

## Validation Specialist

### Essential Duties and Responsibilities

- Develop and maintain the cleaning validation program for a GMP multi-product manufacturing facility including CIP, SIP, dishwasher and autoclave validation, and validation of manual cleaning processes.
- Author validation plans, procedures, protocols and reports. Interact with manufacturing and technical services/engineering departments to facilitate protocol execution as necessary.
- Maintains validation requirements, practices, and procedures to current GMP/FDA standards.
- Effectively communicate the workload and required resources to management to maintain the validation schedule.
- Support the change control system through the generation of validation assessments.
- Support method validation and facility expansion projects on an as-required basis.
- May be required to contribute to or perform IQ/OQ studies on an as-required basis.

### Qualifications

Requires ability to plan, prioritize and organize diversified workload. Must have excellent technical writing, verbal communication skills and attention to detail. Will be expected to provide validation expertise and contribute to multi-department initiatives.

Project management experience with facilities upgrades and major construction projects is desired.

### Education and/or Experience

BS in a scientific discipline and a minimum of 3-5 years related experience in the biotechnology industry, with working knowledge of cGMP. Preference will be given to candidates with multiproduct cleaning validation experience.

Qualified candidates should send resume and cover letter to:

Human Resources  
Insmmed Therapeutic Proteins  
2590 Central Ave.  
Boulder, CO 80301  
[careers@insmed.com](mailto:careers@insmed.com)