

SUSHAN D. SHEREGAR

Boston, MA | sushan.sheregar2@gmail.com | sushansheregar.com

SENIOR PROCESS DEVELOPMENT ENGINEER

Process Development / Manufacturing Engineer with 6+ years of experience driving the design, validation, and scale-up of electro-mechanical and robotic systems, including first-of-its-kind technologies across biotech, medical device, and advanced manufacturing sectors. Proven expertise in low- and high-volume manufacturing, cleanroom operations (Grade A / ISO 5), equipment design, process optimization, and cross-functional collaboration in regulated environments.

KEY SKILLS

Project & Program Management: PMP | Smartsheet | MS Project | PowerBI | A3 | DMAIC | Lean | Six Sigma

Automation & Digital Tools: MES | Epson RC+ | Tableau | Minitab | JMP | SolidWorks | PLM | IBM Maximo

Cross-Functional Leadership: Stakeholder communication | Risk Management | Regulatory Compliance

EXPERIENCE

New Product Implementation Engineer, Boston, MA/Providence, RI

Vertex Pharmaceuticals

November 2024-August 2025

Led design and development of a first-of-its-kind biologics dispensing equipment system for implantable medical devices.

- Reduced projected encapsulation cycle time by 60% through automation, ergonomic layout, and sensor integration.
- Authored URS, FMEA, FRS, and validation protocols for GMP-compliant deployment (IQ, OQ, PQ, AVS, APS)
- Managed \$500k+ CAPEX projects with automation engineers, R&D, vendors to fabricate equipment for commercialization
- Created MES-integrated workflows to capture performance data and enable tech transfer readiness.

Process Development Engineer, Providence, RI

Vertex Pharmaceuticals

August 2021-November 2024

Led process development and introduction of cleanroom lab spaces for a novel medical device to cure type 1 diabetes.

- Led tech transfer from R&D to operations for a first-of-its-kind combination drug-device through IND submission.
- Developed and validated robotic dispensing, heat staking, laser ablation, polymer coating, packaging processes
- Boosted RTY from 1% to 20% by material characterization, refining process parameters, and inspection automation.
- Authored 50+ GMP documents and led closure of Deviations and CAPAs to support compliant cleanroom operations.
- Led process transfer from pilot lab to production floor, qualifying the full device manufacturing process through PQ and optimizing floor layout for scale-up readiness.

Manufacturing Engineer- Cell Lead, Acton, MA

Insulet Corporation

February 2020-August 2021

(Co-Op) January 2019 - August 2019

Led implementation and continuous improvement of assembly lines of a wearable medical device to treat type 1 diabetes.

- Improved efficiency by 70% across the first U.S.-based automated robotic assembly lines, increasing \$204M in revenue.
- Managed 24/7 operations on 12 complex injection molding and laser equipment producing high-volume drug-delivery devices and led process characterization using Minitab and JMP.
- Led lean initiatives and scrum cadences, delivering key KPIs across cross-functional teams.
- Led a team of 5 interns to support SAT, FAT, IQ, OQ, PQ, and TMV activities, while optimizing DMR and BOM workflows and developing the PLM architecture.
- Validated assembly lines at multiple global sites, and performed process capabilities (PpK, CpK, GRR, SPC).

EDUCATION

Certificate in Strategic Management

Harvard Extension School | Cambridge, MA

Jan 2018-Dec 2020

MS in Industrial Engineering, Certificate in Supply Chain Management

Northeastern University | Boston, MA

Sep 2017-Dec 2019

BS in Aerospace Engineering

Florida Institute of Technology | Melbourne, FL

Jan 2014-May 2017