About Portal

Portal aims to transform medicine by enabling patients to self-inject their biological drugs with a revolutionary needle-free device. This innovative drug delivery system is designed to replace auto-injectors and our early studies show it is overwhelmingly patient preferred. Issued from MIT Research and connected to the cloud, the Portal device allows biopharmaceutical companies to differentiate their therapies with a patient-centric drug-delivery solution. Join us on this exciting journey of making patient care and comfort a priority.

At Portal we believe in workplace inclusion - all employees belong, contribute, and thrive in our fast-paced environment. All people need to be represented for all patients to be represented. We encourage you to apply no matter your background - because we understand a diverse culture formulates diverse solutions.

Title: ***Senior Program Manager***
Reports to: **Sr Director of Program Management**
Location: **Boston / Cambridge**

Position Overview:

We are seeking an experienced program a manager to join our dynamic organization.

As a Senior Project Manager (Sr PM) you will be responsible for leading the development of the PRIME needle-free device. You will lead a cross-functional team through the regulatory approval process with the goal of obtaining FDA clearance and launching the device into the market. You will interface with all levels of the company, serving as a bridge to promptly escalate any issues, seek decisions, and solve problems as needed.

The Role

- In this role you will be responsible for achieving successful implementation of multiple projects and managing all activities required to define, design, develop and deliver Portal's products to customers.
- You will be responsible for managing scope, schedule, budget and risk for the entire program and be directly responsible for delivering product on time and on-budget, while meeting the necessary quality standards.
- You will lead a cross-functional project team, which includes R&D (hardware, software and disposables), marketing, regulatory, quality, clinical, supply chain and manufacturing among others.
- You will be responsible for creating and maintaining the tools and frameworks required to track all projects, escalate issues and drive through resolution.

Portal Instruments

Your Day to Day

- You will plan and maintain detailed project schedules, identify key milestones, decisions points and highlight key risks.
- You will track project deliverables and drive tactical execution to maintain project schedules.
- You will identify key project stakeholders, understand their expectations, and effectively communicate with them throughout the program.
- You will ensure design control requirements are met and lead the team thorough a phase-gate design control process.
- You will provide clear and concise project updates, including unbiased communication of project status and issues, to the cross-functional team and senior leadership.
- You will regularly update standardized forms and metrics to help track the project deliverables, identify resource gaps and drive conflicts to resolution.
- You will schedule and conduct team meetings, design reviews, management updates and other meetings as needed.
- You will define meeting objectives, set agendas, drive the meetings and capture meeting minutes, including decisions and action items.
- You will communicate with different stakeholders to ensure product requirements are met and any issues are solved in a promptly manner.
- You will coordinate and track deliveries and services from multiple external vendors.
- You will lead or participate in root cause investigation teams to develop and implement corrective and preventative actions that address design concerns.
- You will serve as a thought partner for senior leadership to identify improvement opportunities and implement best practices.

We'd love to hear from you if you have:

- A bachelor's degree in Mechanical, Electrical or Biomedical Engineering, or other related technical discipline; Master's degree preferred.
- At least 7+ years of industry experience in medical device development, combination product development or drug product development or 5+ years of experience with a Master's degree.
- A demonstrated level of combination product development experience, preferably in drug delivery technologies.
- A proven track record enabling cross-functional teams to deliver complex medical devices with high quality from concept through commercialization and release product management.
- Knowledge and understanding of key aspects of medical device product development and capable of orchestrating and managing the execution of programs to meet quality, program, and business objectives.
- Experience navigating through medical device development in accordance with FDA and other regulatory guidelines such as design controls (21CFR820.30), risk management (ISO 14971), QMS (ISO 13485) and related requirements ISO 11608, ISO 11040, ISO 3951 and ISO 2859.
- You bring excellent written and verbal communication skills.

- You are comfortable taking on new tasks or projects with little direction and adjusting course in response to feedback and information.
- You bring an openness to learn from diverse perspectives and collaborate on multidisciplinary teams.
- You are familiar with project management tools and software such as MS Project and Smartsheet.

Working at Portal

Portal Instruments offers employees the opportunity to work in a fast-paced start-up that values innovation, creativity, accountability, teamwork, and openness while providing excellent leadership and development opportunities. *Which all sounds great… right? But what about the other stuff??*

Pay

We believe in transparency so if your resume meets the job requirements, we will discuss salary range with you right from the start, so feel free to ask us!

Portal offers a competitive salary, and a comprehensive benefits package, including stock options, both Roth and traditional 401(k) retirement plans, and a chance to make a difference in the lives of thousands of patients.

Health & Wellness:

Portal gives you choices by offering both a PPO and HMO healthcare plan - we do our upmost to keep costs low for our employees while still maintaining the level of care you deserve and expect. We also offer competitive dental, orthodontic, vision, and accident insurance plans.

You could also enroll in a FSA, dependent care, and commuter reimbursement accounts or ask about our on-site parking (subject to availability) and our bike room – bonus we have a locker room with shower if you enjoy breaking a sweat on your commute or anytime!

Portal has got you covered; including paid family medical leave insurance, short- and long-term disability, as well as life and AD&D coverages, all 100% company sponsored. Plus, we offer an employee assistance program which includes confidential counseling, financial resources, work-life solutions, free online will preparation, discounts, and more!

Rest & Recharge

Use the 20 days of vacation we give to everyone, because everyone deserves to take a break and our team is encouraged to take *all* their time off each year to recharge!

We also observe 13 company-wide state and federal holidays and often have a company-wide holiday shutdown — sometimes the best way to reward results is with rest!

If you're sick... you're sick! And being sick is certainly no picnic (or vacation!), so in addition to vacation we also offer sick time. We want you to be healthy, so take care of yourself; plus staying home helps protect everyone from illness – Portal's strong team has your back.

More Benefits… seriously!

- Daily lunch
- Casual dress code
- Happy hour
- Annual company sponsored events
- Annual volunteer opportunities and donation match program

To Apply: Please submit a resume and cover letter to: careers@portalinstruments.com.
You will be contacted if your background meets Portal's needs.

Portal Instruments is committed to challenging implicit bias and creating an equitable work environment. We are proud to be an equal opportunity employer. All qualified candidates will receive consideration without regard to race, ethnicity or national origin, sexual orientation, gender identity or expression, genetics, military service, age, family status, or disability.