Seetharam

PROJECT MANAGEMENT - Agile, Risk Management, Clinical Research

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SKILLS

- **Clinical Trial Management:** Study start-up, site selection, Subject acquisition, and CRO/vendor oversight.
- **Regulatory & Compliance Expertise:** ICH-GCP, FDA/EMA regulations, CTA/IND submissions.
- **Risk-Based Monitoring (RBM):** Identification of key risk indicators (KRIs), Tele monitoring strategies.
- **Pharmacovigilance Systems:** Safety data review, signal detection, MedDRA, and adverse event reporting.

WORK EXPERIENCE

Assistant Project Manager R&D **March 2023 – April 2024**
Stimulated Scholars *India*

- Engineered detailed project roadmaps for new product development, including budgets and timelines, improving project delivery efficiency by 20%. Monitored milestones and risk indicators, achieving a 95% on-time delivery.
- Collaborated with cross-functional teams, including R&D, QA, and QC, to maintain seamless project execution. Reduced bottlenecks by 15% through efficient communication, workflow optimization and clinical research.
- Guided cost optimization strategies, also keeping projects within budget constraints by identifying and mitigating potential risks. Negotiated with suppliers, reducing material costs by 8%, leading to savings of 10% week basis.
- Assessed project documentation, including progress reports and timelines, ensuring accurate record-keeping for over 10 active projects. A centralized tracking system using MS Project, improving reporting accuracy by 30%.

Safety & PV Submission Specialist **August 2022 – January 2023**
Premier Research *India*

- Coordinated safety-related queries from clients and regulatory authorities, providing timely resolutions that decreased customer complaints by 12%. Enhanced the regulatory submission process by standardizing templates.
- Reviewed safety reports for accuracy and adherence to global standards, ensuring compliance with international regulations such as ICH E2E, 100% pass rate in audits. Implemented a feedback loop with stakeholders.
- Collaborated with project teams to integrate safety data into submissions, optimizing data accuracy and reducing processing errors by 15%. Monitored regulatory updates and ensured seamless integration of new guidelines.
- Prepared case report documentation, ensuring data integrity and regulatory compliance by maintaining 100% accuracy across all case reports. Adopted digital tools for document tracking, reducing retrieval times by 10%.

Safety & PV Submission Specialist **May 2021 – August 2022**
Syneos Health *India*

- Chaired regulatory reporting & safety submission projects, ensuring compliance by 15%with global standards such as FDA and EMA guidelines, achieving a 100% regulatory acceptance rate for all submissions and actions.
- Managed a team of 18 professionals to deliver high-quality submissions on time, improving team efficiency by 20%. Coordinated interdisciplinary teams to guarantee to ensure all documentation met internal and compliance.
- Improved and optimized regulatory systems that automated overall manual processes, reducing submission time by 10%. Introduced new protocols for quality checks, which improved submission accuracy by 25%.
- Facilitated communication between regulatory authorities and internal teams, improving submission success rates by 18%. Negotiated timelines and submission strategies, ensuring alignment of all stakeholders by 90%.

Operation Specialist **May 2016 – May 2021**
IQVIA *India*

- Facilitated successful FDA/EMA audits by streamlining documentation workflows across 5+ operational departments, ensuring 100% compliance with regulatory standards and reducing audit preparation time by 30%.
- Collaborated with 5+ internal and external teams, ensuring seamless communication across all project stages. Leveraged Agile methodologies to optimize project workflows, resulting in a 20% reduction in project cycle time.
- Implemented protocol modifications, initiating corrective actions that reduced operational delays by 10%. Engaged with stakeholders to ensure protocol changes were in line with regulatory and project requirements.
- Facilitated lifecycle management of 10+ clinical trials, from initiation through close-out, ensuring adherence to timelines. Optimized data collection strategies, improving accuracy by 25% and reducing the data discrepancies.

EDUCATION

PG Diploma in Project Management **May 2024 – January 2025**
Conestoga College, Canada

Bachelor's in Pharmacy **May 2010 – July 2014**
Acharya Nagarjuna University, India

CERTIFICATIONS

- **PMP Certification by Project Management Institute (PMI)**