NOVARTIS

Post Doc Process Expert

Job ID
REQ-10077454
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Швейцария

Сводка

Subject matter expert for all process-specific issues to ensure execution of processes on time, continuously improving in quality and productivity, performed in compliance to cGMP, SOPs and applicable guidelines and functional standards. Supports processes and standards to maintain and improve existing and to implement new innovative concepts and strategies.

Please note that we can only accept applicants who are eligible to work in Switzerland or have completed their studies at a Swiss University.
Please submit a cover letter that includes your motivation for the position and from when you will be available. Thank you.

About the Role

Major accountabilities:

Stewardship – for the product(s) assigned:

· Provide front line support to manufacturing, working with the shift teams, focusing on manufacturing each batch safely, on time, in compliance with the batch instructions and quality requirements.

· Responsible for maintaining the master manufacturing documents of assigned products (e.g. Master Batch Record, Bill of Material (BOM) & Recipe, Quality Risk Assessment...)

· Ensure that all critical parameters are within written Instruction (i.e. Master Batch Record).

· Support steward for assessment of technical changes and process changes (task manager ACC/PCC)

· Supports and performs Quality Risk Assessment

· Ensure that all process changes are managed through appropriate change control procedure.

· Act as Subject Matter Expert (SME) for the product and process knowledge, be highly knowledgeable of product and process trends by providing input to e.g. APQR for analysis and for driving process technology innovations

· Collect data for ongoing process verification (OPV), support product steward in tracking and evaluation of product performance and implementation of CAPAs

· Perform first line evaluation of product and process related issues, perform root-cause investigations (uncritical, major and critical deviations, complaints, OOS, OOE) and implement effective CAPAs.

Validation – for the product(s) assigned:

· Review validation and qualification protocols and reports for technical correctness.

· Support the execution of process validations and qualifications, and short-term improvement projects, liaising with all the relevant parties at shop floor to ensure accurate execution.

Launch & Transfer – for the product(s) assigned:

· Be knowledgeable of process design by providing input during process transfer.

Manufacturing Excellence– for the product(s) assigned:

· Execute process improvements and scale-up.

· Support process optimization establishment and new technology introduction for continued productivity improvement, as appropriate.

Training:

· Support technology trainings and education programs for production operators and others

· Train process changes as needed in the Manufacturing Unit

Audit SME:

· Maintain their processes at inspection readiness level

Background

- BSc. in Biotechnology, Biochemistry or equivalent Scientific degree.

- MSc. in Biotechnology, Biochemistry, Cell Biology, Molecular Medicine, Genetics or equivalent .

- PhD in Biotechnology, Biochemistry, Cell Biology, Natural Science or equivalent.

- Process understanding (R&D, GxP, Sc. data analytics).

- Fluent in English and basic understanding of site local language desirable.

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

Benefits and Rewards: Learn about all the ways we'll help you thrive personally and professionally.
Read our handbook (PDF 30 MB)

Дивизион
Operations
Business Unit
Production / Manufacturing
Место
Швейцария
Сайт
Stein Aargau
Company / Legal Entity
C046 (FCRS = CH046) Novartis Pharma Stein AG
Functional Area
Others
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Employment Type
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Shift Work
No
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Post Doc Process Expert

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