

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-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 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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Documentation Specialist

Job Description

CONTINUUS is looking to hire a full-time Documentation Specialist to assist us in controlling our quality documents. Responsibilities include:

- Procedure, protocol, report, and executable document Initiation during the drug development and manufacturing lifecycle. Tasks include, but are not limited to, formatting, editing, publishing, scanning, and operational and system-related tasks
- Documentation process support through both a hardcopy workflow and utilizing an electronic document management system (eDMS)
- Processing controlled documentation - assignment of numbering, review, formatting, editing, scanning, and filing
- Coordinate LMS assignment, completion, and reporting to ensure training compliance
- Support implementation and process improvement initiatives of document control system workflows
- Organize, file, and archive documentation throughout record management lifecycle
- Maintain organization compliance with Good Documentation Practices (GDP)

Required Qualifications

- A minimum of 1-2 years working within the pharmaceutical or medical device industries
- A team player with excellent interpersonal/communication skills and advanced computer literacy
- Strong knowledge of Microsoft Office (Word, Excel, Power Point, Teams)
- Adept at formatting and the use of styles in Word
- Experience working in a regulated environment
- Ability to consistently meet deadlines
- Profound time management skills and ability to work on several documents at the same time, high attention to detail and accuracy
- Proven ability to work independently, effectively handle multiple projects, and flexibility to shift priorities in urgent situations

Preferred Qualifications

- Experience with electronic document and learning management systems
- Knowledge of cGMP, 21 CFR 210, 211, and Part 11, and the International Council for Harmonisation (ICH) and United States Pharmacopeia (USP) guidelines

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.