

# MY WORK IS A STORY OF HEALTH.

What story will you tell?



**Job Title:** Sr R&D Project Manager

**Requisition ID:** 161532BR

Thermo Fisher Scientific Inc. is the world leader in serving science, with annual revenue exceeding \$25 billion. Our Mission is to enable our customers to make the world healthier, cleaner and safer. Whether our customers are accelerating life sciences research, solving complex analytical challenges, improving patient diagnostics and therapies or increasing productivity in their laboratories, we are here to support them.

**Location/Division Specific Information:**

- Fremont, CA
- Clinical Diagnostics Division

**How will you make an impact?**

The Niche Diagnostics Program Management Office (PMO) is seeking a Senior Project Manager who will manage complex New Product Development projects to successful and timely commercial launch. This role will lead cross-functional new product development teams for In Vitro Diagnostics (IVD) devices in accordance to FDA, ISO 13485, and international regulations, as well as company Design Control procedures and phase gate approval processes. The role will also support RUO products, sustaining projects, and PMO departmental initiatives.

**What will you do?**

- Create and maintain project timelines ensuring project tasks, dependencies and responsibilities are well defined. Utilize critical path techniques in schedule development and project monitoring.
- Establish and manage project budgets in collaboration with Finance and cross-functional departments. Ensure contractual obligations and financial milestones are met.
- Estimate resource requirements over the course of the project and work with management to address resource constraint issues.
- Facilitate the completion of various design control documents (project plans, design inputs, design outputs, risk, etc) and maintain design history files to ensure adherence to quality procedures.
- Identify, document, and mitigate project risks and contingency plans.
- Collaborate with OEM partners to ensure coordination of timelines, identify critical milestones, risk mitigation, and communication of progress.
- Lead project team meetings, drive team decisions, and ensure alignment with internal and external partners.
- Manage scope creep and ensure customer, team, and company needs are met.
- Promote a proactive, positive and professional culture within the Program Management Office. Mentor and coach junior Project Managers.
- Contribute to continuous improvement of PMO processes, related SOPs, and supporting tools.

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## How will you get there?

### Education/Experience:

- Bachelor's degree in life sciences, engineering, or equivalent. PMP (Project Management Professional) certification strongly recommended
- 10 years industry experience in Project Management roles with increasing responsibilities.
- Experience working in an FDA regulated environment is required.
- Advanced understanding of design control quality standards and regulatory compliance requirements for medical device or diagnostics (ex. 510K submissions). Experience in developing Therapeutic Drug Monitoring (TDMs) Tests, Infectious Disease Tests, Toxicology Tests, QC Controls, or Companion Diagnostic test is preferred.
- Strong understanding of product development challenges and methods for resolution. High-level business acumen with experience using financial tools.
- Demonstrated skills using MS Project or related software for Project Management. Solid skills using MS Office, Outlook, Smartsheets, PPM Pro or other project management software.

### Non-Negotiable Hiring Criteria:

- Solid ability to lead complex and virtual cross-functional project teams from feasibility to launch.
- Outstanding organizational skills with ability to multi-task and balance sophisticated and routine work activities.
- Demonstrated ability to lead, direct and manage cross-functional teams, influence business partners and get results through others. Strong conflict resolution skills.
- Excellent written and verbal communication skills with the ability to effectively communicate with team members, functional management and senior leadership.

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