DONALD L. REYNOLDS, Ph.D.
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BACKGROUND SUMMARY

- Twenty-five years of bioanalytical, pharmacokinetic and drug metabolism experience in pharmaceutical industry (Pharma, CRO and Consulting).
- Experienced bioanalytical consultant - provided consulting services for 15 Clients and for greater than 125 departmental employees.
- Extensive experience in coordinating multiple simultaneous US and international bioanalytical projects.
- Proven successful track record of project milestone development and tracking, managing projects, employees, Clients and technical teams, and in timely completion of projects.
- Thorough knowledge of the drug development process from lead generation - lead compound selection ï IND ï NDA - post marketing support as a member of multi-functional matrix and project teams. Experience in preparation of drug development plans.
- Experience in providing support for IND/NDA/BLA submissions and preparing bioanalytical sections for submission.
- Expertise in bioanalytical chemistry and chromatographic theory, including methods development, long term storage stability programs and routine analyses under non-GLP and GLP conditions. Expertise in evaluating and implementing new technologies and designing innovative solutions to address bioanalytical issues at ultra-trace detection limits.
- Experience in quantitative separation science, including reversed-phase, normal-phase, chiral, ion interaction, column-switching, solid-phase extraction, direct injection, indirect photometric, millibore and microbore HPLC and LC-MS/MS.
- Motivated, self-directed leader and team player, with strong bioanalytical, organizational, interpersonal, mentoring and communication skills.

PROFESSIONAL EXPERIENCE

DONALD L. REYNOLDS PhD & ASSOCIATES, INC., Lee's Summit, Missouri **2005 - Present**
President, Bioanalytical and Pharmaceutical Consulting Services **09/05 - Present**

DONALD L. REYNOLDS, Ph.D., Lee's Summit, Missouri **2004 - 2005**
Owner / Pharmaceutical / Bioanalytical Consultant **02/04 – 09/05**

Consultant to pharmaceutical and contract research organizations to support the development of new and generic pharmaceuticals. Provided expertise in the areas of bioanalytical chemistry, drug development, management (scientific, project, Department, business / financial), proposal / milestone costing, development, and tracking, and improvement and systematization of biological analyses.

- Provided on-site bioanalytical expertise in India regarding developing method development and automation strategies, method development troubleshooting, strategies for increasing throughput, SOP and report review / revision and training in methods development and new technologies.
- Presented seminars describing targeted bioanalytical methods development and method validation strategies, sample preparation, column switching and matrix effects.
- Assisted a Client in developing and finalizing SOPs and processes for a new GLP bioanalytical laboratory in India.
- Served as Project Manager and method development consultant for several concurrent Clinical and Preclinical bioanalytical projects outsourced by Client to CRO.
- Performed six due diligence laboratory / process bioanalytical audits for Clients to support GLP and Clinical studies.
- Reviewed assay methodology, validation data and draft reports to ensure data were valid and met acceptance criteria.
- Reviewed and provided guidance for CRO project proposal and pricing processes to improve profitability.
- Developed Client-specific bioanalytical proposal and work plan templates for 3 Clients.
- Serving as peer reviewer for Journal of Chromatography B.

- Reviewed current CRO processes and proposed a project management / milestone tracking system to:
  - Define work / resources / project milestones based on approved proposals.
  - Schedule and track progress of work vs. established milestones.
  - Evaluate individual and departmental real-time metrics.
    - On time delivery (OTD), capacity, utilization, profitability.
  - Monitor and report metrics, revenue recognition / invoicing dates upon milestone completion.

QUINTILES, INC., Kansas City, Missouri **1999 - 2003**

Executive Director, Project Coordination, Bioanalytical Sciences, Drug Metabolism and Pharmacokinetics **06/01 - 11/03**

Defined scope of the Project Coordination (PC) function and managed the activities of 5 employees. Responsible for coordination of Departmental Project, Financial and Schedule / Tracking activities. Managed Client contacts, expectations and communications, defined project scope and resource capacity, determined costs for proposed work, reviewed and revised work orders and Client proposals, established and tracked project milestones and prepared Bioanalytical Work Plans and central study files. Represented Client projects and timelines at internal matrix team and scheduling meetings, identifed out of scope or additional work and delivered Bioanalytical product to the Client. Managed Clients, Business Development, Scientific Managers and Bioanalytical Analysts to facilitate timely completion of work, with on-time delivery to the Client.

