NOVARTIS

Manager, QA Method Validation

Job ID
REQ-10080967
Jun 23, 2026
LOC_US

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 click here.

#LI-Onsite

Role Requirements

Division

DIV_TO
Business Unit
Quality
Location
LOC_US
Site
Carlsbad
Company / Legal Entity
U441 (FCRS = US441) Navigate BioPharma Services, Inc.
Functional Area
FCT_RD
Job Type
Full time
Employment Type
Regular
Shift Work
No
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