NOVARTIS

Senior Manager, Qualification

Job ID
REQ-10075976
Apr 29, 2026
LOC_US

About the Role

Key Responsibilities

- Lead site qualification strategy for equipment and instruments, utilities, and computerized systems across commercial and clinical operations
- Own and maintain the site qualification master plan, validation schedules, and periodic review programs
- Serve as site subject matter expert supporting internal and external inspections and inspection readiness activities
- Drive proactive inspection readiness programs and promote a strong quality and compliance culture
- Develop and implement risk-based qualification strategies aligned with regulatory and company standards
- Manage qualification resources, including contractors, budgets, forecasting, and financial stewardship
- Review and approve qualification documentation including protocols, reports, risk assessments and requirement trace matrices
- Partner with Quality, Engineering, and project teams to ensure compliant and efficient project execution
- Provide coaching, development, and performance management for the qualification team
- Monitor project progress, identify risks, and communicate roadblocks and mitigation plans to stakeholders

Essential Requirements

- Bachelor’s degree in engineering, science, or a related technical discipline
- Minimum of 7 years of experience in engineering, commissioning, qualification, and validation within pharmaceutical or biotechnology manufacturing, including equipment and computer systems validation
- Minimum of 5 years of proven people leadership experience, including coaching, developing, and managing technical teams
- Demonstrated expertise qualifying equipment and instruments, utilities, and computerized systems
- Strong working knowledge of United States Food and Drug Administration regulations, including Title 21 Code of Federal Regulations Parts 11, 210, and 211
- Understanding of international quality guidelines, including International Council for Harmonisation Q8, Q9, and Q10
- Experience managing third-party resources, including both contracted and outsourced services
- Excellent written and verbal communication skills, including technical documentation and inspection interaction

Desirable Requirements

- Experience supporting regulatory inspections as a site subject matter expert for commissioning and qualification activities
- Demonstrated ability to implement continuous improvement or cost optimization initiatives within qualification or validation programs

The salary for this position is expected to range between $114,100 and $211,900 per year. The final salary offered is determined based on factors like, but not limited to, relevant skills and experience, and upon joining Novartis will be reviewed periodically. Novartis may change the published salary range based on company and market factors. Your compensation will include a performance-based cash incentive and, depending on the level of the role, eligibility to be considered for annual equity awards.

US-based eligible employees will receive a comprehensive benefits package that includes health, life and disability benefits, a 401(k) with company contribution and match, and a variety of other benefits. In addition, employees are eligible for a generous time off package including vacation, personal days, holidays and other leaves.

To learn more about the culture, rewards and benefits we offer our people clickhere.

Role Requirements

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

Benefits and Rewards: Learn about all the ways we'll help you thrive personally and professionally.
Read our handbook (PDF 30 MB)

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DIV_TO
Business Unit
Production / Manufacturing
Location
LOC_US
Site
Morris Plains
Company / Legal Entity
U014 (FCRS = US014) Novartis Pharmaceuticals Corporation
Functional Area
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Job Type
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Employment Type
Regular
Shift Work
No
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