- Facilitated establishment of the PC function to meet Client communication needs.
- Personally coordinated > 300 bioanalytical projects for 17 Clients and supervised the coordination of approximately 100 additional bioanalytical projects for eight Clients.
- Facilitated establishment and implementation of new Dose Formulation analysis line of business.
- Provided bioanalytical consultation for two Clients and aided in preparation of drug development plans (pre-IND to Phase II) for several Clients.
- Responsible for developing and implementing a project milestone tracking system (by Tracking Coordinator) to track project resources and timing and to generate on-time delivery, capacity and profitability metrics.

Executive Director, Bioanalytical Methods Development **10/00 - 06/01**

Responsible for rapid development and validation of sensitive, selective, high throughput, automated bioanalytical methods to quantitate drugs and metabolites in biological matrices, defining drug / metabolite stability profiles in biological matrices and identifying sample collection, shipment and storage procedures to preserve sample integrity. Ensured that projects were conducted under GLP guidelines and the FDA Guidance and were correctly documented for global submission. Supervised the daily operations of five employees in the Bioanalytical Methods Development Department, and was responsible for Departmental budgets, Client proposal pricing, resource allocation and SOPs.

- Coordinated the validation of approximately 17 methods, the analysis of > 14,000 samples and issuance of 39 reports to support > 30 non-clinical and clinical studies.
- Organized and chaired a weekly Bioanalytical Method Development Discussion Group to provide a forum for scientific discussion, problem solving, timeline tracking and resource allocation. Decreased assay development time and increased productivity.
- Reviewed proposals for > 20 Clients and provided bioanalytical consultation for two Clients.
- Participated on project teams for several Clients to facilitate development of selected drug candidates.
- Prepared Section 6 bioanalytical summaries for two Client NDA submissions.

Associate Director, Bioanalytics, Biopharmaceutical Sciences Department **01/99 - 10/00**

Coordinated and tracked bioanalytical activities from Discovery - NDA for drug candidates to meet project team and corporate timelines. Developed and validated sensitive and selective bioanalytical methods and performed sample analyses to support non-clinical and clinical studies for selected drug candidates. Responsible for LC-MS/MS and non-LC-MS/MS projects.

- Coordinated bioanalytical support activities for 8 drug candidates. Supervised analysis of > 16,000 samples for approximately 35 studies over 9 months, with >95% on time delivery.
- Served as a bioanalytical consultant to approximately 20 employees and participated on project teams for several Clients.
- Developed, evaluated and applied laser detection and other new technologies to bioanalytical projects.

HOECHST MARION ROUSSEL, INC., Kansas City, Missouri **1995 - 1998**
Research Scientist/Group Leader, Research Bioanalytics, US Bioanalytics Department **08/96 - 12/98**
Research Scientist, US Bioanalytics Department **05/96 – 08/96**
Scientist, Methods Research/Progression Department **07/95 - 05/96**

Provided bioanalytical support for drug discovery and compound selection activities. Developed and validated selective bioanalytical methods at trace levels to quantitate drug molecules and metabolites in biological fluids and performed routine sample analysis activities to support clinical studies for selected drug candidates.

- Developed and validated two methods, supervised development of > 140 methods and contributed to the development of approximately 40 additional methods. Supported completion of > 60 non-clinical and > 10 clinical pharmacokinetic / drug metabolism studies.
- Coordinated the bioanalytical activities of employees in the Research Bioanalytics group. Provided drug discovery support and expertise to aid in the timely selection and development of the best drug candidates.
- Supervised seven laboratory professionals and served as bioanalytical consultant to approximately 30 employees.
- Participated on project and planning teams in several therapeutic areas to facilitate development of selected drug candidates to the NDA. Prepared Section 6 bioanalytical summaries for two NDA submissions.
- Implemented development of a fully tunable solid-state laser system with time-resolved fluorescence (nanosecond time resolution) capabilities with photon counting sensitivity.
- Employed the following techniques: HPLC (conventional, millibore, microbore) with UV and fluorescence detection; LIF (excitation and emission spectra, time-resolved fluorescence); column-switching (millibore - microbore HPLC); solid-phase extraction (HPLC, GC); post-column UV derivatization (HPLC).

