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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Engineering Knowledge Management

Job Description

CONTINUUS is looking to hire a full-time Engineering Technical Writer to join our Engineering Group. The candidate will work closely with our process, mechanical, and automation engineers to complete our technical documentation requirements and maintain our files/records.

Overview

The technical writer will lead / perform the following activities:

- Work collaboratively within the Engineering Group to generate SOPs, reports, protocols, and design guidelines that meet organizational standards.
- Draft technical documents including but not limited to user requirements specifications, vendor documentation requirements, bid packages, requests for proposal, etc.
- Evaluate our current document repositories and develop innovate approaches for improvement.
- Maintain and update documents based on the needs within the group.
- Facilitate and document Design Reviews which entail cross-checking user requirements / P&IDs with submittals / RFI's.
- Review incoming/outgoing documents for completion, consistency, and scope.
- Compile reports, presentations, and project updates.

Required Qualifications

- 3-5 years of similar experience in a cGMP pharmaceutical production setting.
- Broad understanding of the different process and utility equipment used in the pharmaceutical processing Industry.
- Experience drafting user requirement specifications, functional specifications, data sheets, requests for proposal, and other design documents.
- Ability to review and understand engineering drawings (e.g., BFDs, PFDs, P&IDs, electrical diagrams, plant layouts, GAs, etc.)
- Experience with compiling and reviewing engineering turn over packages.
- Experience with drafting vendor scopes and compiling vendor documentation requirements as related to the pharmaceutical Industry.
- Experience preparing for FDA audits.
- AutoCAD experience.
- Thorough experience with 21CFR guidance documents.
- Experience with Computerized Maintenance management systems.
- Strong knowledge of Microsoft Office (Word, Excel, Power Point, Teams).
- High attention to detail and accuracy.
- Possess basic filing & indexing skills and comfortable in the use of printing and scanning.
- Proven ability to work independently and flexibility to shift priorities in urgent situations.
- Proven ability to quickly learn and understand complex topics.
- Superior written and verbal communication skills, with a keen eye for detail.

Preferred Qualifications

- Bachelor's degree in a relevant technical field (e.g., chemical, mechanical, or electrical engineering).
- Experience with Bluebeam Revu 20 is a plus.

	• A team player with excellent interpersonal/communication skills and advanced computer literacy. ***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.***