Analyst - MS&T

Job ID
REQ-10026922

11月 10, 2024

India

摘要

Job Purpose:
The Technical specialist supports MS&T team on sites by collecting data, reviewing or writing technical documents related to validation (e.g. process validation, ongoing process verification, cleaning validation, packaging), APR PQR, technical files, product risk assessment procedures and maintaining a product oversight throughout the lifecycle. The scope includes all drug products bulk (DP), finished products (FP) and all chemical intermediates/APIs under Novartis responsibility. For that purpose, technical specialist collects data from the Novartis Business Units, act in accordance with legislation, internal rules, good practices and business objectives.

About the Role

Major Accountabilities

- Support Validation program including process validation, ongoing process verification

(OPV), risk assessment, cleaning validation, ongoing cleaning verification for Novartis drug product and drug substance manufacturing sites.

- Create validation documentation including process validation protocol/reports, risk assessment, ongoing process verification (OPV) plans/ reports, cleaning validation protocol/reports based on alignment with Site Validation Lead.
- Using monitoring tool such as OPV Monitor or Discoverant perform, OPV evaluations, assess process performance and provide insight, recommendation, and conclusion to the site MS&T Lead/Product Steward.
- Create and review GxP documents including SOPs, working procedures, trend reports, and technical investigations, as and when needed.
- Support tasks related to technical changes, incident investigations for the product and process.
- Provide active support during internal and external audits by collecting and presenting the requested process/ data and reports.
- Coordinate & manage project for a smooth knowledge transfer activity from site/ function to corporate Center.
- Act as single point of contact for the services delivered to sites/ functions by the respective team, including the review of feedback and timely completion of identified actions.
- Coordinates with Global MS&T team, IT team for the ongoing data management, evaluation and reporting in the OPV Monitor OR Discoverant tool.
- Coordination of documents preparation in the right formats (eg. Novstyle for Subway, ESOPS etc) and ensure timely review and approval of the documents.
- Ensure services are delivered on time and in line with partner and Novartis MS&T requirements.
- Coordinates documentation review with the site MS&T, QA, and QC, also Reg CMC where applicable.
- Obtains deviation reports from relevant systems in support to validation to enable conclusions.
- Coordinates and owns DI check with Data integrity manager where applicable.
- Coordinates inputs from respective functions (QA, QC, MS&T), to create the validation documents and decide on the study strategy.
- Coordinates the execution of the study with respective functions. Collects results and creates reports.
- Others:
- Ensure compliance to the Novartis internal quality standards, relevant regulatory requirements, filed product quality standards and service level agreements.
- Implementation of and adherence to all the instructions and requirements for safe work, environment protection, and property protection.
- Other tasks determined during the annual objectives setting process and by KPIs.
  Comply with internal functional requirements such as KPI reporting, ticket management tools and any other internal procedures and processes.
- Assist the department on any other ad hoc activities/ requests to meet the business requirements
- Regularly communicate with partners and obtain feedback on services delivered.

Key Performance Indicators (Indicate how performance for this role will be measured)

- Quality / Accuracy / Right First Time
- Timeliness
- Deviations / Escalations

Ideal Background / Requirements for the role

- Bachelor's degree in Pharmacy, Pharmaceutical Technology, Chemical Engineering, Chemistry or equivalent science streams. Desirable MSc/MS. or equivalent experience.
- Min 5 years of experience in MS&T, Quality Assurance, Regulatory or in the manufacturing of pharmaceutical drug substance or drug products.
- Minimum of 3 years of pharmaceutical process validation and cleaning validation.
- Should have the experience in pharmaceutical process validation protocol/report writing, cleaning validation protocol and report writing, preferably in sterile manufacturing setups, biologics.
- Should be familiar and able to perform basic statistical evaluations using Minitab or other statistical analysis tools.
- Basic knowledge on deviation handling, incident investigations, root cause analysis, and CAPA management.
- Knowledge of risk assessment and risk management programs.
- Should be familiar with regulatory guidance on validation, product filing and post approval changes.
- Basic knowledge of statistical analysis, results interpretation, and usage of statistical tools (Example: Minitab, Statistica etc.).
- Good communication, presentation and interpersonal skills.
- Fluent in English (oral and written).

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You'll receive: You can find everything you need to know about our benefits and rewards in the Novartis Life Handbook. https://www.novartis.com/careers/benefits-rewards

Join our Novartis Network: If this role is not suitable to your experience or career goals but you wish to stay connected to hear more about Novartis and our career opportunities, join the Novartis Network here: https://talentnetwork.novartis.com/network.

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部门
Operations

Business Unit
Innovative Medicines

地点
India

站点
Hyderabad (Office)

Company / Legal Entity
IN10 (FCRS = IN010) Novartis Healthcare Private Limited

Functional Area
Technical Operations

Job Type
Full time

Employment Type
Regular

Shift Work
No

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Accessibility and accommodation

Novartis is committed to working with and providing reasonable accommodation to individuals with disabilities. If, because of a medical condition or disability, you need a reasonable accommodation for any part of the recruitment process, or in order to perform the essential functions of a position, please send an e-mail to diversityandincl.india@novartis.com and let us know the nature of your request and your contact information. Please include the job requisition number in your message.

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