



# MedImmune

**Title:** Validation Engineer III  
**FLSA:** Exempt  
**SIRS Code:** T434-3B

## **Performance Requirements**

### **Essential Job Functions:**

- A. Write validation protocols and reports
- B. Perform validation activities described in validation protocols including thermal studies, cleaning, process, equipment and utilities validation
- C. Maintains an up-to-date knowledge of validation requirements, practices and procedures
- D. Works with validation and metrology contractors when required
- E. Interacts with manufacturing sciences and facilities / engineering departments to facilitate protocol execution as necessary
- F. Good technical writing skills
- G. Able to read P&ID, Isometric and “As Built” drawings
- H. Communicate effectively with supervisor and other departments workload, priorities and issues to maintain validation schedule

### **Additional Job Functions:**

In depth experience in several of these areas:

- Process Validation of biological process
- Method validations
- Filter validations
- Sterility validation
- FAT experience with large automated systems
- Setting validation specifications for purchasing capital equipment
- Project management experience with facilities upgrades and major construction projects
- Experience performing IQ/OQ on large automated systems
- Cleaning validation
- Shipping validation



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### **Physical Demands:**

Noise level: Quiet  
Vision Requirements: Ability To Adjust Focus  
Lifting Limits: Up to 50 lbs

### **Work Environment:**

#### ***Percentage of Time:***

Standing: 26-50%  
Walking: 26-50%  
Sitting: 51-75%  
Hand Use: 0 - 25%  
Hand Reaching: 0 - 25%  
Climbing or Balancing: 0 - 25%  
Stooping or Crouching: 0 - 25%  
Talking and Hearing: 76-100%  
With Mechanical Moving Parts: 0 - 25%

## **Job Description**

### **Position Summary:**

Responsibilities and experience may include the following: Write validation protocols and reports. Perform validation activities. Maintains up-to-date knowledge of validation requirements, practices and procedures. Able to read P&ID, Isometric and "As Built" drawings. Must be proficient in the use of the Kaye Validator or equivalent. In depth experience in processing validation of biological process, method validations, filter validations, sterility validations, FAT experience with large automated systems, setting validation specifications, project management experience with facilities upgrades and major construction projects, experience performing IQ/OQ on large automated systems, cleaning validation and shipping validation. May travel internationally. Represent company at vendor locations.

### **Knowledge**

Complete understanding and wide application of technical principles, theories and concepts in the field. General knowledge of other related disciplines.

### **Problem Solving**

Provides technical solutions to a wide range of difficult problems. Solutions are imaginative, thorough, practicable and consistent with organizational objectives.



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### **Discretion / Latitude**

Works under only general direction. Independently determines and develops approach to solutions. Work is reviewed, upon completion for adequacy, in meeting objectives.

### **Impact**

Contributes to the completion of specific programs and projects. Failure to obtain results or erroneous decisions or recommendations would typically result in serious program delays and considerable expenditure of resources.

### **Liaison**

Frequent inter-organizational and outside customer contacts.

### **Typical Education:**

B.S. in Engineering or Technical Field.

### **Typical Experience:**

5+ years experience

### **Certificates, Licenses, Registrations:**

N/A

## **Capability Profile**

### **Competencies Related to Performance:**

#### **Creativity**

Intellectual Horsepower  
 Decision Quality  
 Functional/Technical Skills  
 Problem Solving

#### **Dealing with Ambiguity**

Technical Learning  
 Learning on the Fly

Organizing  
 Total Work Systems  
 Process Management

#### **Planning**

Informing  
 Standing Alone  
 Sizing up People

#### **Motivating Others**

Peer Relationships  
 Listening  
 Managing Diversity  
 Action Oriented  
 Drive for Results  
 Perseverance  
 Organizational Agility  
 Interpersonal Savvy



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**Technical Knowledge:**

FDA, cGMP

**Functional Skills**

**Language Skills:**

Ability to read, analyze, and interpret general business periodicals, professional journals, technical procedures or governmental regulations. Ability to write reports, business correspondence, and procedure manuals. Ability to effectively present information and respond to questions from groups of managers, clients, customers and the general public.

**Mathematical Skills:**

Ability to work with mathematical concepts such as probability and statistical inference, and fundamentals of plane and solid geometry and trigonometry. Ability to apply concepts such as fractions, percentages, ratios and proportions to practical situations.

**Reasoning Ability:**

Ability to solve practical problems and deal with a variety of concrete variables in situations where only limited standardization exists. Ability to interpret a variety of instructions furnished in written, oral, diagram or schedule form.

**Computer Skills:**

Outlook, Internet Explorer, Excel, Word

**This signature verifies that I have read and understand the contents of this job description.**

Signature: \_\_\_\_\_ Print: \_\_\_\_\_ Date: \_\_\_\_\_

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Signature: \_\_\_\_\_ Print: \_\_\_\_\_ Date: \_\_\_\_\_

Supervisor Signature: \_\_\_\_\_ Print: \_\_\_\_\_ Date: \_\_\_\_\_