

Manufacturing Systems Expert

Job ID
REQ-10021440

9月 05, 2024

Malaysia

摘要

The Manufacturing System 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

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
- 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
- Ensure the transfer of information to production teams following issues or modifications having a technical, quality or HSE impact
- Responsible for MES / MIS technical knowledge transfer to the shop floor
- Ensure the preparation of audits and inspections for related topics
- Collaborate with process experts in the context of deviations related to MES / MIS and
- 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

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部门
Operations

Business Unit
Innovative Medicines

地点

Malaysia

站点

Selangor

Company / Legal Entity

MY01 (FCRS = MY001) Novartis Corporation (Malaysia) Sdn. Bhd. (19710100054)

Functional Area

Technical Operations

Job Type

Full time

Employment Type

Regular

Shift Work

No

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