



Scientific Project Manager

This position is part of a growing multidisciplinary team focused on development of multiplexed immunoassay microarrays and related products for diagnostics and life science research. This position will report to the head of research and development. In addition to working with research and development personnel, this position must also be able to work in a matrixed environment with personnel from marketing, manufacturing, and quality assurance to successfully deliver projects on time and on budget.

Position Responsibilities:

- Lead all company product development projects and project teams that include staff from multiple departments. Coordinate communication and resolve issues between team members.
- Utilize the design control process within ISO 13485 to plan, budget, prioritize, resource, and document each project throughout the entire product lifecycle, from initiation, feasibility, launch, sustaining engineering, to termination.
- Assist in the development of product specifications. Document and map those specifications to project deliverables (goals and milestones).
- Document and facilitate the transition of products to the manufacturing department, including transfer of validated systems, processes, protocols, and QC documentation.
- Coordinate with and manage third-party vendors as needed to complete projects on time and on budget.
- Identify, manage, and mitigate risks that could negatively impact project due dates, expenditures, deliverables, and quality.
- Prepare and present to team members and management on the status of projects on a timely basis, including data, timelines, changes, and risk assessments.
- Perform assay development as required, including experimental design and execution.
- Prepare and present experimental results and conclusions to the team members and management.
- Observe all company policies and ethical, legal and regulatory requirements applicable to the business.

Requirements:

- B.S. in biology, immunology, biochemistry, biotechnology, biomedical engineering or related field with more than 4 years of experience in an industrial position, M.S with 2 years of experience, or Ph.D. with 1 year of experience.
- Experience with new product development, preferably from concept to launch.
- One year of product development project management experience in the Diagnostics, Pharmaceutical, Medical Device or Biotechnology market areas.



- Experience working in a quality control system, preferably ISO 13485.
- Experience utilizing project management software (e.g. Microsoft Project).
- Trained in standard laboratory techniques, record documentation and laboratory safety.
- Experience with design and performance of multi-tasked experimental plans.
- Supervisory and team management experience.

Other skills and competencies:

- Prefer PMI Certification in Project Management.
- Scientific proficiency, preferably in immunoassay development.
- Effective organizational, verbal, and written communication skills.
- Competent with MS Office Suite of software.
- Ability to be flexible, multi-task, and work with associates across multiple disciplines in a rapidly evolving, small company.