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: ***Global Development and Submission Leader for PRIME 1 ml SQ (VP level)***
Reports to: **CEO**
Location: **Boston / Cambridge**

Position Overview:

We are seeking a highly accomplished and visionary Global Development Leader to join our dynamic organization. As the Global Development Leader for Portal's lead asset, the PRIME 1ml SQ (fertility), a needle-free administration system for infertility treatment. You will be responsible for leading and overseeing the successful late-phase development and commercialization of the PRIME 1ml subcutaneous system. You will provide strategic direction, drive cross-functional collaboration, and ensure the timely delivery of a system that meets the highest level of quality and regulatory requirements for the treatment of fertility.

The Role

- In this role, you will be responsible for all activities related to late phase development, FDA submission/clearance, and launch of our PRIME 1 ml SQ system for fertility treatment
- You will also work closely with the CEO and Chief Business Officer to partner with pharma companies who will be submitting their assets with PRIME as a combination product to the FDA
- You will be in charge of drug product testing required for FDA submission requirements in fertility treatment
- You will lead post-approval lifecycle management activities and any post-launch support for PRIME 1 ml SQ in close collaboration with the SVP of Advanced Development & Manufacturing, CEO, and Chief Business Officer

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Your Day to Day

- You will identify and work closely with external medical device technology firms to execute all human factors design, testing and development work, and any late phase development activities required for FDA submission of PRIME.
- You will be the technical lead responsible for the device portion of the combination product development with pharma partners including Design Control, Design Inputs, Design Verification, Design Validation, Risk Management and Human Factors Engineering customizing to the individual pharma partner
- You will interpret and apply knowledge of applicable guidance, regulations, standards, and industry best practices to medical devices and combination product design and development process including leading the team through analysis of key risk/benefit tradeoffs during the development process.
- We will depend on you to translate customer needs into product and system level requirements and specifications in close collaboration with the engineering and marketing teams
- You will apply your sound understanding of combination product regulatory requirements to compile device-related CMC sections for IND/IMPD/BLA as needed for pharma partners.
- You will identify and hire appropriate SMEs for drug product-related activities, human factors, as required
- You will lead or participate in root cause investigation teams to develop and implement corrective and preventative actions that address design concerns related to human factors usability findings
- You will be judged on your ability to be a cross-functional leader who can inspire and direct the team to deliver PRIME to the market including working closely with Engineering, Project Management, Quality Assurance, Regulatory Affairs, Commercial, Manufacturing, etc.
- You will be responsible for the project planning, execution, and resource allocation to ensure on-time delivery of the PRIME 1 ml SQ program, while maintaining quality, cost-effectiveness, and compliance with global regulations.
- You will lead our risk management efforts for our lead program including Identifying potential risks and develop strategies to mitigate them throughout the late phase development process. You will be expected to proactively communicate risks to stakeholders and implement corrective actions as needed.
- As a start-up, managing budget and finding creative ways to deliver products while “bootstrapping” resources is a necessity – you are someone who thrives in such an environment and is committed to the efficient utilization of resources and adherence to financial goals
- Provide critical thought partnership as a member of the executive team to drive data and evidence needed for regulatory submission.
- We will look to you to participate in Design and Manufacturing reviews.

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

- An advanced degree (MEng, MS, PhD) in Chemical, Mechanical, Electrical or Biomedical Engineering, or other related technical discipline.
- At least 10+ years of relevant industrial experience in device integration and development, combination product development, drug product development with a major pharmaceutical, biotechnological or a generic pharmaceutical company.
- A demonstrated level of combination product development experience, including pre-filled syringes, pre-filled cartridges, auto injectors, on-body devices and/novel devices for delivery of complex formulations.
- Understanding of systems thinking (drug+ primary container+ device+ software/app) and experience with human factors/ usability engineering.
- Do you have experience with the development of connected devices? This is preferable.
- Experience of working within device regulatory requirements and industry processes such as design controls (21CFR820.30) EU MDR 2017/745, risk management (ISO 14971), QMS (ISO 13485) and related requirements ISO 11608, ISO 11040, ISO 3951 and ISO 2859
- Experience submitting and responding to FDA for the following filings: 510K/IND/IMPD/BLA is required.
- You bring excellent written and verbal communication skills.
- Colleagues would describe you as team-oriented, progressive thinker with a can-do attitude who enjoys participating in an innovative and creative work environment.
- You love startups and starting up. 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.

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.

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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.