NOVARTIS

Sr QA Compliance & Reg CMC Facilitator

Job ID
REQ-10036305
Ene 14, 2025
Estados Unidos

Resumen

The Senior Compliance Specialist & Regulatory CMC Facilitator is responsible for maintaining the Morris Plains Change Control QMS, and support on-site regulatory CMC as RegCMC Facilitator and ensuring compliance with current regulatory requirements.

This role is located 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.

Location: Morris Plains, NJ #LI-Onsite

About the Role

Key Responsibilities:

- Lead and facilitate the site CCRB (Change Control Review Board) in support of all Product (Process, Analytical, Systems as relevant (e.g. LIMS, MES, etc.)) and Asset (Equipment, Facility, Utility) change controls for all GxP changes including clinical and commercial operations.
- Ensure that CCRB decisions are made in a timely manner and with cross functional site support and further aligned across CGT platform and escalated to Global platform CCRB as warranted.
- Responsible for oversight of the day-to-day execution of the change management process; ensuring the overall compliance of the Change Control Quality System through ongoing monitoring and metrics to ensure timely supply to the markets in compliance with regulatory and cGMP requirements.
- QMS Functional Representation Role
- RegCMC Facilitator supporting regulatory CMC activities and evaluations and ensuring alignment and strategy with site personnel and RegCMC associates. This also includes ensuring the link with Change Controls prioritization is clearly established for alignment with submission timing.

Essential Requirements

- BA/BS in Chemistry, Microbiology or Biological Sciences or related discipline In lieu of degree relevant work experience may be accepted.
- 10+ years of related pharmaceutical experience, preferred to include cell gene therapies
- 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, Compliant, BPDR, Recall, Change Control, manufacturing processes, Packaging process, Regulatory inspection, technical writing
- Excellent Organization and communication skills

Novartis Compensation and Benefit Summary: The pay range for this position at commencement of employment is expected to be between $108,500 and $201,500/year; *however, while salary ranges are effective from 1/1/25 through 12/31/25, fluctuations in the job market may necessitate adjustments to pay ranges during this period. Further, final pay determinations will depend on various factors, including, but not limited to geographical location, experience level, knowledge, skills, and abilities.* 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.

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.

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