JOHN REED

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PROJECT MANAGEMENT FOCUS

Pharmaceutical & Biotechnology | Operations & Clinical Research | Product Management

Highly motivated and experienced project management professional with expert proficiency in clinical management, operational efficiency, and management reporting. Comprehensive understanding of diabetes, respiratory, and cardio/pulmonary research. Technical talent and analytical expertise transferable across industries and specialized management practices. Synthesize, review, and analyze complex data, contributing valuable insight to enhance the decision-making process. Regarded for the ability to drive processes and motivate cross-functional teams; work well under pressure to manage and meet multiple project deadlines. An articulate presenter with outstanding interpersonal skills; adept at persuasion, power, and influence. Additional strengths include:

- ✓ Clinical Data Management
- ✓ Vendor and Resource Management
- ✓ Regulatory Compliance Monitoring
- ✓ Multi-Tasking and Project Management
- ✓ Vendor Relations and Alliance Management
- ✓ Client Collaboration and Leadership Skills
- ✓ High-Profile Management Presentations
- ✓ Strategic and Tactical Planning
- ✓ Strong Problem Solving Abilities
- ✓ Continuous Process Improvement

PROFESSIONAL EXPERIENCE

GILEAD SCIENCES, INC. (formerly MYOGEN), Boulder, CO (2005-Present)
Associate Manager / Manager / Project and Portfolio Management (2007-Present)
Documentation Project Manager / Regulatory Affairs Associate II (2005-2007)

Lead development project team meetings supporting multi-functional areas, including Pre-clinical, Regulatory, Clinical, CMC, Commercial, and Medical Affairs for one of the fastest-growing, multi-product, global research-based pharmaceutical Fortune 500 companies in the world, with annual revenues of $5.3 billion and 4,000 employees. Develop and manage project timelines, lead the design and implementation of the project development plans, and produce quarterly reports to senior management. Identify stakeholder interests for dissemination strategy of key project information. Actively participate in regulatory submission meetings for in-licensed development projects and help identify gaps in the legacy documents. Facilitate provision of information among the company, external consultants, and partner organization for the eCTD, IND, and MAA. Direct the planning, review, and approval of regulatory documents for submission to domestic and global regulatory agencies. Manage the flow of information required for NDA, MAA, and other submissions. Coordinate the preparation and transport of electronic and paper documentation from partner organizations as needed.

- **Identified risks, key success factors, and processes** that directly and positively contributed to project delivery, overall objectives, and corporate goals.
- **Ensured timely delivery in support of MAA project efforts** by facilitating meetings and managing expectations and information flow between alliance partners.
- **Employed a multitude of timely strategies** to ensure the approval and successful U.S. launch of LETAIRIS and worldwide registration activities through regulatory support.
- **Demonstrated exceptional organizational leadership** in managing diverse cross-functional teams aimed at enhancing quality and establishing more effective and efficient decision making.

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nSPIRE HEALTH (formerly QUANTUM RESEARCH, INC.), Louisville, CO (2000-2004)
Senior Project Manager / Project Management Team Leader

Reviewed sponsor draft protocols, CRFs, for accuracy to identify device requirements and primary endpoints, coordinated with software engineers on user specifications, and designed documents as needed. Conducted User Acceptance Testing (UAT) prior to software release. Developed study-specific user manuals for investigative sites outlining software use. Presented ATS guidelines for spirometry at sponsor investigator meetings and provided protocol specific training to the study monitors, PIs, and coordinators. Facilitated the development of project specific SOPs. Monitored collected data for procedural correctness and protocol compliance and identified sites in need of further training. Directed development of data reporting and query programs according to the sponsor's needs. Led project management meetings, represented project teams, and reported progress to upper management. Managed projects and directed the quality assurance (QA) and project support teams consisting of over 16 people.

- **Reduced or mitigated program risks** by leading QA review meetings with project management teams.
- **Optimized protocol** and managed project milestones according to sponsor timelines.
- **Served as primary point of contact** for protocol and technical support to investigative sites.
- **Monitored data quality** to identify training needs of sites to ensure useable data obtained.

UNIVERSITY OF COLORADO, HEALTH SCIENCES CENTER, Denver, CO (1997-2000)
Professional Research Assistant / Senior Study Manager, NIDDM Research Studies

Oversaw National Institute Health and American Diabetes Association grant budgets and subcontracts including completion of funding agency reports. Facilitated protocol development and implementation oversight. Managed protocol submissions to IRB and CRC for approval. Monitored clinic sites for protocol compliance and data integrity. Tracked enrollment and held weekly recruitment update meetings with staff and PI. Hired and trained study staff.

- **Consistently met quality goals** under tight deadlines without compromising quality.
- **Completed special projects** while managing multiple responsibilities simultaneously.

EDUCATION

UNIVERSITY of COLORADO – Denver, CO (1997)
Bachelor of Science in Biology

PROFESSIONAL DEVELOPMENT

Project Management Professional (PMP) Training
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
Previously held SoCRA (Society of Clinical Research Associates) CCRP Certification

ADDITIONAL INFORMATION

Computer Skills: MS Office (Excel, Word, PowerPoint), Project, Access, Outlook
Device Experience: Holter Monitors, 12-lead ECG, Cardio Collect,
Spirometry, DigoDoser Spirometer, Piko Monitor