About Portal Instruments

Portal Instruments is redefining how advanced injectable therapies are delivered.

Founded on MIT research, we are building a next-generation drug delivery platform that enables high-volume, high-viscosity biologics to move from IV infusion to subcutaneous injection, unlocking a new generation of at-home therapies.

Our lead platform, PRIME Nexus™, combines reusable hardware with software-tunable delivery to enable therapies that were previously not feasible outside the clinic.

We have secured development partnerships with leading biotech companies and are now entering the most critical phase of the company: scaling from advanced engineering to clinical-ready and manufacturable systems.

Role Information

Title: Quality Manager
Reports to: VP, Quality & Regulatory Affairs
Location: Hybrid (Primary location: Boston/Cambridge, MA)

Position Overview

Reporting to the VP, Quality & Regulatory Affairs, the Quality Manager will be a hands-on operational leader of Portal's Quality Management System as we advance PRIME Nexus®, our reusable electromechanical drug delivery platform, through development, verification & validation, clinical use, and commercial launch. You will own and run core QMS processes day-to-day, partnering closely with engineering, software, manufacturing, supplier quality, and clinical teams to keep the program audit-ready and moving.

This is an opportunity to take ownership of how quality actually runs at Portal — to drive practical, compliant, and efficient processes that directly enable a novel drug delivery platform to reach patients.

What You'll Do

Your Impact

- Keep Portal's QMS running cleanly and audit-ready across CAPA, document control, change control, training, and supplier quality
- Partner cross-functionally with engineering, software, manufacturing, and clinical teams to translate quality requirements into practical, executable solutions

- Coach and elevate the broader organization on design controls, risk management, and good documentation practices

Key Responsibilities

- Own and execute core QMS processes day-to-day, including document control, change control, training, CAPA, nonconformance, internal audits, and management review preparation
- Lead design control activities for the electromechanical drug delivery device, including DHF maintenance, design reviews, traceability, and verification & validation documentation
- Drive risk management activities (ISO 14971), including hazard analysis, dFMEA/pFMEA/uFMEA, risk-benefit analysis, and risk file maintenance throughout the product lifecycle
- Manage complaint handling and post-market surveillance, including intake, investigation, MDR/vigilance evaluation, trending, and reporting
- Plan and conduct internal audits and supplier audits; manage supplier qualification, quality agreements, and supplier corrective actions in partnership with operations
- Support FDA inspections, notified body audits, and partner audits, including preparation, hosting, real-time response, and follow-up actions
- Partner with software and systems engineering on IEC 62304 software lifecycle activities, cybersecurity documentation, and software validation
- Support human factors and usability engineering activities, ensuring documentation aligns with IEC 62366 and FDA HFE expectations for at-home use
- Drive continuous improvement of QMS workflows, templates, and electronic systems (eQMS) so that processes remain compliant, lean, and easy to follow
- Develop and deliver QMS, design controls, and risk management training for the broader Portal team
- Maintain and report quality metrics and KPIs to support management review and leadership decision-making

What We're Looking For

Required Qualifications

- Bachelor's degree in engineering, physical sciences, or life sciences
- 7+ years of quality experience in medical devices, with at least 2 years in a quality lead or manager role
- Strong working knowledge of FDA 21 CFR Part 820, ISO 13485, and ISO 14971; familiarity with EU MDR
- Hands-on experience with design controls for electromechanical or software-containing medical devices
- Experience operating CAPA, complaint handling, document control, and internal audit programs

- Experience supporting FDA inspections, notified body audits, or external partner/customer audits
- Strong communication, organizational, and cross-functional collaboration skills, with the ability to operate in a fast-paced, evolving environment

Preferred Qualifications

- Experience with drug-device combination products and 21 CFR Part 4
- Experience with reusable medical devices, including reprocessing/cleaning validation
- Familiarity with IEC 62304 (software lifecycle), IEC 60601-1, IEC 62366 (usability), and ISO 10993 (biocompatibility)
- Experience implementing or administering an electronic QMS (e.g., Greenlight Guru, MasterControl, Veeva)
- ASQ CQA, CQE, or CMDA certification, or equivalent
- Experience working in a venture-backed or growth-stage medical device company

Working at Portal Instruments

Portal offers the opportunity to work on meaningful technology with real patient impact, alongside a highly collaborative and mission-driven team. We value innovation, accountability, transparency, and thoughtful problem-solving—and we believe great work happens when people feel supported and empowered.

Compensation

Salary Range (Massachusetts):

The expected base salary range for this role in Massachusetts is $110,000–$150,000, subject to confirmation with HR based on market benchmarking and internal equity.

Compensation for candidates in other U.S. locations may vary based on geographic market factors. This role may also be eligible for additional compensation and benefits.

Benefits & Perks

Health & Wellness

- Medical plan options including PPO HSA and HMO HSA eligible plans
- Competitive dental, orthodontic, vision, and accident insurance
- Flexible Spending Accounts (medical, dependent care, commuter)
- Employee Assistance Program with counseling, financial tools, and legal resources

Financial & Protection

- Stock options
- 401(k) with Roth and traditional options
- 100% company-paid short- and long-term disability
- Company paid life and AD&D insurance
- Paid Family and Medical Leave

Rest & Recharge

- 20 days of vacation annually (encouraged to use)
- 13 company observed holidays
- Periodic company-wide holiday shutdowns
- Sick time separate from vacation

Additional Perks

- Daily lunch (Cambridge office)
- Casual dress code
- On site bike room, lockers, and showers (subject to availability)
- Happy hours and company sponsored events
- Annual volunteer opportunities and donation match program

Inclusion & Equal Opportunity

At Portal, we believe all employees should feel they belong, contribute, and thrive. We know that diverse teams create better solutions for diverse patients, and we encourage applicants from all backgrounds to apply.

Portal Instruments is an equal opportunity employer. All qualified applicants will receive consideration for employment without regard to race, ethnicity or national origin, sexual orientation, gender identity or expression, genetics, military service, age, family status, or disability.

How to Apply

Please submit a resume (and cover letter if applicable) to careers@portalinstruments.com. Candidates will be contacted if their background aligns with Portal's needs.