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 CMC Development

Job Description

CONTINUUS is looking to hire a full-time Head of Chemistry, Manufacturing and Control (CMC), who will work as part of a dynamic team in the design, development, and implementation of novel approaches in the development and commercialization of API and Drug Products (Oral solid and sterile injectables)

Roles and responsibilities

The ideal candidate must establish, manage and lead the CMC development team for drug substances and drug products from early phase **through commercial development**. This entails:

- Working with select third-party manufacturers working with Quality and Regulatory teams, negotiate effective supply/technical agreements. Identify contract analytical laboratory sites required to guide and support third party manufacturing relationships
- Direct/oversee **contract manufacturing, testing, packaging** and **labeling operations for the company's drug substances** and **drug products.** Act as primary liaison with contractor(s) on assigned projects.
- Participate in product development project team leadership as the CMC functional area representative
- Working with **Quality Control**, develop **SOP**'s and internal guidelines related to the production, disposition and management.
- Work with Regulatory, Quality Control and Senior Management to ensure that all company policies are adhered to, and all external manufacturing activities comply with relevant regulations
- Design and execute the development plan to support global submissions of **DMF** and **ANDA**
- Prepare, in collaboration with functional area experts, **CMC regulatory filing sections** (domestic and international)
- Working with head of manufacturing and quality, develop production plans to support commercial **development** and adjust plans as appropriate to meet regulatory and **cGMP** requirement and corporate objectives
- Provides comprehensive **project analysis** to senior management, as required, in the form of reports or presentations as needed

Required Qualifications

- BS/MS or PhD in a Chemistry, Biology or Chemical Engineering. Advanced graduate degree (MS or PHD are preferred)
- Industry experience of 5 years or more in relevant CMC expertise in one or more area including analytical, chemical process development, drug product development or manufacturing technology
- Documented evidence of prior successful CMC project leadership from early phase, late phase leading to commercialization and regulatory approval.
- A minimum of 5 years of experience in CMC project management, development, scale-up and **clinical/commercial development** and manufacturing in the biotechnology or pharmaceutical industry
- Experience in leading and direct management of research, analytical laboratories, process development, and manufacturing
- Documented experience in achieving regulatory approval of new drugs, generic drugs, or biologicals
- Good understanding of **cGMP** and **FDA** regulations and guidelines relating to CMC-related areas

	• Knowledge of global CMC-related regulatory requirements and guidelines • Excellent leadership, managerial and communications skills in a cross-functional environment *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.*