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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Lead Process Automation Engineer

Job Description

CONTINUUS is looking to hire a full-time Lead Process Automation Engineer to join our Engineering Group. This engineer will lead the industrial control and automation efforts within the Engineering Group. There are several Process Automation Engineer positions open, and the candidate will be placed based on relevant experience and knowledge.

Overview

Lead the **industrial process controls and automation** 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 providing leadership, automation expertise, and instrumentation support for the design, engineering, construction, and qualification of pharmaceutical projects.

- Lead the development and implementation of integrated process control systems (**DCS, PLC, SCADA**) for novel continuous manufacturing processes for small-molecule pharmaceuticals.
- Coordinate across multiple internal disciplines (e.g., chemical, mechanical) as well as external resources (e.g., vendors, EPC firm, PM groups, etc.) to develop technical/engineering specifications.
- Develop the design and specifications for **historical trending, electronic batch records**, and **remote notification** systems.
- Perform automation related job functions as assigned, including, I/O lists, instrumentation lists and the **specification of instrumentation/valves** and control elements.
- Work collaboratively with stakeholders to understand the needs and requirements of the **HMI screens** and lead implementation efforts.
- Identify, qualify, and collaborate with third party system integrators.
- **Oversee automation integrators** during the build-out of the new facility, **support IQ/OQ endeavors** and participate in systems analysis, validation, and verification. Responsible for validation associated with equipment and software changes.
- Ensures controls and instrumentation maintenance activities are performed to conform to GxP's, SOP's, OSHA, and environmental requirements.
- Expected to be a major contributor in providing continuous process improvements.

Required Qualifications

- 10-12 years in pharmaceutical industry technical operations with specific experience in an industrial real-time controls environment.
- Expertise in the hardware and software in all phases of design, construction, validation, and maintenance of the following automation platforms:
    - **DCS (DeltaV),**
    - **MES (Syncade),**
    - **PLC (Allen-Bradley)**
    - **Historian (OSI PI)**
    - **PAT (synTQ and associated instrumentation)**
- Experience with industrial process control systems including DCS, PLC, and SCADA based systems.
- Knowledge and experience with pharmaceutical **process valves and instrumentation.**
- Expertise in **ISA standards** and the interpretation of **P&IDs**.
- Expertise in cGMP and **GAMP practices** in the life sciences industry.

- Expertise in the review and design of electrical and controls circuit schematics, process instrumentation specifications, electrical and controls installations and **protection techniques in electrically classified spaces** (e.g., I.S., X.P., N.I., X/Y/Z purges, etc.), and industrial control networks / busses.
- Expertise in leading a team of junior engineers, electricians, and instrumentation technicians.
- Experience with the development of control system network architectures.
- 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/or executing Commissioning, Equipment Qualification, and Performance Qualification documents.

Preferred Qualifications

- Bachelor's degree in Engineering - ME/EE/ChemE/Automation/Manufacturing – or equivalent degree.
- Knowledge of **NEC** as it pertains to industrial control systems.
- 10+ years of process engineering experience in a cGMP setting for small-molecule pharmaceutical production with familiarity in both upstream and downstream processes. Experience with aseptic processing is a plus but not required. Knowledge of continuous processing is highly preferred.
- 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.

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.