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

QA Vendor Management Specialist

Job Description

CONTINUUS is looking to hire QA Vendor Management Specialist to assist us in the Supplier Management and Supplier Auditing process. Responsibilities include:

- **Plan, conduct, review** and **report supplier site** and **questionnaire audits** including third-party and **outsourced audits** for new and existing domestic and international suppliers in line with internal policies and procedures.
- Complete and assist in completion of **Supplier Quality Agreements,** Supplier Audits (questionnaire and site), Risk Assessments, Risk Control Plans, License Review, Supplier Initiated Changes (SICs), Supplier Qualification, Supplier Complaints and Follow-up's.
- Quality management of supplier related activities including but not limited to, material qualification for **GxP** use, **changes to existing materials, Parts or Services procured.**
- Ensure supplier records are current for all approved suppliers including audits, questionnaires, assessments, supplier change controls and quality agreements.
- Manage **supplier complaints** and liaise with **suppliers** to resolve supplier quality issues.
- Work with suppliers to ensure compliance with regulatory changes or updates and maintenance of valid licenses.
- Monitor **supplier license renewal** for applicable services and perform expansion of service and new supplier requests.
- Perform impact assessments and execute action plans for supplier change notifications (i.e., facility change, supplier change controls).
- Negotiate supplier quality agreements and perform amendments to quality agreements if required.
- Review and approve **investigations/corrections** performed by a supplier.
- May assist in preparing for and hosting of **regulatory inspections/audits.**

Required Qualifications

- BS degree in life sciences or related engineering discipline
- A minimum of 5-7 years working within the **pharmaceutical** or **medical device industries**
- Experience with statistical and **six sigma methods**, risk management tools, internal and external auditing
- Effective written and oral communication skills at individual, team, and organizational levels
- Experience working on cross-functional teams and managing relationships in collaborative, constructive manner with internal departments and international vendors and partners
- Ability to handle multiple priorities within rapid timelines to meet project team goals
- Proficiency in Good Documentation Practices (GDP)
- Experience using Microsoft Office Suite and MasterControl is plus
- Mastery of **cGMP, 21 CFR 210, 211, and Part 11,** and the International Council for Harmonization (ICH) and United States Pharmacopeia (USP) guidelines

Preferred Qualifications

- MS in life sciences or related engineering discipline and 5+ years of pharmaceutical experience preferred

CONTACT US @ Harry Kandaras hkandaras@continuuspharma.com	• American Society for Quality certifications (e.g., **CQA**, **CQE,** etc.) or other related accredited institutional certifications • Experience **designing** and implementing a **quality metrics** dashboard • 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.*