Analista de Valida ç ã o de M é todos Sr

Job ID
REQ-10058155

7月 29, 2025

Brazil

摘要

-Highly skilled and experienced laboratory professional who contributes by performing analytical release testing, investigational support, research support, and stability testing

About the Role

Descri ç ã o do cargo

Major accountabilities:

- Support the implementation of national and international standards and guidelines established for requirements of analytical method validation and transfers.
- Perform the execution (analytical or documental) of method validation, forced degradation study, transfer activities and comparative studies such as dissolution profile, equivalence and performance studies according to what is established in local and international guidelines and

Novartis standards and procedures.
- Ensure full compliance with quality systems procedures, such as change control, OOS and OOT results and deviations detected in results during method validation.
- Perform the execution of activities related to protocols and reports elaboration, statistical analysis application for method validation and samples and materials amount calculation to perform experimental tests.
- Support and conduct analytical technical discussion with global AS&T, Manufacturing Site, TRD, Regulatory Affairs, Project Manager, Third Party Laboratories, etc.
- Provide analytical technical support to the countries regarding Testing Monographs routine applications.
- Perform gap assessment evaluation on global validation package in order to check the compliance with relevant legislations.
- Support the elaboration and guarantee adherence to Validation Master Plan and accomplishment with launches/submissions business priorities at each country.
- Rewrite the Testing Monograph into Novartis template and manage translation service of AS&T documents generated at the Hub, when necessary.
- Collaborate in internal and external audits related to AS&T and QC and establish CAPA plans for the findings, when identified. Follow up CAPA implementation in a timely manner.
- Collaborate and provide technical support during deficiency letters answers issued by the Health Authorities, regarding AS&T topics.
- Support and conduct analytical investigation activities according to the demand, in compliance with local and global procedures, applying properly quality tools in order to identify the root cause and ensuring the implementation of preventive/corrective actions.
- Collaborate and act actively on the housekeeping program, maintaining the lab clean, organized, standardized, and identified according to 6S methodology.
- Keep equipment and analysis bench in perfect condition before and after each analysis, following quality standards and cleaning procedure, assuring the usage of solutions and laboratories supplies within shelf-life.
- Ensure adherence to ALCOA+ principles during routine analysis and zero analytical deviation attributed to Data Integrity.

Key performance indicators:

- Plan, perform and follow up on processes, procedures, and activities related to analytical method validation, forced degradation studies, Third Party Laboratory Studies (REBLAS) and transfer activities to support launches and post-approval variations to all countries onboarded at AS&T.
- Prepare and update policies, standard operational procedures and work instructions guaranteeing safe, reproducible, and compliant processes in line with regional and global health authority and corporate standards.
- Collaborate in the compliance with local and global performance indicators and implement the corresponding actions and / or remediation plans when necessary.
- Meet the Health, Safety and Environment guidelines and policies, as well as the ones for Information Security Risk Management, Good Laboratory Practices, Good Documentation Practices and Data Integrity principles.

Minimum Requirements:
Work Experience:

- A bachelor ' s degree related to the pharmaceutical area, Chemical or biological, titled with a professional license.
- Desirable knowledge of Lean, Six Sigma, computerized systems related to the pharmaceutical industry.
- Proven experience in the Pharmaceutical Industry (minimum 5 years of experience).
- Previous experience in Development and Analytical Method Validation.
- Desirable experience in key areas such as Quality Assurance, Quality Control, Stability or Analytical Services.
- Knowledge in quality systems, risk management and application of local and international sanitary regulation.
- Desirable experience in project management and budget control.

Skills:

- Solid knowledge in Good Laboratory Practices (GLP) and Good Manufacturing Practices (GMP).
- Solid knowledge in Analytical Method Validation.
- Statistical knowledge for the evaluation of analytical results.
- Knowledge in the use of pharmacopoeias such as USP, EP, BP, JP, etc. Local and international requirements.
- Knowledge of local, regional and international regulatory standards, such as ANVISA, ICH, FDA, EMA, ANMAT.
- Extensive experience in physicochemical analysis of finished product.
- Knowledge in quality system, such as change control, deviation investigation, OOS, OOT and OOE in the laboratory.
- Knowledge in CFR 21 part 11 and data integrity.
- Knowledge in quality system

Languages :

- English conversation, listening and writing at an advanced level.
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部门
Operations

Business Unit
Innovative Medicines

地点
Brazil

站点
Guido Caloi

Company / Legal Entity
BR03 (FCRS = BR003) NOVARTIS BIOCIENCIAS S.A

Functional Area
Quality

Job Type
Full time

Employment Type
Regular

Shift Work
No

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