**Richard Graves Roop, PMP**

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**SPECIFIC EXPERIENCE**

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| **Job** | **Overview** | **Key Responsibilities** |
| Senior Project Manager  Parexel  RTP, NC | Led day-to-day operations of cross-functional teams in multi-regional Phase I and oncology clinical trials, ensuring completion of all study deliverables with the highest level of data quality and alignment to regulatory requirements (FDA, MHRA, EMA), ICH/GCP guidelines, quality standards, protocols, and client standard operating procedures (SOPs). | * **Project Planning & Coordination:** Developed integrated timelines and managed project plans to ensure timely execution. Monitored progress, tracked deliverables, and aligned team efforts to meet scope, quality, and regulatory expectations. Promoted audit readiness via proactive reviews and collaborations (project documentation, electronic Trial Master File, protocol deviations, etc.). Monitored and ensured clinical quality delivery, including tracking key quality indicators, reviewing compliance with protocols, and resolving quality issues as they arose. * **Stakeholder Collaboration & Communication:** Led cross-functional teams, facilitated regular stakeholder meetings, and ensured that project milestones, risks, and updates were communicated effectively. Maintained meeting minutes and documented decisions and actions for project files and lessons learned or post-mortem reviews. * **Vendor Management:** Assessed, selected, contracted after negotiation, and initiated vendors. Collaborated closely with vendors to ensure the successful execution of the clinical trials, including managing timelines, budgets, and deliverables in accordance with contractual agreements. Performed in-stream change management as needed. Facilitated effective communication and collaboration between internal teams and external partners. * **Risk Management:** Created and maintained project risk management plan to structure risk management activities. Developed and maintained project risk log. Documented and implemented risk mitigation strategies to ensure project timelines, including cohort enrollment plans remained on track. Closed out risks that were fully mitigated. * **Budget Management:** Planned and managed overall project budget, with frequent reporting to both management and internal finance teams. Tracked revenue and invoicing in alignment with contract milestones and budget targets, ensuring that financial deliverables were met. * **Data Management:** Contributed to case report form and edit check development. Planned data cleaning activities, data reviews, and database locks for internal purposes (governance reviews), external meetings (FDA interactions), and clinical study reports. * **Meeting Management:** Planned, led, and documented meetings at both the program and project level, maintaining action and decision logs throughout study conduct. Met with key functional leads frequently to discuss and remediate issues that arose throughout studies. |
| Senior Project Manager  Celerion, Inc.  RTP, NC | Managed strategic planning and operational execution of tobacco research trials, ensuring compliance with regulatory standards and organizational goals. | * **Financial Oversight:** Forecasted and managed study budgets, ensuring accountability and timely reporting. * **Resource Management:** Managed team resourcing across multiple clinical trials, ensuring that the right team members were allocated correctly. Collaborated with functional groups and external stakeholders to ensure alignment on timelines, costs, and contractual deliverables. * **Site Recruitment Strategies:** Managed site recruitment strategies and materials, formulated and tracked site enrollment progress to targets, and regularly updated internal and external stakeholders throughout study conduct and suggested options for recruitment obstacles. * **Business Development:** Contributed to bid defense preparations, including development of comprehensive proposals aligned with the sponsor's requirements, estimations for timelines and resources, preparation for potential questions, and development of presentation materials. * **Mentoring:** Accelerated career growth for mentees through targeted guidance and feedback. |
| Project Manager  North Carolina Medical Board  Raleigh, NC | Optimized intradepartmental operations and improved communication methodologies and directly supervised employees within my department. | * **Leadership Team:** Planned, led, and documented leadership team meetings, maintaining action and decision logs throughout study conduct. * **Executive Team:** Added meetings as an ad-hoc member representing the Leadership Team and providing insight into the Chief Executive Officer department operations. * **Site Security Improvement:** Led the initiative to improve the security and safety preparations for the medical board office building. * **Records Management:** Serve as liaison to the State of North Carolina on medical board record retention and led efforts to secure historical records onsite from unexpected or unintentional destruction via electronic archiving. |
| Senior Project Manager  Syneos Health  RTP, NC | Oversaw multiple vaccine clinical trials, ensuring compliance with FDA regulations and organizational goals. | * **Project Management & Delivery**: Coordinated study timelines, budgets, and deliverables, ensuring adherence to ICH/GCP guidelines and project-specific plans. Performed kick-off meetings for internal, CRO, and other vendors. * **Vendor & CRO Management:** Proactively managed CRO and other vendors to ensure the successful execution of the clinical trials, including managing timelines, budgets, and deliverables in accordance with contractual agreements. * **Quality Management**: Collaborated with Clinical Quality Assurance to plan quality assurance activities including planned and requested audits, coordinated the resolution of audit findings, and oversaw the initiation and follow-through of corrective and preventative actions (CAPA). * **Process Improvement:** Participated in SOP development and revision and contributed to the development of best practices. Identified opportunities for process improvements, such as a new team training meeting at protocol inception, to optimize the efficiency of project planning, conduct, and delivery via intensive collaboration. |