



Systems Engineer

Location: Rockville, MD [100% on-site]

Type: Full-Time

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 pharmaceuticals supply chain. As a young organization, ODP offers an exciting opportunity for passionate scientists and engineers to make a difference in the world while developing career paths for advancement. ODP is seeking a Systems Engineer to support the development of our next generation medicine manufacturing platforms.

Responsibilities:

- Using Design Controls to facilitate the design and development of next-generation (portable, distributable and end-to-end continuous process) pharmaceutical manufacturing system, for drug substance and drug product.
- Lead Risk Management within Engineering function, interfacing with stakeholder from other functions, i.e. analytical development, formulation development, manufacturing, GMP Ops and QARA.
- Conduct Requirements Identification, Development and Analysis:
 - Capture User Requirements via Use Case Development and Activity Modeling,
 - Translate business objectives into system level requirements
 - Facilitate analysis and trade-off studies to balance requirements against technical and cost feasibility
- Conduct Requirements Management:
 - Manage the evolution of requirements through baselines and requirements traceability matrixes (RTM)
 - Working with cross-functional teams, develop and publish specifications
 - Facilitate Functional Analysis, including translating user needs from chemical or formulation processes (process parameters) into system requirements
 - Support development of test plans and verification procedures
 - Model activities, sequences/ interactions, and system/operational states to capture & analyze requirements

Minimum Hiring Standards:

- Bachelor's degree in engineering, mathematics, or another STEM major
- 5 to 10 years of related systems engineering experience
- Experience in medical device or pharmaceutical industry
- Hands on experience with Design Controls, ISO 13485 and Risk Management, ISO 14971
- Experience in DFMEA/FMEA, Six Sigma, and Risk Management
- Experience in Requirements Management Software, Jama Connect preferred
- Experience with medical device or pharmaceuticals manufacturing development
- Experience in project management
- Strong management and interpersonal skills
- Ability to work collaboratively with multi-disciplinary cross-functional research teams
- Strong written/oral skills required, and ability to communicate technical concepts to a non-technical audience
- Energy and passion to thrive in a start-up environment and to deliver on the mission of On Demand Pharmaceuticals



COVID-19 Vaccination Policy: With limited exceptions, 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 within two weeks of new employment. 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 (including pregnancy, gender identity, or related medical conditions), sexual orientation, marital status, physical or mental disability, past or present military service or any other characteristic protected by law