About Portal Instruments

Portal Instruments is redefining how advanced injectable therapies are delivered.

Founded on MIT research, Portal develops innovative drug-delivery platforms that enable patients to self-administer complex biologics safely, comfortably, and reliably. Our lead platform, PRIME Nexus®, is a reusable, software-tunable drug-delivery system designed to support high-viscosity and large-volume injectables, with both needle-assisted and needle-free delivery options depending on therapeutic needs.

Portal partners with biopharmaceutical companies and key players in the medical device ecosystem to integrate our delivery platforms into drug–device combination products that improve patient experience, reduce cost of goods, and support successful commercialization. Guided by human-factors science, rigorous engineering, and real-world usability, Portal is building the next generation of patient-centric drug delivery solutions.

Role Information

Title: Senior Quality Engineer
Reports to: *VP, Quality and Regulatory*
Location: Hybrid (Primary location: Boston/Cambridge, MA)

Position Overview

This role is a critical part of Portal's mission to advance PRIME Nexus® toward commercialization. You will work cross-functionally with engineering, regulatory, manufacturing, and external partners to help scale a novel drug-delivery platform that directly impacts patient experience and therapeutic success.

This role will support quality processes for medical device development and manufacturing at Portal Instruments. The QE will represent Quality on internal and external project teams for both design and manufacturing. This role will support quality systems, product design verification & validation, medical device software verification and validation, manufacturing process validation, customer feedback, and corrective and preventive action investigations and implementation.

This is an opportunity to take ownership, solve complex problems, and contribute meaningfully at a pivotal stage of Portal's growth.

What You'll Do

Your Impact

- Contribute directly to the development, validation, and commercialization of Portal's drug-delivery platforms
- Collaborate across disciplines to solve complex technical and operational challenges and translate requirements into practical, compliant solutions

Key Responsibilities

- Support new product development and product realization through all design control phases. Support verification & validation (test plans, protocols, reports), test method validation,

incoming inspection, lot release of engineering, clinical and commercial devices, nonconforming product disposition, review of design documentation, calibration and equipment validation (IQ/OQ/PQ)

- Maintain the risk management file for Portal Instruments products throughout their lifecycle. Collaborate with cross-functional teams on design and process related risk management activities.
- Work with software team to support device software development, verification, and release in compliance with IEC 62304 and relevant regulatory requirements
- Support continuous improvement of quality system procedures in accordance with 21 CFR 820, ISO 13485, EU MDR, MDSAP, and ISO 14971
- Lead corrective and preventive processes as required, including documentation of CAPA, root cause investigation, and implementation of improvement activities
- Conduct and/or participate in internal and external audits as needed
- Partner cross-functionally to translate quality requirements into practical, compliant solutions
- Act as subject matter expert for quality engineering practices
- Partner with Engineering and Operations to ensure designs are effectively transferred to manufacturing
- Engage with internal and external stakeholders, including vendors and partners
- Foster collaboration, cross-functional communication, and risk-based decision making

What We're Looking For

Required Qualifications

- BS or MS degree in Engineering, Science, or related discipline
- 5+ years of quality assurance or design assurance experience in the medical device, biotech, or pharmaceutical industry
- Strong working knowledge of 21 CFR 820, ISO 13485, and ISO 14971
- Proven track record supporting new product development
- Knowledge of statistical sampling and data analysis methods
- Ability to work effectively in a fast paced, collaborative environment
- Strong communication skills and comfort working cross functionally

Preferred Qualifications

- Experience with drug-device combination products and working knowledge of relevant standards (e.g. ISO 11608)
- Knowledge and experience with MDSAP, EU MDR, IEC 62304, and ISO 60601
- Exposure to human factors engineering, usability, or patient centric design
- Experience supporting products through development, validation, and commercialization
- Experience working with contract manufacturers and establishing relationships with suppliers

Portal Instruments

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 $120,000 – $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.