Process Expert

Job ID
REQ-10026980
Oct 21, 2024
Italia

Resumen

Responsible for developing, implementing and managing the site performance qualifications and requalification of existing equipment and cycles as well any new equipment. Responsible for developing, implementing and managing the site process validation, primary packaging validation, process performance qualification, cleaning validation and revalidation strategies to meet cGMP and quality requirements on time and on budget to ensure that programs are compliant with Regulatory Authorities' expectations and related SOPs. Responsible for scale-up cold kits by developing and executing a validation strategy according to cGxP. Executing and managing equipment performance qualifications, requalification, periodic reviews and process, primary packaging, shipping and cleaning validation activities to meet cGMP requirements on time and quality to ensure that site validation programs are compliant with global regulatory expectations. Validation Expert - Support Product Steward in maintaining the process control strategy.

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 andconducting regular product specific data trending.
- Participate in transfers and launches by aligning on the product validation approach. Providetechnical expertise for pre-validation / validation strategy.
- Ensure equipment is in qualified state and qualified ranges are aligned to meet processparameters
- Assess impact of technical changes, assess their technical feasibility and determine scope / designof 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 registrationdocumentation.

- Validation:
- Establish a qualification and requalification program (PQ) for the site and execute activitiesaccording 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 toauthorities.
- 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 activitiesincluding 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 programsTraining:
- Own the Training Curriculum for own Profile and internal or external contributorsNovartis Manufacturing Manual:· Support implementation of Novartis Manufacturing Manual principle 3 where applicableKey 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
- Pharmaceutics.
- Process and Cleaning Validation.
- Process Control.
- Process Engineering.
- Risk Management.
- Root Cause Analysis (Rca).
- Scheduler.
- Six Sigma.
- Sop (Standard Operating Procedure).

Languages :

- English.

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Operations
Business Unit
Innovative Medicines
Ubicación
Italia
Sitio
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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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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