

CONTINUUS Pharmaceuticals Job Posting

COMPANY

CONTINUUS Pharmaceuticals, Inc.

LOCATION

25-R Olympia Avenue
Woburn, MA
(20 minutes north of Boston)

EMPLOYMENT TYPE

Full Time - U.S.-based

START DATE

ASAP

ABOUT CONTINUUS

CONTINUUS Pharmaceuticals is a spin-out company from the Novartis-MIT Center for Continuous Manufacturing. We design and develop innovative continuous manufacturing processes for pharmaceutical clients, providing an exceptional "one-stop solution" for the entire drug development and manufacturing cycle.

Rather than producing medicines through traditional batch processes, CONTINUUS offers a breakthrough Integrated Continuous Manufacturing (ICM) technology for small molecule drugs. The synthesis of the active pharmaceutical ingredient and final dosage form are integrated into a seamless and completely automated process. This novel method will allow "on-demand" manufacturing of pharmaceuticals with significant advantages in production lead time, quality, and cost.

Our pipeline is rapidly growing, with exciting projects with pharmaceutical and generic companies, as well as contracts with the US Government. Concurrently, we are transitioning to a commercial phase, where we will leverage our novel ICM platform to produce low-cost, high-quality drugs for patients worldwide. Essential to our evolution will be talented new team members who will contribute greatly to this mission. We look forward to meeting you.

<http://continuuspharma.com>

CONTACT US @

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Head of Pharmaceutical Development – Drug Product

Job Description

The Head of Drug Product Development will be responsible for drug product related activities across the CONTINUUS Pharmaceuticals portfolio including formulation development **and drug product manufacturing** from early phase development through commercial launch. This position will collaborate with members of the **Leadership team, Development team, CMC team**, Quality Assurance and Regulatory Affairs to develop and implement drug product manufacturing and regulatory strategies for CONTINUUS Pharmaceuticals drug product candidates. The Head of Drug Product Development will be well-versed in formulation technologies, formulation development, as well as **Regulatory and cGMP requirements and expectations**, to navigate the development of **sterile injectables and oral solid dosage forms**.

Position Requirements

May include some or all of the following:

- **Management:** Build, recruit and retain a world class Drug Product Development team. Direct and manage the day-to-day activities associated with the development of sterile injectable and OSD drug product candidates.
- **Drug Product Formulation Development:** Direct formulation development activities and lead the drug product team in the CONTINUUS **pharmaceuticals aseptic and OSD** drug product laboratories.
- **Drug Product Analytical Methods and Specifications:** Collaborate with the Analytical Development team to develop methods and establish phase appropriate specifications for drug products.
- **Drug Product Technology Transfer:** Accountable for the development and implementation strategy of the technology transfer of drug product candidates from the lab/pilot plant scale to the commercial manufacturing scale.
- **Drug Product Manufacture:** Participate In the design and implementation of the CONTINUUS Pharmaceuticals ICM (Integrated Continuous Manufacturing) Factory with focus on the **sterile injectable vial filling** operation and **OSD** production area.
- **Regulatory Support:** Author, review and finalize drug product documents for NDA/ANDA submissions, as well as annual reports. Maintain a current knowledge of **CMC regulations** and guidance.

Preferred Qualifications

- 10+ years of relevant industry experience, with experience in a drug product development function including sterile vials and OSD.
- MS or PhD in Pharmaceuticals, Pharmaceutical Chemistry or equivalent.
- Develops and maintains constructive relations with key internal and external colleagues.
- Evaluates change proposals for global regulatory impact and plans global variations and amendments.
- Ability to create cohesive teams and maximize people development opportunities within the organization.
- Ability to be an effective and impactful player in complex and evolving projects and to communicate effectively with senior leaders.
- Proven decision-making abilities.

- Comfortable in a hands-on environment
- Good interpersonal skills plus the ability to work in a diverse working community
- Excellent written and verbal communication skills
- Ability to work independently and as part of a team in a fast-paced environment
- Demonstrated ability to juggle multiple competing tasks and demands
- Strong attention to detail

We are an Equal Opportunity Employer - all qualified applicants will receive consideration without regard to race; color; religion; sexual orientation or transgender status; gender identity or expression; pregnancy or related medical conditions; workplace hazards to reproductive systems; national origin and ancestry; age; veteran status; current physical or mental disability or history of; intellectual or learning disability; genetic information; homelessness status; sexual harassment; marital or civil union status; lawful activity outside of the workplace such as tobacco use; or any other characteristic protected by law.