https://www.biolink360.com/job/senior-product-development-engineer-drug-delivery/

Senior Product Development Engineer

Hiring organization
BioLink 360

Employment Type
Full-time

Industry
Medical Device/Pharma

Job Location
Boston, MA
Remote work possible

Date posted
October 1, 2022

Description

Position: Senior Product Development Engineer

Reports to: VP Product Development

Location: Boston, MA (hybrid role)

Salary Range: 130-160K plus benefits and equity

Focus for this role will be on product design, development, and design for high volume manufacturability. This company is on the cusp of bringing novel technology which will revolutionize drug delivery. The person hired for this role will be the Lead Engineer, reporting to a VP. As the product is commercialized, this person would potentially build out a department, and expand teams as new indications are approved. This Engineer will be instrumental in the company's success, and be visible with all company Executives. Someone who can work hands on to execute in the moment and think strategically for the company scaling.

Responsibilities

- Support product development in support of pre-clinical and clinical studies.
- Generate all required documents to support device related components of design control requirements (21 CFR 820, ISO 13485 ISO 14971) and regulatory requirements for combination products (21 CFR Part 4).
- Develop test methods, generate and maintain design specification, write protocols & reports, lead prototype generation, design verifications & validations, conduct FMEA's, etc. in line with ISO 14971 Risk Management.
- Lead the selection and management of outside vendors which include external consultants with specialties spanning Human Factors, Industrial Design, Packaging, Manufacturing, Engineering, Biocompatibility, Quality, and Regulatory.
- Mentor junior team members in the drug-device combination process.

Qualifications

- BS in Mechanical or Biomedical Engineering and strong background in life science product development.
- 5+ years of direct experience leading product development of medical devices, ideally drug-device combination products.
- Understanding of material & test specs generation, protocol & report writing, process & test development, prototyping, design verification, DOE/SPC process optimization & validation (IQ, OQ, PQ), FMEA.
- Experience in the development of regulated medical devices or combination products under Design Control (21 CFR 820 / ISO 13485) and ISO 14971.