John Reed
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SUMMARY OF QUALIFICATIONS

PROFESSIONAL

- **Experienced professional across multi indications; Diabetes, Respiratory, Cardio/Pulmonary**
- **Twelve years experience in the Research Industry**
- **7 years Project Management experience**
- **Vendor relations, Alliance Management, Resource Management**
- **Experienced Project Manager leading both strategic and tactical project teams**
- **Managed 16+ employees over multiple functional areas**
- **Investigator meeting trainings**

Project Management	**Data Management**	**Medical Devices**	**Clinical Management**
Vendor Management	**Monitoring**	**Regulatory**	**Multi-site Project Teams**

PROFESSIONAL EXPERIENCE

Gilead Sciences Inc, *a fortune 500 Co*., Boulder, CO (formerly Myogen) (Jan 05 – Present)

Feb 09 – present - Manager, Project & Portfolio Management
May 07 – Jan 09 - Associate Manager, Project Management
Dec 06 – Apr 07 - Regulatory Affairs Associate II
Jul 05 – Nov 06 - Documentation Project Manager
Jan 05 – Jul 05 - Document Specialist

- Lead Development Project Team meeting(s) with participating leads from all functional areas; Pre-clinical, Regulatory, Clinical, CMC, Commercial, and Medical Affairs
- Attend all functional area subteam meetings supporting functional lead, contribute to project strategies and identify risks to overall project and corporate goals
- Develop and manage project timelines along with leading the design and implementation of the Project Development Plan(s), manage quarterly reporting to senior management
- Facilitate alliance partner meetings and manage expectations. Manage information flow between alliance partner(s) in support of the projects MAA efforts insuring timely delivery
- Identify stakeholders for dissemination of key project information
- Provide regulatory support to ensure the approval and successful US launch of LETAIRIS and worldwide registration activities
- Participate in eCTD meetings for other development projects and help facilitate the activities needed for organizing the legacy documents
- Facilitate provision of information between Gilead, external consultants, and GSK (partner organization) for the eCTD/IND/MAA
- Direct the planning, review, and approval of regulatory documents for submission to domestic and global regulatory agencies
- Managed the flow of information required for NDA, MAA, and other submissions
- Facilitate the preparation and transport of electronic and paper documentation from partner organizations as needed

Quantum Research, Inc (now nSpire Health) **(Oct 00 – Dec 04)**
Senior Project Manager, Project Management Team Leader *Louisville, CO*

- Review Sponsor draft protocols, CRFs to identify device requirements and primary endpoints, coordinate with software engineers on user specifications and design docs needed
- Conduct User Acceptance Testing (UAT) prior to software release
- Develop study-specific user manuals for investigative sites outlining software use
- Present ATS guidelines for spirometry at Sponsor Investigator meetings and provide protocol specific training to the study Monitors, PIs, and Coordinators
- Facilitate the development of project specific SOPs
- Monitor collected data for procedural correctness and protocol compliance and identify sites in need of further training
- Point of contact for protocol and technical support to investigative sites
- Direct development of data reporting and query programs according to the Sponsor's needs
- Lead Quality Assurance (QA) review meetings with project management teams to identify program risks
- Lead Project Management meetings and represent/report the project teams progress with upper management
- Manage protocol and project milestones according to Sponsor timelines
- Manage and direct the QA, Project Management and project support teams consisting of 16+ people

University of Colorado Health Sciences Center, NIDDM Research Studies **(Jun 97 – Oct 00)**
Professional Research Assistant, Senior Study Manager *Denver, CO*

- Oversee National Institute Health and American Diabetes Association grant budgets and subcontracts including completion of funding agency reports
- Facilitate protocol development and implement oversight
- Manage protocol submissions to IRB and CRC for approval
- Monitor clinic sites for protocol compliance and data integrity
- Track enrollment and hold weekly recruitment update meetings with staff and PI
- Manage hiring and training of study staff

Relevant Sales/Management Experience Prior to Research

Seattle Fish Company **(1992-1995)**
Sales Representative *Denver, CO*

- Retail and wholesale seafood sales
- Established and maintained 130 accounts from Castle Rock to Pueblo
- Developed Military accounts through the bidding process

Lois Carole LTD **(1989-1993)**
Retail Sales Manager *Denver, CO*

- Responsible for daily operation of a high-end clothing boutique
- Managed; staff scheduling, shipping and receiving of merchandise and maintained inventory control

Marlowe's Restaurant **1982**
Floor Supervisor *Denver, CO*

- Assisted in the interviewing, hiring and training of 70 plus employees prior to restaurant opening
- Implemented computerized register order placement system
- Managed operational floor duties and scheduling for wait staff

H. Brinker's/Marina Landing Restaurant ***(*1980-1982)**
Assistant Food Buyer *Englewood, CO*

- Responsible for all consumables for both restaurants within a 5 restaurant group
- Obtained price quotes, maintained inventory, audited receipts, calculated monthly billing, developed inventory control for all 5 restaurants and compiled monthly food and liquor costs

EDUCATION

Bachelors of Science Biology August 1997
University of Colorado Denver, CO

DEVICE EXPERIENCE

Holter Monitors
12 lead ECG, Cardio Collect
Spirometry
DigoDoser Spirometer
Piko Monitor

COMPUTER SKILLS:

Microsoft Project
Microsoft Excel
Microsoft Power Point
Microsoft Word
Microsoft Outlook

Training:

PMP Exam Prep/Project Management Tricks of the Trade (Exam being scheduled)
Risk Minimization Action Plan and Risk Management Strategy
Clinical Project Management: In the Pharmaceutical Industry/Running a Clinical Trial
Regulatory Affairs IND Phase and CTD/NDA Phase
SoCRA (Society of Clinical Research Associates) CCRP (lapsed)

References available upon request