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| **Position Title:** | Senior Manager/Associate Director, Device Development |
| **Department:** | Drug Product and Device Development |
| **Hiring Manager:** | Eva Williams |

**Our vision is a world where science, passion, and compassion create better todays and more tomorrows.**

**Overview of Role:**

Astria Therapeutics is seeking a highly motivated and innovative device development Sr. Manager/Associate Director to join our growing team. This role will provide oversight for combination product development with a keen focus on device development, including characterization testing, human factors/usability engineering, design verification, design validation, and will play a key role in advancing CMC strategy for Astria’s pipeline. The candidate will report to the Head of Drug Product and Device Development, and work closely with key internal and external stakeholders to revolutionize drug development and enhance patient lives through innovative dosage and drug delivery systems.

**Responsibilities:**

* Technical lead responsible for combination product development from early stages of device selection through design validation. Responsible for all aspects of Design Control including Design Inputs, Design Verification, Design Validation, Risk Management and Human Factors Engineering.
* Apply sound and functional knowledge of applicable guidance, regulations, standards, and industry best practices to medical devices and combination product design and development process.
* Provide technical expertise and lead efforts to evaluate suitable device technologies by conducting exploratory research to gather user insights and design trends. Translate user needs into product and system level requirements and specifications.
* Provide use-safety engineering and usability risk management expertise throughout product development in accordance with internal processes and external standards.
* Develop and maintain Design and Development Plan, Design History File, Traceability Matrix, and actively drive/participate in Design Reviews, Design Control Boards, and Design Change controls.
* Onboard and manage Human Factors, User Research and Visual Design vendors and Develop Usability Engineering files in compliance with IEC and ISO standards.
* Design and execute Human Factors studies to evaluate product user interface- including hardware, software, packaging, instructional material, and training.
* Apply sound understanding of combination product regulatory requirements to compile CMC sections for IND/IMPD/BLA.
* Drive program execution excellence while ensuring efficient and timely escalation of urgent issues/risks to leadership.

**Qualifications:**

* Advanced degree (MEng, MS, PhD) in Chemical, Mechanical, Electrical or Biomedical Engineering, or other related technical discipline from an accredited institution with 7+ years of relevant industrial experience in device integration and development, combination product development, drug product development with a major pharmaceutical, biotechnological or a generic pharmaceutical company.
* A demonstrated level of combination product development experience, including pre-filled syringes, pre-filled cartridges, auto injectors, on-body devices and/novel devices for delivery of complex formulations.
* Understanding of system thinking (drug+ primary container+ device+ software/app) and experience with human factors/ usability engineering.
* Experience with the development of connected devices is preferable.
* Experience of working within device regulatory requirements and industry processes such as design controls (21CFR820.30) EU MDR 2017/745, risk management (ISO 14971), QMS (ISO 13485) and related requirements ISO 11608, ISO 11040, ISO 3951 and ISO 2859.
* Experience with IND/IMPD/BLA filings and Design History files for combination products are required.
* Excellent written and verbal communication skills. Team-oriented, progressive thinker with a can-do attitude who enjoys participating in an innovative and creative work environment.