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 2022

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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Validation Engineer

Job Description

CONTINUUS is looking to hire a full-time Validation Engineer who will work as part of a dynamic team who will perform the following tasks:

- Support the validation program for cGMP facility, utilities and equipment lifecycle activities including commissioning, qualification (IQ/OQ/PQ), and validation in laboratory and commercial manufacturing settings
- Lead/support a team of validation contractors, coordinating CQV activities for design, commissioning, qualification, cleaning, and process validation
- Draft, review, and execute validation documentation including: validation plans, risk assessments, user requirements/design/functional specifications, FATs, CQV protocols, reports, traceability matrix, and standard operating procedures
- Execute commissioning and qualification protocols and deviation resolution
- Utilize the electronic Validation Lifecycle Management System and eQMS
- Provide support for additional quality activities including: site change control, QA assessment for GxP work orders, requalification activities, FDA inspection preparedness team, and manufacturing process improvement.

Required Qualifications

- BS degree in life sciences or related engineering discipline
- A minimum of 5-8 years of direct validation experience within the life sciences industry and cGMP environments
- Effective written and oral communication skills
- Ability to manage multiple projects, create and work within internal timelines, solve problems, deliver on commitments, and utilize interpersonal skills in a cross-functional team
- Exceptional proficiency in Good Documentation Practices (GDP)
- Knowledge of cGMP, 21 CFR 210, 211, and Part 11, and the International Council for Harmonisation (ICH), ASTM E2500, ISPE Baseline Guide Vol. 5 for C&Q, GAMP 5, and United States Pharmacopeia (USP) guidelines

Preferred Qualifications

- MS in life sciences or related engineering discipline, or 8+ years of pharmaceutical experience preferred
- Experience utilizing electronic Validation Lifecycle Management Systems
- Experience with the following utilities: WFI, clean steam, process gases, HVAC
- Experience with the following systems: vial fillers, terminal sterilizers, automated visual inspection, CIP, DeltaV, MES, PLCs, BAS
- Experience with Cleaning Validation and Process Validation
- Experience with health authority audits

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.