QMS Document Control Specialist (FDA regulated QMS)
Location: Rockville, MD [will consider hybrid, 50% time minimum on-site]
Type: Temp/ Temp to perm

On Demand Pharmaceuticals (ODP) (www.ondemandpharma.com) is changing the way we make and distribute medicines—by providing them to anyone, anywhere, anytime. ODP is creating innovative manufacturing platforms to enable our vision to produce critical medicines at the point of care and to secure the pharmaceutical supply chain. As a young organization, ODP offers an exciting opportunity for passionate team members to make a difference in the world while developing career paths for advancement. ODP is seeking a QMS Document Control Specialist to support the team.

Responsibilities:

- Serve as system/application super user and administrator for QMS Document Control process area
    - Perform Document/Records Control program planning and management, program assessment, prepare written materials, identify and resolve problems.
    - Manage the routing, review, approval, distribution and archival of new and revised standard operating procedures (SOPs), manufacturing batch records, Quality Control test methods/specifications and other related controlled documents in the QMS to support Operations and Quality departments
    - Work directly with Operations, Manufacturing, GMP Engineering, QC, R & D and QA to process, revise, issue, track, and archive GXP controlled documents in the electronic QMS.
    - Oversee and manage all controlled document training and the Quality System Training records
    - Maintain documentation for licenses and certifications
    - Support and maintain all Quality System documentation within the QMS for GMP compliance.
    - Review documentation for compliance to Document Controls process requirements. As assigned, interface with stakeholders to develop, redline, maintain required documentation

Minimum hiring standards:

- 2-3 years' experience with FDA-regulated QMS document controls
- Experience with electronic document management systems

Preferred hiring standards:

- Experience with Qualio
- 2-3 years' experience as Quality Engineer in FDA regulated environment
- Experience in front-room of FDA inspection or Notified Body audit

COVID-19 Vaccination Policy: With limited exceptions, up to date COVID-19 vaccinations are required for all ODP employees who work on-site at our headquarters. Employees must present proof of full vaccination (ex. CDC card) or submit exemption requests to the Director of People Operations before their start date. Exceptions to the policy are available only for those who need an accommodation for a qualifying medical reason or sincerely held religious belief or practice.

Please click here to submit an application for this position.

On Demand Pharmaceuticals is an equal opportunity employer. On Demand Pharmaceuticals does not discriminate in employment with regard to race, color, religion, national origin, citizenship status, ancestry, age, sex, sexual orientation, marital status, physical or mental disability, military status or unfavorable discharge from military service or any other characteristic protected by law.