mass balance, and metabolite profiling and identification studies with [^{14}C]-labelled compound. At least one study experience on each type.
  - ✓ Plasma and dose formulation MV (4 compounds, 2 species), BA and TK parameter analysis supporting for 4-weeks and reproductive toxicology studies.
- Perform hands-on bioanalytical assay for PK and PD samples by LC-MS/MS in support of discovery and development programs. (Two projects of small molecule compounds)
- Interpret TK analysis results (systemic exposures) in conjunction with DMPK and pharmacology studies to estimate therapeutic index and starting dose in humans. (Two projects)
- Present project DMPK information in meetings and communications at interdisciplinary project teams. (four projects)
- Write regulatory documents and package towards IND (IMPD and IB) focusing on 2.4/2.6.4/2.6.5 eCTD documents.

Jul 2018 – Jun 2021 Senior Scientist/Study Director, DMPK Department,
Covance Pharmaceutical R&D (Shanghai) Co., Ltd.

- **LC-MS/MS and LC-HRMS Method Development/Validation and Bioanalysis**
  - LC-MS/MS method development and full method validation in plasma (free MMAE in ADC Drug, SN-38, and peptide), urine, bile, feces, and tissues.
  - LC-HRMS method development and validation for quantitation of peptide (GLP-1 analogue), oligonucleotides (siRNA), and endogenous compounds (thyroid hormones T3 and T4, lactic acid) in plasma and tissues.
  - Sample analysis supporting for PK and/or PD samples in various matrices.

- **Lead Projects of IND Research**
  - **Small molecule**
    Lead DMPK package (*in-vivo* and *in-vitro*) projects, formulation comparison or bridging PK projects for NMPA and FDA IND filing, including study design, internal and external coordination, schedule, protocol, data review, PK parameter calculation, and regulatory report.
  - **Large molecule**
    Lead antibodies and ADC (MMAE as payload) PK and bio-similarity for NMPA and FDA IND filing, including study design, internal and external coordination, schedule, protocol, data review, PK parameter calculation, and regulatory report.

- **Lead Projects of Bioequivalence and Early PK Screening**
  - Lead bioequivalence and early animal PK screening projects, including study design, internal and external coordination, protocol, MD and bioanalysis, PK parameter calculation, and Excel report.

- **Metabolite Identification of Small Molecules**
  - Responsible for MetID projects *in vitro* (liver microsomes and hepatocyte, GSH trapping) and *in vivo* (plasma, urine, bile, and feces), including method development, protocol, sample preparation, data process and analysis, report, etc.

Professional Skills

- Expertise in LC-MS/MS techniques including knowledge of various MS and LC platforms, and proficiency in quantitative LC-MS/MS method development, validation, and sample analysis in various matrices with AB SCIEX series.
- A thorough understanding of knowledge of pharmacokinetic concepts and in-depth experience with modern approaches (ICH guideline and FDA, EMA, NMPA guidance, and literature) in DMPK used to support IND projects and drug discovery projects.
- Hands-on experience in detection, identification, structural elucidation and determination of metabolites *in-vivo* and *in-vitro* with Thermo Q-Exactive HRMS.
- Proficient with software such as Phoenix WinNonlin and GraphPad Prism.
- Trained in SimCYP software for DDI assessment.
- Good interpersonal communication skills and excellent oral and written English skills.
- Excellent skills in Word, Excel, and PowerPoint.

Publications and Presentations

1. Simultaneous Determination of Amlodipine and Valsartan in Human Plasma by UHPLC-MS/MS [J], Shenyang Pharmaceutical University, 2019, 36(10):887-893.
2. The Food Effect on the Pharmacokinetics of Esomeprazole in Dogs, Poster, Covance internal, 2019
3. A Sensitive UPLC-MS/MS Method for Determination of Thyroid Hormones T3 and T4 in Serum Samples, Poster and Presentation, Covance internal, 2020