



MedImmune, Inc.

Title: Senior Manager QA
FLSA: Exempt
SIRS Code: S497-3B

Performance Requirements

Essential Job Functions:

- A. Auditing internal and external - utilizing risk based strategy.
- B. Sound understanding of document systems management. Sound understanding of change management utilizing a risk based approach.
- C. Operational Excellence utilizing tools such as DMAIC and root cause analysis.
- D. Managing "quality at the source" utilizing on the floor real time review and investigations.
- E. Managing work and data utilizing electronic system tools such as Trackwise and SAP.
- F. Managing product release utilizing systematic process flows.
- G. Supporting the supplier qualification program in the area of Pack and Label for clinical manufacturing.
- H. Managing training for manufacturing, QA and other related support functions.
- I. Line management and staff supervision includes scheduling, recruiting and performance management.
- J. Operating skills including timely decisions, managing and measuring work along with good overall time management.
- K. Develop staff and set priorities.
- L. Managing and measuring work through metrics along with good overall time management.

Additional Job Functions:

- A. Independently identify and resolve complex problems through good decision quality utilizing functional and technical skills. Manage conflict and stand alone on issues. Ability to confront direct reports.
- B. Proven track record in developing or leading teams. Work on teams. Ability to lead multiple teams within and outside the organization. Ability to work as a team member. Ability to work collaboratively with strong listening skills.
- C. Ability to take strategic initiatives and translate into tactical solutions. Ability to initiate and develop strategic initiatives. Ability to develop strategy and negotiate senior management approval. Implementation of strategy is through staff.
- D. Able to professionally communicate verbally, in writing and represent the function effectively. Good listening skills, interpersonal savvy, and peer relations. Ability to effectively present complex data and strategy to large groups.



MedImmune, Inc.

Title: Senior Manager QA
FLSA: Exempt
SIRS Code: S497-3B

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: 0 - 25%
Sitting: 51-75%
Talking and Hearing: 76-100%



MedImmune, Inc.

Title: Senior Manager QA
FLSA: Exempt
SIRS Code: S497-3B

Job Description

Position Summary:

Responsibilities and experience may include the following: Auditing (internal and external - utilizing risk based strategy, specializing in label printing, translations, and pack and label vendors. Experience in electronic document systems for review and approval of documents. Change management using electronic system utilizing a risk based approach. Operational Excellence utilizing tools such as DMAIC and root cause analysis. Experienced in a Quality at the Source model utilizing on the floor real time review of batch records during production at CMOs. Electronic system utilizing tools such as Trackwise, ClinApps or equivalent, and SAP. Product release utilizing systematic process flows. Review and approval of documents such as SOPs, deviations, change control requests, corrective and preventive action plans, validation protocols/reports, technical reports, etc., that are submitted to QA for approval. Interprets and implements applicable regulations, guidances, and internal quality procedures; manages quality systems and assists in facilitating regulatory compliance inspections. Assist QA Management to develop the department budget and analyze headcount requirements. Line management and staff supervision includes scheduling, recruiting and performance management. Organizing work systems. Strong time management skills. Writes and reviews regulatory submission documents to Board of Health. Sr. Managers may travel internationally and interact with regulatory organizations. May be assigned to due diligence business meetings.

Freedom To Act:

Assignments are received in objective-orientated terms. Provides guidance to subordinates based on organizational goals and company policy. Work is reviewed in terms of meeting the organizations objectives and schedules. Establishes operating policies and procedures that affect subordinate organizational units. Interprets, executes, and recommends modifications to organizational policies.

Supervision Relationships:

Accomplishes results through subordinate supervisors, or exempt specialist employees. Subject to approval, modifies the organizational structure of centralized functions and units. Often responsible for managing a staff function of the company.

Operations Involvement / Direct Work Involvement

Responsible for all projects assigned to the organizational unit. Acts as an advisor to subordinate supervisors or staff members to meet schedules or resolve technical or operational problems. Directly participates in establishing and administering many centralized functional projects. Develops and administers budgets, schedules, and performance standards.



MedImmune, Inc.

Title: Senior Manager QA
FLSA: Exempt
SIRS Code: S497-3B

Impact:

Exerts influence in the development of objectives and long-range goals of the organization. Erroneous decisions or recommendations would normally result in critical delays and modifications to projects or operations; cause substantial expenditure of time, human resources, and funds; and jeopardize future business activity.

Liaison:

Inter-organizational and outside customer contact.

Typical Education:

B.S. in Biology, Chemistry, Engineering or related fields.

Typical Experience:

8+ years work experience in field with a minimum of 4 years in a managerial role.

Certificates, Licenses, Registrations:

ASQ Certified Quality Engineer or Auditor, preferred

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

Signature: _____ Print: _____

Date: _____

Supervisor Signature: _____ Print: _____

Date: _____



MedImmune, Inc.

Title: Senior Manager QA
FLSA: Exempt
SIRS Code: S497-3B

Capability Profile

Competencies Related to Performance:

<u>Creativity</u>	Process Management	<u>Building Teams</u>
<u>Innovation Management</u>	Priority Setting	<u>Managing Vision & Purpose</u>
Decision Quality	Directing Others	Negotiating
Problem Solving	Command Skills	Managing Diversity
<u>Dealing with Ambiguity</u>	Conflict Management	Drive for Results
Perspective	<u>Motivating Others</u>	Customer Focus
Organizing	Comfort Around Higher Management	

Technical Knowledge:

N/A

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, InSight, Internet Explorer, MS Powerpoint, MS Project, MS Excel, MS Word