Process Expert (m/f/d)

Job ID
REQ-10015993
Jul 24, 2024
Italy

Summary

Location: Ivrea, Italy

Role Purpose:
Provide front line technical and scientific expert support for all process-specific topics to ensure execution of processes on-time (business continuity); in compliance to cGMPs, SOPs and applicable guidelines and functional standards (e.g.HSE) and to allow continuously improving in quality, productivity efficiency.

About the Role

Operational activities

- Provide front line expert support for all process-specific topics to production
- During build up Phase, review/supervision/management of activities related to the qualification of the facilities, utilities and manufacturing lines.
- Coordinate and ensure the completion of all production operations on time, in accordance with the documentation and in compliance with GMP, SSE and 5S rules
- Ensure real time shop floor support as an expert on technical problems and ensuring that appropriate immediate corrective/remediation actions are implemented
- Perform real time batches follow-up and batch records technical review
- Ensure that all production documents are systematically up to date and that the production documents necessary for the validation / revalidation of processes are available

Compliance activities

- Ensure timely treatment of deviations, complaints, OOE, OOS, and the implementation of effective CAPAs within agreed timelines
- Lead thorough Root Cause Investigation process using investigation tools and methodology
- Collaborate with Engineering and Validation experts in the context of process deviations
- Ensure that all process changes in assigned products are managed through appropriate change control procedure
- Collaborate with Engineering and Validation Experts regarding the definition of the validation strategy
- Participate in continuous improvement and productivity projects
- Provide support to teams for the implementation of improvements, actions 5S, the exploitation of production data and the implementation of controls charts
- Actively participate in the development of production staff in the continuous improvement process. Provide operational support to teams during technology transfers

Quality and HSE

- Promote and improve the Quality culture in collaboration with Quality Assurance.
- Participate to, in collaboration with Quality Assurance, the upgrading, and the improvement of Quality by initiating, organizing and checking the practical application on the shop floor
- Ensure overall inspection readiness for area of responsibility
- Be responsible for the compliance to the principles and practices described in the "Novartis Manufacturing Manual" and their implementation on the site for his area

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Thousands of people die of cancer around the world every day. At Advanced Accelerator Applications, a Novartis company, our mission is to transform lives through radioligand therapy in nuclear medicine to fight several leading types of cancer. How will we continue to be on the cutting edge of medicine? We believe new groundbreaking solutions can be found at the intersection of medical science and digital innovation. That a diverse, equitable and inclusive environment inspires new ways of working. We believe our potential can thrive and grow in an unbossed culture underpinned by integrity, curiosity and flexibility. And we can reinvent what's possible, when we collaborate with courage to aggressively and ambitiously tackle the world’s toughest medical challenges. Because the greatest risk in life, is the risk of never trying!

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Business Unit
Innovative Medicines
Location
Italy
Site
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Company / Legal Entity
IT58 (FCRS = IT058) AAA Italy Srl.
Functional Area
Research & Development
Job Type

Full time
Employment Type
Regular
Shift Work
No
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