Title: Sr. Manager/Associate Director, Device Development
Hiring Manager: Vice President, Technical Operations
Function: Technical Operations
Location: Waltham, MA

Position Summary:

The Sr. Manager/Associate Director, Device Development position will serve as the project's technical lead across internal and external device development efforts leading to clinical and commercial regulatory submissions and subsequent commercial product release. The ideal candidate will be a hands-on and multi-disciplinary technical leader with a strong background in engineering biologic drug delivery systems. The candidate will provide engineering leadership in all phases of drug-device combination product development while working with internal and external stakeholders.

The successful candidate will report to the VP, Head of Technical Operations, and will be responsible for the following:

Key Responsibilities:

- Provide technical leadership to cross functional internal and external development teams through clinical combination product development, product registration and commercialization.
- Establish strong collaborative relationships and demonstrate ability to influence internal teams and external design and development partners, suppliers, and contract manufacturing service providers.
- Use technical expertise and engineering rigor to lead all technical project execution activities and assume overall ownership of the design and development process including but not limited to product requirements, design and development documentation, combination product test methods, deviation investigation & root cause analysis, design verification and validation (V&V) strategy and execution.
- Support the optimization of design and development process while maintaining compliance to all relevant regulatory requirements and international standards.
- Provide oversight to all suppliers, vendors, and contract manufacturing organizations supporting the design and development process of the combination product.
- Provide strategic technical input into the regulatory, clinical, and commercial program decisions.

- Lead and maintain the combination product risk management process inclusive of leading risk assessments, and identification & implementation of risk control measures with the cross-functional team.
- Collaborate closely with the drug product and formulation team throughout the design and development process to ensure development of safe and effective product.
- Work with project and program managers to formulate and maintain the project plan and schedule to meet all business and regulatory milestones.
- Stay current with industry trends, new technologies, and regulatory changes related to combination products.

Qualifications:

- Bachelor's degree in engineering with a minimum of 11 years of experience in FDA Class II or Class III medical devices (or) a master's in engineering with a minimum of 7 years of experience in FDA Class II or III medical devices.
- A minimum of 7 years of experience in developing drug delivery and combination products such as pre-filled syringes, auto-injectors or on-body devices for biologics
- Proficiency in working with drug development and manufacturing teams to ensure smooth interactions at the transition points.
- Proficient in managing external stakeholders and vendors.
- Extensive working knowledge and application of 21 CFR 820/Part 4, EU MDR, ISO 14971, ISO-13485, ISO 11040 and ISO-11608 series and other standards as well as drug cGMPs as they relate to the design and manufacture of medical devices and combination products.
- Experience with device development methodologies, including Design Control, Risk Management, and Usability Testing
- Must be able to communicate and collaborate effectively at all levels, both verbally and in writing.
- Must be able to work with ambiguity and use good judgement in making decisions.

Desired Qualifications:

- Experience in statistical analysis packages (Stat Ease, Minitab) preferred.
- Experience with regulatory submissions and meeting support.
- Experience in Biologics and Biotechnology
- Knowledge of adjacent functions such as Human Factors Engineering

- Knowledge of the latest development in the industry and provide key input into new device technology development.

About Upstream Bio:

Upstream Bio is a public company based in Waltham, MA. We are developing verekitug, the only known antagonist currently in development that targets the receptor for Thymic Stromal Lymphopoietin (TSLP). We have advanced this highly potent monoclonal antibody into separate Phase 2 trials for the treatment of severe asthma and chronic rhinosinusitis with nasal polyps (CRSwNP) and plan to initiate development in chronic obstructive pulmonary disease (COPD). Our experienced team is committed to maximizing verekitug's unique attributes to address the substantial unmet needs for patients underserved by today's standard of care. Learn more about us at upstreambio.com.

Interested candidates, please contact:
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