

Quality Facilitator

Job ID
REQ-10031163
Dic 04, 2024
Estados Unidos

Resumen

The Quality Operations Department Facilitator plays a critical role in driving continuous improvement, ensuring compliance with industry standards, and enabling teams to achieve high-quality operational outcomes. Collaborating closely with production/quality, facilities and engineering, and management, they proactively identify and address issues while implementing best practices.

Additionally, the facilitator provides leadership and strategic guidance to the Quality teams, ensuring the effective execution of the operational plan in compliance with regulatory requirements (Health Authorities, SOX, OSHA, etc). This includes optimizing efficiency and cost-effectiveness by focusing on process improvements through OPEX initiatives, ramp-up activities, change control management, and document updates.

Location: Morris Plains, NJ, LI-#Onsite
Shift: Monday- Friday

About the Role

Key Responsibilities:

Continuous Improvement & Operational Excellence: Lead and manage continuous improvement initiatives and Operational Excellence (OPEX) projects to optimize processes, reduce waste, and enhance operational efficiency. Leverage Lean and Six Sigma methodologies, along with project management techniques, to drive cost-effective improvements and reduce controllable expenses within the department.

Ramp-Up Support: Provide critical support during production ramp-up phases, ensuring smooth transitions and scaling of processes to meet operational demands, while maintaining quality and efficiency.

Change Control Management: Assist in overseeing change control processes, ensuring all modifications are thoroughly documented, reviewed, and approved in full compliance with regulatory and quality standards.

Documentation Accuracy: Maintain and update department-specific documentation, ensuring all records meet internal and external regulatory standards and are up to date and accurate.

Cross-Functional Collaboration: Collaborate closely with the Production Unit (PU) and Quality Control (QC) leadership teams to support and execute initiatives, ensuring alignment with overall business objectives.

Strategic Planning: Translate organizational goals into actionable strategic plans, enabling the PU/QC teams

to effectively plan and execute future activities to meet or exceed targets.

Performance Delivery: Drive continuous improvement in quality, productivity, and cost-effectiveness to ensure the organization remains compliant and competitive in the marketplace.

Team Communication & Engagement: Foster a high-performance, collaborative team environment. Ensure that team members are regularly informed and aligned through effective communication, including team meetings and other updates.

Leadership Support: Act as a trusted partner to area leaders by supporting various leadership activities, including delegation of authority when needed, ensuring smooth and efficient operations.

Quality Culture: Champion a culture of quality throughout the organization, ensuring all team members understand and prioritize adherence to quality standards and regulatory requirements.

Essential Requirements:

Bachelor's degree required; Advanced degree or specialization certifications is preferred.

Relevant educational experience should include any of the following:

- Quality Management or Quality Assurance
- Engineering (e.g., Industrial Engineering or Manufacturing Engineering)
- Pharmaceutical Sciences or Biotechnology
- Operations Management or Business Administration
- Chemical Engineering or Biochemical Engineering

Minimum of 5 years' experience in the pharmaceutical/Biotechnology industries with Quality Assurance, Operations, and Management Experience.

Hands-on Quality Assurance: Direct experience in applying quality assurance methodologies and ensuring product and process integrity, with attention to detail in defect identification and resolution.

Regulatory Compliance: Demonstrated experience ensuring compliance with cGMP, USP, FDA, SOX, and OSHA guidelines, particularly in regulated industries such as pharmaceuticals, biotechnology, or manufacturing.

Project Management Experience: Proven ability to lead and manage projects, from inception to completion, using modern project management methodologies (Agile, Lean, Six Sigma, etc.) and tools like MS Project or similar.

Operational Efficiency: Involvement in OPEX (Operational Excellence) initiatives, process improvements, and continuous improvement programs that drive productivity, quality, and cost-efficiency.

Change Control Management: Experience in managing change controls and updates to documentation or processes, ensuring a smooth transition and minimal operational disruption.

Pharmaceutical/Biotechnology or Manufacturing Industry: Experience working in industries where compliance with stringent regulatory standards is critical (e.g., pharmaceuticals, biotechnology, medical devices, food manufacturing, or high-tech manufacturing).

Team Leadership: Experience in leading and motivating cross-functional and interdisciplinary teams in quality initiatives, with a proven track record of driving results.

Mentorship and Coaching: Experience mentoring or supervising junior staff and providing guidance on best practices in quality assurance and process improvement.

The pay range for this position at commencement of employment is expected to be between \$118,400 and \$177,600 per year; however, base pay offered may vary depending on multiple individualized factors, including market location, job-related knowledge, skills, and experience. The total compensation package for this position may also include other elements, including a sign-on bonus, restricted stock units, and discretionary awards in addition to a full range of medical, financial, and/or other benefits (including 401(k) eligibility and various paid time off benefits, such as vacation, sick time, and parental leave), dependent on the position offered. Details of participation in these benefit plans will be provided if an employee receives an offer of employment. If hired, employee will be in an “at-will position” and the Company reserves the right to modify base salary (as well as any other discretionary payment or compensation program) at any time, including for reasons related to individual performance, Company or individual department/team performance, and market factors.

Why Novartis: Helping people with disease and their families takes more than innovative science. It takes a community of smart, passionate people like you. Collaborating, supporting and inspiring each other. Combining to achieve breakthroughs that change patients’ lives. Ready to create a brighter future together?
<https://www.novartis.com/about/strategy/people-and-culture>

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The Novartis Group of Companies are committed to working with and providing reasonable accommodation to individuals with disabilities. If, because of a medical condition or disability, you need a reasonable accommodation for any part of the application process, or to perform the essential functions of a position, please send an e-mail to us.reasonableaccommodations@novartis.com or call +1(877)395-2339 and let us know the nature of your request and your contact information. Please include the job requisition number in

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Innovative Medicines

Ubicación

Estados Unidos

Estado

New Jersey

Sitio

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Company / Legal Entity

U014 (FCRS = US014) Novartis Pharmaceuticals Corporation

Functional Area

Quality

Job Type

Full time

Employment Type

Regular

Shift Work

No

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