

Process Expert

Job ID
REQ-10026980
Oct 21, 2024
Italy

About the Role

Major accountabilities:

- Stewardship, Launches/Transfer:
- Support Product Steward in maintaining the process control strategy.
- Provide technical expertise and facilitate establishment of Quality Risk Assessment (as needed).
- Monitor all critical variables and key variables as appropriate using statistical analysis and conducting regular product specific data trending.
- Participate in transfers and launches by aligning on the product validation approach. Provide technical expertise for pre-validation / validation strategy.
- Ensure equipment is in qualified state and qualified ranges are aligned to meet process parameters
- Assess impact of technical changes, assess their technical feasibility and determine scope / design of technical batches, challenge technical risk and business benefit of technical changes proposed.
- Contribute to registration strategy and support registration activities providing experimental data obtained during the validation activities, which will be used to prepare the related registration documentation.
- Validation:
- Establish a qualification and requalification program (PQ) for the site and execute activities according to plan and defend to authorities.
- Perform equipment periodic reviews according to internal procedures
- Define and implement validation strategy (process, cleaning, ongoing verification) and defend to authorities.
- Overall responsibility for establishment, prioritization, execution and tracking of Validation Master Plan for process, cleaning, packaging validation and ongoing process verification (OPV).
- Ensure equipment is qualified and manufacturing and cleaning processes are validated; overview on site state of validation is maintained.
- Establish and monitor validation KPIs. Maintain all validation activities in an inspection ready status.
- Author validation protocols and reports.
- Establish local procedures & templates for respective validation documentation.
- Ensure that all Site validation activities are performed and are in line with the current AAA (or applicable) Novartis requirements and cGMP, handling any deviations associated to these activities including oversight of pre-validation and validation resulting from technical changes.
- Support MS&T activities in ensuring that responsible departments execute and maintain the VMP activities.
- Partner with Engineering, IT, QC, AS&T to define the interfaces to equipment, utilities and system qualification, analytical method validation. Execute equipment qualification and requalification
- Provide all necessary information to perform the validation documentation, align with stability experts and

QC labs to organize the stability samples. Manufacturing Excellence:

- Contribute to efficiency improvement programs Training:
- Own the Training Curriculum for own Profile and internal or external contributors Novartis Manufacturing Manual:
 - Support implementation of Novartis Manufacturing Manual principle 3 where applicable
 - Key Performance Indicators
 - Maintenance of Site Validation Master Plan, no overdue validation and qualification activities
 - Timely creation (and fulfilment) of Project Validation Master Plans.
 - Meet established validation milestones according to approved validation plans.
 - Validation execution according to plan, as a measure of appropriate validation readiness activities.
 - Audit and inspection outcomes as a measure of validation compliance with global regulatory expectations.
 - Transfers/launches implemented on target without preventable validation related issues.
 - Validation protocols executed and reports delivered according to schedule.
 - Validation/annual monitoring/revalidation activities scheduled in collaboration with stakeholders to ensure that site activities continue with minimal disruption
- Pharmaceuticals.
- Process and Cleaning Validation.
- Process Control.
- Process Engineering.
- Risk Management.
- Root Cause Analysis (Rca).
- Scheduler.
- Six Sigma.
- Sop (Standard Operating Procedure).

Languages :

- English.

Role Requirements

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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Division

Operations

Business Unit

Innovative Medicines

Location

Italy

Site

Saluggia

Company / Legal Entity

IT58 (FCRS = IT058) AAA Italy Srl.

Functional Area
Technical Operations
Job Type
Full time
Employment Type
Regular
Shift Work
No

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