# 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

#### Q4 2021

#### ABOUT CONTINUU

CONTINUUS Pharmaceuticals is a spinout company from the Novartis-MIT Center for Continuous Manufacturing. We design and develop innovative continuous manufacturing processes for pharmaceutical clients, providing an exceptional "one-shop 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 @

smascia@continuuspharma.com

btakizawa@continuuspharma.com

## **Project Engineer**

## **Job Description**

CONTINUUS is looking to hire a full-time Project Engineer to join our Engineering Group. This engineer will play a key role on engineering initiatives spanning both our lab and cGMP manufacturing facility. They will provide a strong blend of leadership, technical expertise, and project management across multiple engineering projects to deliver on cost, time schedule, quality, and functionality.

## **Overview**

- Determine the needs and expectations of a given project and determine a project plan including but not limited to: requirements definition, concept development, detailed engineering, procurement, installation, and CQV.
- Plan and coordinate multiple projects working with stakeholders at all levels, with direct responsibility for budgeting, schedule, personnel, and project planning.
- Liaising with contractors, suppliers, and internal company stakeholders to meet project objectives.
- Risk identification and mitigation to ensure the engineering project remains on track to a successful completion.
- Design and implement engineering controls to ensure laboratory and plant safety (e.g., hazardous material handling, electrical classifications) across a diverse array of settings and processes.
- Draft and implement operational and safety procedures.
- Commissioning and gualification responsibilities.
- Support our capital projects engineering function.
- Provide recurring project updates.

## **Required Qualifications**

- A minimum of 10 years working within the pharmaceutical industry in technical and project management roles.
- Proven project management skills in contract management and project controlling.
- A strong blend between technical competency as related to pharmaceutical production processes and project management experience.
- Strong understanding of the different production processes (e.g., reactions, crystallizations, filtration, drying, clean-in-place, steam-in-place, etc.) and utilities (e.g., WFI, instrument/process air, etc.) involved in pharmaceutical production plants.
- Experience with manufacturing operations management.
- Experience in creating design documents, drafting user requirement specifications, technically evaluating bids, reviewing vendor equipment drawings/documentation packages, participating in FAT's and SAT's, etc.
- Experience with developing and executing Commissioning, Equipment Qualification, and Performance Qualification documents.
- Knowledge of process safety and risk analysis.
- Ability to write clear and comprehensive operational procedures and technical reports.
  - Demonstrated ability to motivate teams.

## **Preferred Qualifications**

•

- BS degree or higher in Chemical or Mechanical Engineering. Candidates with a strong background in automation/controls will also be considered.
- Relevant codes and standards (such as ASME boiler and pressure vessel code, ASME BPE, ANSI, ASTM, FDA cGMP, OSHA, relevant portions of NEC/NFPA as applicable, etc.)
- Experience with high potent compound handling is a plus.
  - Experience in both lab, Pilot plant and cGMP manufacturing environments is a plus.

<ul> <li>Microsoft Project or other project management tool.</li> <li>Clear oral and written communication skills.</li> <li>Self-motivated and organized professional looking to assist designs and make an impact in the life science industries.</li> <li>Ability to play a positive role as part of a team with a reliable and consistent approach to work.</li> <li>Professional Engineering license in Massachusetts.</li> </ul>
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.