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-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 the final dosage form is integrated into a seamless and 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 @

hkandaras@continuuspharma.com

Computer System Validation (CSV) Engineer

CONTINUUS is looking for a highly-motivated CSV Engineer to join our Quality team. The successful candidate will support CSV efforts for enterprise Information Technology (IT) and Operational Technology (OT) systems for our Integrated Continuous Manufacturing (ICM) facility. The CSV Engineer will support and take lead on computer system validation activities while ensuring compliance with policies and procedures.

Key responsibilities:

- An active participant in building a culture of quality.
- Author/Review validation documentation - such as user requirements functional requirements, validation plans, IQ/OQ/PQ documentation, risk assessments, test scripts, trace matrix requirements, deviations, and validation summary reports,
- Lead the development of controlled documentation, processes, and system use documentation (system admin, user admin procedures) for enterprise IT and OT systems.
- Ability to manage various projects, create and work within internal timelines, solve problems, deliver on commitments, and utilize interpersonal skills in a cross-functional team.
- Administer electronic Validation Life Cycle Management system, QMS, and train users.

Minimum qualifications/attributes:

- Three to five years of direct CSV experience in a GxP environment.
- Bachelors or Masters in Computer Science, Life Sciences, or other relevant disciplines.
- Knowledge and a solid understanding of GAMP, cGMP, 21 CFR Part 11, Annex 11, and relevant FDA regulations
- Strong organization skills, professional oral and written communication skills, and attention to detail
- Be a team player in a fast-paced startup environment
- Willingness to learn and take on responsibilities

Preferred qualifications:

- Experience in research and development
- Experience managing direct reports and working with external vendors

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.