



MedImmune

Title: Senior Manager, Validation
FLSA: Exempt
SIRS Code: S484-2A

Performance Requirements

Essential Job Functions:

- A. Direct day-to-day operations of validation services for Development and Clinical Manufacturing environment.
- B. Direct operations to minimize downtime of Pilot Plant equipment.
- C. Direct the validation (verification as applicable) activities including Facility start-up, temperature mapping of controlled temperature units (stability chambers, refrigerators, freezers, incubators) facility, utility and equipment cleaning , facilities, utilities and process equipment (automated) and automated systems. Also, direct validation of QC instruments and methods.
- D. Present overviews of validation programs to regulatory agencies as necessary.
- E. Responsible for ensuring training of employees to assure up-to-date knowledge of practices and procedures.
- F. Controls the Validation Department budget.
- G. Develops a competent staff capable of implementing company and quality objectives.
- H. Must be able to read and interpret P&ID, Isometrics and “As Built” drawings.
- I. Communicate effectively to management across departments and staff goals, priorities and policy.
- J. Responsible for setting Validation Policy for Development and Clinical Manufacturing, interpreting international regulations and leveraging applicable industry best practices.

Additional Job Functions:

Must be knowledgeable and proficient in the methods and management of validation and change control processes. Must be familiar with product development, manufacturing systems and related analytical methods. Must be familiar with validation of computer systems and automated systems. Must be knowledgeable with FDA cGMP and European regulations and guidelines. Knowledge in broad scope of analytical methodologies and principles. Must possess excellent management communication, interpersonal, and organizational skills. Must have experience in the preparation of the validation portions of regulatory submissions. Must be able to demonstrate proficiency in industry validation best practices for Clinical Manufacturing.



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Physical Demands:

Noise level: Quiet
Vision Requirements: Ability To Adjust Focus
Lifting Limits: Up to 25 lbs

Work Environment:

Percentage of Time:

Standing:	26-50%
Walking:	26-50%
Sitting:	26-50%
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%
Working With Risk of Electrical Shock:	0 - 25%



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Job Description

Position Summary:

The Senior Manager, Validation is responsible for directing validation managers, specialists, and engineers. Responsibilities include personnel scheduling, forecasting project requirements, and preparation of validation master plans. The Senior Manager assures that facilities, laboratory equipment, utility systems and process equipment are validated and that final validation summary reports are written. The Senior Manager is responsible for preparing and controlling the annual budget and for project coordination with MedImmune staff and outside consultants as necessary.

Freedom to Act

Assignments are received in task-and objective-orientated terms. Provides direction to subordinates based on general policies and management guidelines. Work is reviewed upon completion for adequacy in meeting objectives. Interprets and executes policies and procedures that typically affect subordinate organizational units. Recommends modifications to operating policies.

Supervisor Relationships

Accomplishes results through lower-level subordinate supervisors or through experienced exempt employees who exercise significant latitude and independence in their assignments. Often heads a centralized functional activity.

Operations Involvement / Direct Work Involvement

Functions as an advisor to a unit regarding tasks, projects, and operations. Becomes actively involved in daily operations only when required to meet schedules or to resolve complex problems.

Impact

Ensures that projects are completed on schedule and within budget. Erroneous decisions or recommendations or failure to complete assignments would normally result in serious delays to assigned projects resulting in considerable expenditure of additional time, human resources, and funds.



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Liaison

Frequent contacts with internal personnel and outside customer representatives at various management levels concerning operations or scheduling or specific phases of projects or contracts. Conducts briefings and participates in technical meetings for internal representatives concerning specific operations.

Typical Education:

Bachelors: Engineering (Chemical, Biochemical, Electrical)

Typical Experience:

7-10 years experience

Certificates, Licenses, Registrations:

N/A



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Capability Profile

Competencies Related to Performance:

<u>Creativity</u>	Priority Setting	Customer Focus
Intellectual Horsepower	Timely Decision Making	<u>Building Teams</u>
Decision Quality	Managing & Measuring Work	Integrity and Trust
Functional/Technical Skills	Time Management	Self Development
Problem Solving	Developing Others	Managing Diversity
<u>Dealing with Ambiguity</u>	Standing Alone	Action Oriented
Organizing	Confronting Direct Reports	Drive for Results
Total Work Systems	Hiring and Staffing	Perseverance
Process Management	<u>Motivating Others</u>	Presentation Skills

Technical Knowledge:

Process Validation, Method Validation, Filter Validation, Sterility Validation, IQ/OQ Experience, Cleaning and Shipping Validation

Functional Skills

Language Skills:

Ability to read, analyze, and interpret common scientific and technical journals, financial reports, and legal documents. Ability to respond to common inquiries or complaints from customers, regulatory agencies, or members of the business community. Ability to write speeches and articles for publication that conform to prescribed style and format. Ability to effectively present information to top management, public groups, and/or boards of directors.

Mathematical Skills:

Ability to apply advanced mathematical concepts such as exponents, logarithms, quadratic equations, and permutations. Ability to apply mathematical operations to such tasks as frequency distribution, determination of test reliability and validity, analysis of variance, correlation techniques, sampling theory, and factor analysis.

Reasoning Ability:



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Ability to define problems, collect data, establish facts, and draw valid conclusions.
Ability to interpret an extensive variety of technical instructions in mathematical or diagram form and deal with several abstract and concrete variables.

Computer Skills:

Outlook, Internet Explorer, MS Project, MS Excel, MS Word

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

Signature: _____ Print: _____ Date: _____

Supervisor Signature: _____ Print: _____ Date: _____