



## **Validation Manager**

**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 Validation Manager to support the team.

The Validation Manager will report directly to the Director of GMP Engineering, and work directly across teams, including Operations and Quality, to help ensure that equipment, computerized systems, and processes are qualified and turned over in a timely and compliant manner. The Validation Manager is responsible for the Validation and coordination of operation of machinery and process within the plant. This may be IT systems, various pieces of machinery or Cleaning processes.

### **Responsibilities**

- Manage all operational validation activities within the client's organization, including sub-contractor management.
- Develop and implement a compliant validation strategy for our team.
- Support the development of an efficient compliant and cost-effective calibration, maintenance, and spare parts program.
- Support Commissioning activities as they lead to equipment qualifications
- Support Development Engineers and Equipment Vendors in developing Turn Over Packages
- Work closely with all functional departments to ensure the turnover and continued maintenance of a validated environment according to cGMP and other regulatory requirements
- Be capable of delivering high-level reporting to ODP directors and other leadership.
- Manage the process for the creation of documentation and requirements to include but not limited to the following:
  - Computer Systems Validation Plans
  - Equipment Validation Plans
  - Cleaning Validation Plans
  - Utility/Facility Validation Plans
  - Environmental Monitoring Validation Plans
  - Quality Control Validation Plans
  - Cleaning Validation Plans
- Scheduling, planning, and review of validation activities.
- Manage all facets of assigned validation projects while maintaining strong communication with ODP stakeholders.



**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:**

- Validation Management experience within the laboratory, or pharmaceutical industries
- Good understanding and application of Current GMPs and regulatory requirements.
- Experience in a wide range of validations including Computer Systems Validation, equipment, cleaning, laboratory, and utility and facilities validation plans.
- Excellent communication / interpersonal skills
- Previously have managed or supervised a team of experienced engineers in a similar industry.
- Be a motivator and leader for such a team.
- Attention to detail.

**Education and Experience:**

- Bachelor’s degree in science/engineering/computer as a minimum.
- At least 5 years of experience in delivering validation projects and leading/directing validation project teams

[Please click here to submit an application for this position.](#)

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