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

Q3 2021

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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Senior Aseptic Filling Process Engineer

Job Description

CONTINUUS is looking to hire a full-time Senior Downstream Process Engineer to join our Engineering Group. This engineer will lead the downstream sterile solution process, equipment, and facility design efforts. There are several downstream engineering positions open, and the candidate will be placed based on relevant experience and knowledge.

Overview

Lead the downstream process engineering activities for our new **cGMP facility** used to produce small-molecule APIs in different dosage forms (e.g., oral solid dosages, **sterile solutions**). The scope of this position includes sterile solution downstream processing (i.e., **API transport / storage, formulation, sterile filtration, vial filling, terminal sterilization, and automatic visual inspection**).

Required Qualifications

- 8-10 years of engineering experience for a cGMP fill-finish pharmaceutical production setting.
- Experience with the following unit operations as pertaining to the downstream process. These systems include **API transport/storage, formulation, sterile filtration, vial filling, terminal sterilization, and automatic visual inspection.** Experience with every unit operation is not required, but the ability to quickly understand and build a working knowledge of a new unit operation is a requirement.
- Experience in the design of **aseptic processing** equipment and facilities with a strong understanding of **sterilization concepts and methods** is required.
- Experience and strong understanding of **cGMP facility** requirements especially those related to producing **sterile solutions** (ISO room classifications, environmental monitoring, material / personnel flows, water-for-injection, high quality air systems, HVAC with HEPA filtration, mold identification and mitigation, clean-in-place, steam-in-place, etc.).
- Excellent understanding of fundamental engineering principles and the engineering life cycle related to **process design** through implementation (e.g., **installation, validation, change control,** and **process improvement**).
- 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.
- Ability to carry out detailed engineering activities, including but not limited to the following:
    - Engaging in plant-wide risk assessments (e.g., PHA)
    - Preparation of process calculations
    - **Drafting and review of BFDs, PFDs, P&IDs, layouts, etc.**
- Experience with developing and/or executing Commissioning, Equipment Qualification, and Performance Qualification documents.
- Experienced in start-up of critical process utilities such as WFI.
- Thorough understanding of Statistical Process Control & Process Capability CpK.

Preferred Qualifications

- Bachelor's or higher in Chemical, Mechanical, or Electrical Engineering.
- Knowledge of continuous processing fundamentals.
- 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.) is a plus.

- Experience with weigh/ dispense, cGMP parts washers, autoclaves, isolator specification and operation, or packaging is a plus.
- Experience with potent powder processing and containment is a plus.
- Clear oral and written communication skills.
- Self-motivated and organized professional looking to lead designs and make an impact in the life science industries.
- Ability to play a positive role as part of a team with a reliable and consistent approach to work.
- Strongly motivated and shows professional initiative.
- Six-Sigma Black Belt certified with Lean Experience.

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.