



## **Computer System Validation (CSV) Engineer**

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

**Type:** Full Time

On Demand Pharmaceuticals (ODP) ([www.ondemandpharma.com](http://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 Computer System Validation Engineer to support the team.

The Computer System Validation Engineer will report directly to the Validation Manager, and work across teams, including Operations and Quality, to help ensure that direct impact computerized systems are qualified and maintained in a qualified state. The engineer will also lead the effort to commission no impact computerized systems as needed.

### **Duties/Responsibilities**

- Participate in development of User Requirements, Installation, Operational, and Performance Qualification Protocols
- Execute IQ/OQ/PQ protocols
- Knowledge of Good Documentation Practices
- Knowledge of the equipment delivery standards such as 21 CFR Part 11 Compliance, Data Integrity, and ASTM2500
- Assist in the writing of Standard Operating Procedures (SOPs)
- Support third-party qualification and commissioning efforts
- Contribute to System Classification and System Risk Assessment activities
- Lead efforts for Periodic Review of Qualified Equipment
- Support the creation and execution of Change Controls and CAPAs
- Systems include:
  - IT Infrastructure
  - GMP Network
  - Custom-developed LabView applications
  - Programmable Logic Controllers (PLCs)
  - Human Machine Interface (HMI) for filler, Building Management System (BMS), Environmental Monitoring System (EMS)
  - Enterprise Software such as a Computerized Maintenance Management system (CMMS), Quality Management System (QMS), and an electronic Validation platform (Kneat)

### **Required Skills/Abilities:**

- A “Can do” problem solving attitude and approach.
- Effective communication skills and an ability to work efficiently across multi-disciplinary teams to help achieve organizational objectives
- Excellent analytical and problem-solving skills.
- Excellent written and verbal communication skills.
- Excellent organizational skills and attention to detail.
- Adept at navigating and building strong and professional relationships with all ODP personnel and partners.



- Sets an example by modeling the required behaviors and holding other employees and peers accountable for their actions by identifying and acting on behavior which is inconsistent with company and safety standards.
- Able to multitask and adapt quickly to new requests and needs.
- Contributes to a work environment where performance management, continuous quality improvements in service and professional practice are pursued.

**Preferred Skills/Abilities:**

- Computer System Validation experience within the medical device, laboratory, or pharmaceutical industries
- Good understanding and application of Current GMPs, regulatory requirements, and Good Engineering Practices.
- Excellent communication / interpersonal skills
- Be a motivator and leader within the team
- Attention to detail

**Education and Experience:**

- Bachelor's degree in science/engineering/computer systems as a minimum.
- At least 5 years of experience in delivering validation projects

**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.