NOVARTIS

Manager, QA Method Validation

Job ID
REQ-10080967
Июн. 23, 2026
США
Available in: English

Сводка

Location: Carlsbad, United States

You'll play a critical role at the intersection of quality, innovation, and patient impact—leading laboratory method validation for assays and devices used in clinical and GMP laboratory settings. As a trusted quality leader, you will shape how analytical methods are brought to life in a highly regulated environment, partnering closely with scientific and cross-functional teams to solve complex challenges, strengthen compliance, and enable the delivery of high-quality data that supports breakthrough therapies.

Relocation Support: This role is based in Carlsbad, California. Novartis is unable to offer relocation support: please only apply if accessible.

About the Role

Key Responsibilities

- Lead review and approval of method validation protocols, reports, and supporting data for accuracy and compliance
- Provide quality guidance on analytical method validations/verifications, troubleshooting, and impact assessments
- Serve as Quality representative on in vitro diagnostic design teams
- Evaluate and provide guidance on risk assessments, impact assessment, deviations, and corrective actions
- Ensure adherence to regulatory and company requirements
- Lead and/or support audits and inspections including preparation and follow-up
- Assist with quality management of technology transfer
- Maintain oversight of documentation, procedures, and training compliance

Essential Requirements

- Bachelor's degree in engineering, medical technology, biological sciences, or related field and a minimum of 8 years' experience in clinical and/or GMP laboratory environments. With an advanced degree, fewer years of experience may be required.
- At least 3 years experience supporting in vitro diagnostic development
- Experience, understanding, and familiarity with regulatory requirements and other compliance requirements and guidelines (such as GxP, Part 11, ICH, ISO, CLIA/CAP, IVDR, QSR)
- Basic understanding of molecular biology, immunology, immunohistochemistry, flow cytometry, fluorescent in situ hybridization
- Familiarity with statistical analysis
- Strong communication, collaboration, and presentation skills

Desirable Requirements

- Experience with ligand binding assays, flow cytometry, and digital pathology
- Proven track record of identifying and executing on continuous improvement

The salary for this position is expected to range between $114,100 – $211,900 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.

#LI-Onsite

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)

EEO Statement:

The Novartis Group of Companies are Equal Opportunity Employers. We do not discriminate in recruitment, hiring, training, promotion or other employment practices for reasons of race, color, religion, sex, national origin, age, sexual orientation, gender identity or expression, marital or veteran status, disability, or any other legally protected status.

Accessibility & Reasonable Accommodations

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 your message.

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Functional Area
Research & Development
Job Type
Full time
Employment Type
Regular
Shift Work
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