U NOVARTIS

Manufacturing Systems Expert

Job ID REQ-10021438 Sep 06, 2024 Indien

Zusammenfassung

MES Expert providing technical expertise in support of all issues linked to electronic batch records (eBRs). MES Expert supporting MES deployment, implementation and continuous improvement in the Manufacturing Units and providing shop floor routine technical support.

About the Role

Job Description

Your Responsibilities:

Your responsibilities include, but not limited to:

Define User requirement specifications (Voice of customer)

· Design and create electronic batch files (EBR) with respect for quality, costs and deadlines

- · MBR / BOM/ Recipe creation in production IT systems
- · Participate in the qualification and risk assessment processes

 \cdot Propose and technically validate the choice of solutions proposed by the IT teams and Automation in collaboration with the Quality team

• Participate to the deployment of MES across the manufacturing units, runs performance qualification and validation batches (commissioning of the line) with the manufacturing units

• Responsible for the manufacturing documentation update following the implementation of electronic batch files • Provide training for MES users in partnership with the training team

• Ensure follow-up and processing of deviations and Change Control in compliance with deadlines and applicable regulations • Real time shop floor troubleshooting with the implementation of appropriate immediate corrective actions

 \cdot Ensure the transfer of information to production teams following issues or modifications having a technical, quality or HSE impact \cdot Responsible for MES / MIS technical knowledge transfer to the shop floor \cdot Ensure the preparation of audits and inspections for related topics

 \cdot Collaborate with process experts in the context of deviations related to MES / MIS and \cdot continuous process improvement

• Participate to change management in close collaboration with change champion and P&O partner • Ensure the application of local rules, procedures and policies

What you'll bring to the role:

* Minimum 5 year experience in GMP manufacturing process support role · Proven experience in MES expert role

* University degree in Science is required, Pharmacy or Chemical Engineering, Pharmaceutical Technology or equivalent job experience

*Competencies · Good scientific and technical (automation) understanding · Deep process understanding

·*Quality and compliance skills

·*Team player with strong team spirit

* Change management, adaptability, ability to work under pressure

* Mastering of automation and computer skills

·*Good understanding of regulatory requirements across multiple health authorities

*Mastering of manufacturing execution systems (MES, SAP, or other as applicable)

* Good office software applications

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

Commitment to Diversity and Inclusion:

Novartis is committed to building an outstanding, inclusive work environment and diverse teams' representative of the patients and communities we serve.

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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

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Abteilung Operations **Business Unit Innovative Medicines** Ort Indien Website Hyderabad (Office) Company / Legal Entity IN10 (FCRS = IN010) Novartis Healthcare Private Limited **Functional Area Technical Operations** Job Type Full time **Employment Type** Regular Shift Work No Apply to Job

Accessibility and accommodation

Novartis is 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 recruitment process, or in order to perform the essential functions of a position, please send an e-mail to <u>diversityandincl.india@novartis.com</u> 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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