About Portal Instruments

Portal Instruments is redefining how biologic 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: transitioning from advanced engineering to clinical-ready, scalable manufacturing.

Role Information

Title: Director of Manufacturing

Reports to: CEO

Location: Boston/Cambridge, MA (on-site presence required)

Position Overview

We are seeking a Director of Manufacturing to build and lead the execution engine that will take our NEXUS™ platform from advanced engineering to clinical-ready and scalable production

This is a mission-critical leadership role with end-to-end ownership of:

- Manufacturing execution
- Supply chain management, including vendor management
- Manufacturing readiness and design transfer governance
- Production readiness and scale-up

You will operate at the center of the organization, working across engineering, program management, external partners, and pharma collaborators, to ensure that Portal delivers reliably, predictably, and at scale.

This role is about creating and maintaining the system that builds the product. You will be accountable for ensuring that what is designed can be built, scaled, and delivered on time.

What You'll Do

Mission: Drive the Manufacturing strategy and execution that enables Portal to deliver complex drug delivery systems reliably, at scale, and on time across multiple global pharma partner programs, throughout the lifecycle of the product.

Key Responsibilities

1) Manufacturing Strategy & Execution

- Define and execute the end-to-end manufacturing strategy
- Lead design transfer from R&D to manufacturing
- Ensure DFM/DFA principles are embedded early in development
- Drive readiness for clinical builds, pilot production, commercial launch and scale-up
- Identify and implement opportunities to drive down cost of goods sold (COGS)

2) Process Development & Desing Transfer

- Own the design transfer process, ensuring manufacturing procedures, work instructions, and process validations (IQ/OQ/PQ) are completed to support regulatory submissions (510(k), PMA, or CE mark as applicable).
- Develop and validate manufacturing processes for precision electromechanical subassemblies, including drive mechanisms, electronic components, sensors, and final device assembly.
- Partner with R&D to embed Design for Manufacturability (DFM) and Design for Assembly (DFA) principles throughout product development.
- Establish and manage process controls, inspection criteria, and process FMEAs to ensure consistent, reproducible output.

3) Supply Chain & Vendor Management

- Lead make-vs-buy analyses and manufacturing feasibility assessments
- Build and manage a supplier base for critical components including actuators, injection-molded parts, PCBAs, among others.
- Establish in-house vs. outsourced manufacturing boundaries; identify, qualify, and manage contract manufacturing organizations (CMOs) and component suppliers.
- Lead tooling strategy, pilot builds, and production ramp
- Ensure alignment across all vendors (scope, timeline, deliverables)
- Establish supplier qualification programs, incoming quality inspection protocols, and supplier scorecards.

4) Quality Systems & Regulatory Compliance

- Ensure all manufacturing activities comply with 21 CFR Part 820 (QSR), ISO 13485, and applicable IEC standards (e.g., IEC 62133 for battery-powered devices).
- Partner with Quality to develop and maintain Device History Records (DHR), Device Master Records (DMR), and supporting documentation.
- Lead manufacturing readiness for regulatory inspections (FDA, Notified Body) and internal audits.

- Drive corrective and preventive action (CAPA) processes related to manufacturing nonconformances.

5) Program Execution (in partnership with PM)

- Partner with Program Management to ensure on-time delivery
- Identify and mitigate operational risks
- Drive manufacturing readiness as a core part of program success

6) Cross-functional Integration

- Act as the bridge between engineering, manufacturing, and quality to ensure that design decisions translate into scalable, manufacturable products.
- Ensure designs are manufacturable, scalable, and cost-effective
- Partner with Engineering and Quality to align design, validation, and manufacturing readiness
- Ensure manufacturing readiness aligns with ISO standards and FDA expectations
- Develop and track key manufacturing KPIs including yield, cycle time, cost of goods (COGS), and on-time delivery.

What Success Looks Like

Within 9–12 months, you will have:

- Delivered clinical-ready devices on time across multiple partner programs
- Established a scalable and reliable manufacturing strategy
- Built a high-performing operations function
- Eliminated late-stage manufacturing risks through early integration
- Created a clear path from prototype, to clinical, to commercial and scale-up
- Identify and implement opportunities to drive down costs

What We're Looking For

Required Qualifications

- Experience with interdisciplinary engineering with a degree related to Mechanical, Industrial, Electrical, or Software Engineering.
- 10+ years of experience in medical devices, industrial, or a regulated industry with at least 3 years in a leadership role.
- Experience working within quality systems (e.g., ISO 13485, design controls)
- Six Sigma, Lean Manufacturing, or similar process improvement certification.
- Proven ability to operate in a fast-paced, high-accountability environment

- Strong bias for action with the ability to go deep technically when needed and solve problems
- Experience operating in environments where speed, ownership, and ambiguity are critical to success
- Proven track record of:
    - Bringing products from prototype → clinical → scale
    - Managing external manufacturing partners
- Deep experience in:
    - Injection molding
    - Electromechanical systems
    - Assembly processes

Strongly Preferred Qualifications

- Experience at leading MedTech or Hi-Tech companies such as: Insulet, Medtronic, BD, Anduril, SpaceX, Tesla, etc.
- Experience with:
    - Auto-injectors or wearable injectors
    - High-volume disposable + reusable systems
    - ISO 13485, ISO 11608, IEC 60601

Leadership

- Strong operator with bias for action and leading from the front
- Hands-on but strategic
- Comfortable with ambiguity and fast-paced environments
- Able to challenge engineering constructively
- Excellent cross-functional and interdisciplinary communicator

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.

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.