MARION LABORATORIES / MARION MERRELL DOW, INC., Kansas City, Missouri **1989 - 1995**
Scientist, Methods Research/Progression Department **05/92 - 07/95**
Senior Associate Scientist, US Clinical Pharmacokinetics / Bioanalytics **10/91 - 05/92**
Scientist, Clinical Pharmacology / Drug Dynamics Department **05/89 - 10/91**

Developed and validated selective bioanalytical methods at trace levels to quantitate drug molecules and metabolites in biological fluids and performed routine sample analyses to support clinical studies for selected drug candidates.

- Developed and validated seven methods, supervised development of 13 methods and contributed to the development of approximately 30 additional methods.
- Coordinated the research activities of seven laboratory employees and served as bioanalytical consultant to approximately 35 employees.
- Provided bioanalytical methods development consultation services to a contract research organization.
- Chaired a multi-disciplinary project team and participated on five additional teams in several therapeutic areas to facilitate development of selected drug candidates to the NDA.
- Evaluated and applied new technology to bioanalytical methods development.
- Acquired knowledge of lasers (gas, dye, solid-state, optical parametric oscillators (OPO)), flow cell design and detection schemes applicable to laser-induced fluorescence detection. Designed and initiated development of a fully tunable solid-state laser system with time-resolved fluorescence (nanosecond time resolution) capabilities with photon-counting sensitivity.
- Employed the following techniques: HPLC (millibore, microbore), with UV, fluorescence and electrochemical detection; column-switching (millibore, microbore HPLC); chiral (AGP, HPLC); solid-phase extraction (HPLC, GC); derivatization (GC-MS); capillary GC-MS (NICI); capillary GC (NPD, ECD); LC-MS/MS.

PARKE-DAVIS PHARMACEUTICAL RESEARCH, Ann Arbor, Michigan **1982 - 1989**
Senior Scientist, Pharmacokinetics/Drug Metabolism Department **02/85 - 05/89**
Scientist, Pharmacokinetics/Drug Metabolism Department **12/82 - 02/85**

Designed and performed bioanalytical, pharmacokinetic and drug metabolism studies to support non-clinical and clinical development of anti-allergy drug candidates from discovery - NDA. Developed and validated sensitive and selective bioanalytical methods, performed sample analysis, designed and implemented non-clinical pharmacokinetic and drug metabolism studies and designed clinical first-in-man protocol design synopses and for selected drug candidates and relevant metabolites.

- Developed and validated 12 methods, supervised development of eight methods and contributed to the development of approximately 20 additional methods. Completed 35 preclinical and six clinical pharmacokinetic / drug metabolism studies to support development of assigned compounds.

- Supervised one laboratory professional and served as scientific consultant to approximately 35 departmental employees.
- Created and chaired a monthly Bioanalytical Discussion Group to provide a forum for scientific discussion and problem solving to increase departmental bioanalytical expertise. Regularly presented seminars describing various aspects of chromatographic and separation techniques and new analytical methodology. Decreased departmental assay development time and increased productivity.
- Participated on multi-disciplinary project teams in several therapeutic and non-therapeutic areas to facilitate the development of selected drug candidates from discovery to the NDA.
- Employed the following techniques: HPLC (conventional, millibore), with UV and fluorescence detection; column-switching (millibore HPLC); solid-phase extraction (HPLC, GC); derivatization (HPLC).

EDUCATION

Ph.D. - Pharmaceutical Chemistry, 1983, The University of Kansas, Lawrence, Kansas, USA
M.S. - Pharmaceutical Chemistry, 1980, The University of Kansas, Lawrence, Kansas, USA
B.S. - Pharmacy, 1976, Ferris State College, Big Rapids, Michigan, USA

AFFILIATIONS

American Association of Pharmaceutical Scientists (AAPS), 1986 - Present
Registered Pharmacist, State of Michigan, 1976 ï Present
Registered Pharmacist, State of Missouri, 2005 ï Present
Scientific Committee Member - North American Bioanalytical Forum, Kansas City, MO, 2000 ï Present

REFERENCES

Available upon request