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: ***Sr. Director, Chemistry, Manufacturing, and Controls (CMC)***
Reports to: ***Global Development Leader for PRIME 1ml SQ (fertility)***
Location: **Hybrid with primary location Boston**

Position Overview

We are seeking an experienced and talented Chemistry, Manufacturing, and Controls (CMC) leader with expertise in combination drug delivery products to join Portal. As the CMC Leader, you will play a crucial role in ensuring regulatory compliance and driving the successful development, manufacturing, and commercialization of the Portal's lead asset, PRIME 1 ml SQ (fertility), a needle-free administration system for infertility treatment. You will collaborate with cross-functional teams, regulatory authorities, and external partners to provide strategic regulatory guidance and expertise throughout the entire product lifecycle.

The Role

- In this role, you will be responsible for the management of Portal's CMC-related activities for the lead asset, Portal PRIME 1 ml SQ (fertility). This hands-on position will lead all CMC aspects of development, including drug product stability, characterization, clinical supply, formulation and analytical methods development as needed
- You will be a key member of the pharma partnering team who will work with partners as they develop their assets for the Portal device. You will provide a key advisory role for partner drug product teams as they characterize their assets in the PRIME device for their specific applications
- You will be in charge of drug product testing required for FDA submission requirements in fertility treatment and develop the procedures whether at Portal or with key vendor partners and also be responsible for completing all submission-related documentation
- You will be responsible for supporting Portal clinical studies from a drug product perspective

Your Day to Day

- You will immediately identify, diligence and select Contract Manufacturing Organizations (CMOs) for formulation work, analytical work, GMP manufacture and supply as appropriate
- You will develop drug product acquisition and testing strategies as needed to meet clinical and submission needs including ensuring ensure product quality, regulatory approvals and operational flexibility of supply chain
- You will work closely with the Quality team to implement stage-appropriate analytical methods and ensure that all partner CMOs/CROs are in compliance with all relevant regulatory standards
- You will write and/or review CMC sections of regulatory documents and submissions; represent Portal as the CMC expert in front of regulatory authorities
- We expect you to work collaboratively with relevant internal parties to meet current and future needs of Portal internal and partnered programs including uninterrupted drug supply for clinical trials
- You will be responsible for establishing and maintaining detailed project plans; define risks and continually evaluate ways to optimize timelines and parallel process while appropriately managing risk
- You will build and lead the CMC team as CMC responsibilities grow within the organization

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

- An advanced degree (MS, PhD) in Chemical Engineering, Pharmaceutical Chemistry or Organic Chemistry along with and 10+ years of CMC experience in the biotech/pharmaceutical industry, including work with contract manufacturers
- Experience in drug product/formulation development, analytical assay development, clinical and commercial cGMP production including process validation experiments, preapproval inspections, and commercial manufacturing
- Extensive experience managing US and International CMOs for the manufacture of drug substance and drug product
- Experience with authoring/reviewing regulatory documents (IND, CTA, NDA), specifically Module 3 sections of an IND/NDA, and FDA information requests, interfacing with regulatory agencies, and knowledge of relevant FDA regulations
- Strong analytical, organizational, and time management skills with a track record of identifying and implementing novel solutions
- Demonstrated agility and ability to navigate and be successful in a fast-paced, dynamic work environment
- 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.

Portal Instruments

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

Portal Instruments

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.