NOVARTIS

TRD QA CGT Modality Head

Job ID
REQ-10080989
июл 10, 2026
США
Available in: English

Сводка

Location: East Hanover, NJ
Please note that this role will be based onsite

This role is based in East Hanover, NJ, US. Novartis is unable to offer relocation support for this role. Please only apply if this location is accessible for you.

Role Purpose:
Lead/manage and/or provide quality oversight in development and research functions, including clinical trial processes, medical/clinical/preclinical safety systems and procedures, product release and handover, or projects in order to ensure compliance with health authorities requirements, internal standards and a full adherence to patients' safety, rights and well-being. Provides risk analysis and quality expertise to internal stakeholders in order to make critical decisions. Drive a culture of quality through business partnering and supporting the quality mission and strategy.

About the Role

Major Accountabilities:

- Ensure establishment, maintenance and effectiveness of quality and data management systems and practices and oversee all aspects of quality, which may include GCP, PV, GLP, GMP (including medical device), IP, change and design control, training, complaints audits, quality certifications, etc.
- Proactively provide strong QA leadership to the business by ensuring considerable quality and organization awareness in research and development activities
- Lead and manage a global QA organization and/or global quality project team and contribute to and regularly monitor the implementation of the annual Quality Plan
- Ensure adherence to global and local safety and regulatory internal and health authority standards, including GCP, GLP, GMP, PV, IP
- Ensure adequate oversight of proactive quality risk management process including quality risk assessments, to ensure risks are detected and remediated, and submission/inspection readiness activities
- Establish/ lead core governance for deviation/incident management for critical or major deviations, provide regulatory guidance and drive initiatives relevant to quality oversight of internal monitoring and outsourced activities
- Support inspections preparation and facilitation and participate in audits and inspections follow -up activities including CAPA preparation
- Communicate lessons learned from deviations/incidents, audits and inspections and drive a culture of proactive, risk -based behaviour
- Reporting of technical complaints / adverse events / special case scenarios related to Novartis products within 24 hours of receipt
- Distribution of marketing samples (where applicable)

Key Performance Indicators:

- Quality Management System for GxP up to date and implemented
- Quality oversight on global and local clinical vendor established

Work Experience:

- Audit & Inspection Management
- Quality Management Systems
- Quality Assurance
- GxP Experience
- Good Manufacturing Practices (cGMP)
- People Management
- Quality Compliance
- Drug Development
- Research
- Drug Regulatory Affairs
- Technological Expertise
- Complaints Management
- Good Laboratory Practice (GLP) Analytics
- Incident Management
- Patient Safety
- Pharmacovigilance

Languages:

- English.

Novartis Compensation and Benefit Summary:

The salary for this position is expected to range between $176,400 and $327,600 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.

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.

Дивизион
Development
Business Unit
Quality
Место
США
Состояние
New Jersey
Сайт
East Hanover
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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TRD QA CGT Modality Head

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