

Sr. Compliance Specialist

Job ID
REQ-10024392

10月 03, 2024

USA

摘要

The Senior Compliance Specialist is responsible for maintaining the Morris Plains QMS and Inspection Management.

This role is required to be on-site in Morris Plains, NJ. Novartis is unable to offer relocation support for this role: please only apply if this location is accessible for you.

365 days a year, we aspire to be the best manufacturer of Cell & Gene therapies to ensure our patients have the treatments they need to live longer, healthier lives.

LI- #onsite

About the Role

Key Responsibilities:

- Responsible for Trending of Deviations Quarterly and ICP (Investigator Certification Program)
- Maintaining ICP Certification to support Quality records within the QMS system
- Maintaining Novartis Auditor Certification
- QMS Functional Representation Role
- Market Notifications (BPDR, PDR, Recall)
- APQR Governance- author and/or review the PQR/APQR data contributions aligned with compliance activities.
- Quality Plan Management
- Risk Assessment Approval and oversight of Governance
- Monthly KPI/KQI Reporting
- QMR Management (Monthly, Quarterly)
- Compliance Alert Management
- Audit/Inspection Management (Logistics, Response, CAPA Governance)
- Aseptic Team Member
- Data Integrity Point of contact and support the DI Plan
- Change Control Management Support to Sr Reg CMC Facilitator

Essential Requirements:

- BA/BS in Chemistry, Microbiology or Biological Sciences or related degree.
- 8+ years of related pharmaceutical experience, preferred to include cell gene therapies
- At least 3 years of experience with Change Control and Risk Assessment is a must
- Experience in Quality Control, Quality Assurance, Documentation Control, Compliance
- Knowledge of GMPs/Regulatory
- Knowledge of deviation, CAPA, Complaint, BPDR, Recall, Change Control, manufacturing processes, Packaging process, Regulatory inspection, technical writing
- Demonstrate Excellent leadership
- Demonstrate a proven track record with Health Authorities and Customer Audits

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.

Commitment to Diversity and Inclusion:

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

protected status. We are committed to building diverse teams, representative of the patients and communities we serve, and we strive to create an inclusive workplace that cultivates bold innovation through collaboration and empowers our people.

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>

Join our Novartis Network: Not the right Novartis role for you? Sign up to our talent community to stay connected and learn about suitable career opportunities as soon as they come up: <https://talentnetwork.novartis.com/network>

Benefits and Rewards: Read our handbook to learn about all the ways we'll help you thrive personally and professionally: <https://www.novartis.com/careers/benefits-rewards>

EEO Statement:

The Novartis Group of Companies are Equal Opportunity Employers who are focused on building and advancing a culture of inclusion that values and celebrates individual differences, uniqueness, backgrounds and perspectives. 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. We are committed to fostering a diverse and inclusive workplace that reflects the world around us and connects us to the patients, customers and communities we serve.

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.

部门
Operations

Business Unit
Innovative Medicines

地点
USA

站点
Morris Plains

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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