Associate Director Drug Metabolism Pharmacokinetics

AREAS OF EXPERTISE

- **CRO/external vendor monitoring**
- **GLP/GxP**
- **Protocol design**
- **LC-MS laboratory design and build**
- **Laboratory and project management**
- **Method development and validation**
- **LIMS and instrument IQ/OQ/PO**
- **Laboratory automation**
- **Clinical supply logistics**
- **Clinical PK and TK study design**
- **Write SOPs**
- **Regulatory submissions**
- **Bioanalytical expert**
- **Dried blood spot collection and analysis**
- **Nonclinical dose formulation analysis**
- **National organization leadership (AAPS)**

INTRODUCTION

Consultant has over 20 years of bioanalytical (BA) laboratory management and drug development experience working in mid to large pharma supporting regulated clinical and non-clinical studies (small molecules, biomarkers and biotherapeutics). Expertise in planning and executing clinical pharmacokinetic and toxicokinetic studies, preparation of regulatory submissions (IND, NDA, sNDA and BLA), laboratory design and implementation, CRO and external vendor monitoring and oversight in a GxP environment.

WORK EXPERIENCE

06/2013 – Present
Industry Consultant
Duties:

- Audit, qualify and monitor bioanalytical CRO activities for clients, including method development and validation, and sample analysis. Provide strategies to follow FDA and EMA Bioanalytical Guidance in a fit-for-purpose regulatory framework.
- Advise client on issues and strategies related to remediation activities.
- Prioritize response activities for findings, prepare deviations and NTF related to GxP compliance, including current and previous bioanalytical guidance.
- Coordinate remediation activities and provide support for the bioanalytical portion of method validation, nonclinical and clinical studies.
- Preparation of nonclinical IND summaries and IB sections. Advise clienets on strategies for future studies.

2006 – 11/2012
Celgene Corporation
Senior Principle Scientist (Associate Director), Drug Metabolism Pharmacokinetics Department (DMPK)
Duties:

- Oversight of the bioanalytical portion of nonclinical and phase I-IV clinical studies including apremilast, lenalidomide, thalidomide, amrubicin, sotatercept, Abraxane and azacitidine.
- Managed projects outsourced to CROs and external vendors, ensuring compliance with GxPs.

- Contribution to long-term corporate strategic goals and tactical objective development and implementation.
- Prepare and submit bioanalytical and drug metabolism data for regulatory submissions (6 IND and 5 NDAs).
- Management of a team of PhD/MS/BS level manager/scientists.

2001 – 2006
Forest Laboratories (Forest Research Institute)
Assistant Manager, Bioanalytical and Drug Metabolism Department
Duties:
- Performed clinical and nonclinical study protocol design, method development, and evaluated pharmacokinetic, toxicokinetic and metabolism data to support project compound development.
- Oversight method development activities, preparation of SOPs, report preparation and data review.
- Management of a team of Senior Scientist, Study Leaders, and laboratory scientist (staff of 5-10: PhD/MS/BS).
- Allocation of departmental resources, planning and monitoring timelines and budgets.
- Prepare and submit bioanalytical and drug metabolism data for regulatory submissions (1 IND and 1 NDA).
- Undertake due diligence activities for compound in-licensing leading to 2 new development projects.
- Preparing contracts, CDAs and monitors the work of CROs related to assigned projects.
- Project Managing the Watson Bioanalytical LIMS IQ/OQ/PQ leading to on-time and within budget.
- Departmental coordinator for Watson Bioanalytical LIMS and Laboratory Automated Workstations.

1995 – 2001
Abbott Laboratories
Senior Scientist, Drug Analysis Group
Duties:
- Plan and execute clinical and nonclinical studies involving PK assessments.
- Production of bioanalytical data from toxicokinetic and clinical pharmacokinetic studies.
- Providing toxicokinetic calculations and interpretations for GLP toxicological studies.
- Supervising laboratory personnel performing routine sample analysis and method development.
- Implementation of new technologies including LC/MS and laboratory automation.

1993 – 1995
Sandoz Pharmaceuticals
Assistant Fellow, Drug Substance Group
Duties:
- Represent Analytical R&D on a project team responsible for the development of drug candidates. Responsible for analytical support, methods development, writing and validating analytical methods for pre-NDA drug substances.

EDUCATION

1993
University of Georgia, College of Pharmacy
Ph.D.
Master of Science: Medicinal Chemistry

1988
Samford University, College of Arts and Science
Bachelor of Science: Chemistry

1984
University of the South, College of Arts and Science
Bachelor of Science: Biology

AWARDS

- Recipient of a United States Pharmacopeia Fellowship Award, 1991-92, 1992-93
- Pharmaceutical Manufacturers Association Visiting Scientist, 1993-94
- Celgene Innovation Award, 2012
- AAPS APQ Section Distinguished Service Award, 2016
- AAPS APQ Section Leadership Progression, 2011-2016 (2015 APQ Section Chair)
- Non-Clinical Dose Formulation and Analysis Focus Group Leadership, 2008-2012 (2010 Focus Group Chair)

MAJOR ACCOMPLISHMENTS

- Planned and successfully executed Celgene's first dried-blood spot collection clinical PK study.
- Implemented bioanalytical development plan for the biotherapeutic sotatercept as a roadmap for future projects, including PK, immunogenicity and cell-based neutralizing assay development.
- Recipient of the 2012 Celgene Innovation Award for preparing a successful justification for EMA to accept bioanalytical data for a pivotal thalidomide bioequivalence study.
- Improved outsourcing efficiency though development of a standardized process to monitor CROs and external vendors decreasing cost and shortening deliverable timelines.
- Designed and built state of the art LC-MS/MS laboratory including laboratory automation.
- Delivered a Watson LIMS IQ/OQ/PQ on-time and within budget.
- Elected to the American Association of Pharmaceutical Scientist (AAPS) Leadership in 2011 with a five-year leadership progression.
- Published a book chapter on Bioanalytical Method Development and Sample Analysis.
- Organized focus group and published two white papers on non-clinical dose formulation analysis for GLP studies.