Mfg Technical MES System Specialist

Job ID
REQ-10019473

9月 14, 2024

USA

摘要

The Manufacturing Execution Systems (MES) Specialist will provide oversight and execution for the automated digitalized business processes, information flow and documentation for the production lifecycle. This role supports the maintenance, functionality, and change updates of the MES system to manufacture biopharmaceutical products for the Morris Plains, Cell Processing Operations.

Novartis is unable to offer relocation support for this role. Please only apply if the location is accessible for you.

About the Role

Key Responsibilities:

- Skilled in Master Batch Record (MBR) creation and maintenance using MES (Manufacturing Execution Systems).

- Update Manufacturing SOPs as required. Own and support Change Control tasks, Quality Events, and CAPAs related to MES updates.
- Support all aspects of the MES system - paperless manufacturing instructions, paperless in process control, enforces process sequencing and electronic go/no go decisions, process validation ranges, formulas to ensure the final yield is within acceptable percentages, interface with SAP System to issue materials to Master Batch Records (MBR) that are acceptable & released.
- Coordinate the review and revisions of procedures, R&D documentation, and FDA regulations for inclusion in Production instructions and Quality Control manuals.
- Communicate with broader MES global team to ensure alignment with the Global format and structure.
- Exceptional oral and written communicator who is proactive, responsive, and able to work independently with all levels of the organization. Ability to handle multiple conflicting tasks in a fast-paced environment is a must. Very high attention to detail is critical, including strong technical writing and proofreading skills.
- Responsible for ensuring compliance with Federal, State and local regulations and adherence to all company policies and procedures relating to GMP ' s, Health, Safety & Environmental Protection.

Essential Requirements:

- Bachelor ' s degree required.
- Minimum 3 years ' experience in a regulated cGMP environment or other regulatory related industry.
- 1 - 3 years Manufacturing Execution Systems Experience required
- Strong aseptic manufacturing knowledge background preferred.
- Skilled in Master Batch Record Creation and Maintenance for both Production using MES (Manufacturing Execution Systems).
- Must possess full fluency in MS Office (Word, Outlook, PowerPoint, MES, ERP, database management) and be an excellent communicator.
- Must be service-minded, flexible, and possess strong interpersonal skills.

Why Novartis: Our purpose is to reimagine medicine to improve and extend people ' s lives and our vision is to become the most valued and trusted medicines company in the world. How can we achieve this? With our people. It is our associates that drive us each day to reach our ambitions. Be a part of this mission and join us! Learn more here:

https://www.novartis.com/about/strategy/people-and-culture.

The pay range for this position at commencement of employment is expected to be between $84,000 and $126,000 Annual; 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. You can find everything you need to know about our benefits and rewards in the Novartis Life Handbook. https://www.novartis.com/careers/benefits-rewards

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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
Technical Operations

Job Type
Full time

Employment Type
Regular

Shift Work
No

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