



MedImmune

Title: Quality Engineer III – Quality Assurance
FLSA: Exempt
SIRS Code:

Performance Requirements

Essential Job Functions:

- A. Responsible for Quality Engineering functions in site Quality Assurance.
- B. The Quality Engineer supports functions that impact Manufacturing, Facilities, Validation, Quality Control and Quality Assurance.
- C. Implements quality policies, oversees change management and non-conformance systems. Assists in facilitating regulatory compliance inspections.
- D. Utilizes Operational Excellence (Six Sigma) tools in assessing quality systems.
- E. Drives efficiency initiatives in Quality.

Additional Job Functions:

- A. Participates in the development of new systems/operations required to run manufacturing facilities.
- B. Responsible for ensuring that Facility Operations meet current GMP requirements.
- C. Manages project plans to assure timely completion of projects.
- D. Supports the evaluation and lifecycle of aspects of change management and non-conformance.
- E. Investigates and assesses the impact of deviations that may occur during manufacture, testing or distribution of products or during the administration of quality systems. Identifies root causes and recommends/implements corrective actions to prevent recurrence.
- F. Performs in-plant inspections of active production areas to resolve problems and to ensure compliance with SOP and regulatory requirements.



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Physical Demands:

Noise level: Quiet
Vision Requirements: Close Vision
Lifting Limits: Up to 40 lbs

Work Environment:

Percentage of Time:

Standing: 0 - 25%
Walking: 0 - 25%
Sitting: 76-100%
Hand Use: 76-100%
Hand Reaching: 51-75%
Climbing or Balancing: 0 - 25%
Stooping or Crouching: 0 - 25%
Talking and Hearing: 76-100%



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Job Description

Position Summary:

Responsibilities and experience may include the following: Validation in pharmaceutical environment. Operational Excellence and/or ASQC certifications. Change management. Risk based management. Project management tools. Process flow diagram and process map. Participates in the development of new systems/operations required to run clinical manufacturing facilities. Supports the evaluation and lifecycle of all aspects of change management. Investigates and assesses the impact to deviations that may occur during manufacture, testing or distribution of products or during the administration of quality systems. Identifies root causes and recommends/implements corrective actions to prevent recurrence.

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.

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

Inter-organizational and outside customer contact.

Typical Education:

B.S. or Engineering. At least 3 years of experience in a biotechnology related industry. Preferably with hands on operational experience.

Typical Experience:

5+ years experience



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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:

Database knowledge, cGMPs

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 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, Access, TrackWise, LMS, Documentum, Visio, SAP, Microsoft Project, Excel, Word

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

Signature: _____ Print: _____ Date: _____

Supervisor Signature: _____ Print: _____ Date: _____