

Validation Expert

Job ID
REQ-10028115

11月 07, 2024

Spain

摘要

The Validation Expert executes and manages process, primary packaging, and cleaning validation activities and change management activities to meet cGMP requirements on time and quality to ensure that site validation programs are compliant with global regulatory expectations.

Work location: La Almunia de Doña Godina (Zaragoza).

About the Role

Major accountabilities:

- Support site validation planning by writing and maintaining master plans for processes, cleaning, packaging processes and ongoing verification for processes and cleaning.
- Support process validation lifecycle activities by ensuring a state of control is maintained through ongoing process verification (OPV). Ensure that appropriate variables are identified

for on-going monitoring as a contributor to quality risk management activities.

- Author and review process, packaging or cleaning validation protocols & reports, ongoing process and cleaning verification protocols & reports.
- Support execution of validation activities at the shop floor. Support validation lead for KPI reporting.
- Reviews Master Batch Records and associated change controls. Confirm revalidation need based on technical changes.
- Maintain all activities and projects under own responsibility in an inspection ready status.
- Provides technical expertise (and may facilitate) pre-validation risk assessments using risk management tools.
- Work collaboratively and cross functionally to help ensure that process risks are analyzed, appropriately controlled and appropriately documented.
- Ensure that all Site validation activities are performed and are in line with the current Novartis requirements and cGMP, manage deviations associated with process validation and makes recommendations for deviation resolution as well as prevention of reoccurrence.

Minimum Requirements:

Work Experience:

- Education: BSc. in Chemistry, Pharmacy, Chemical Engineering or Pharmaceutical Technology.
- 2-3 years of experience in manufacturing/ manufacturing science and technology/technical development/quality.
- Thorough understanding of manufacturing processes and related process equipment.
- Strong working knowledge of quality systems and regulatory requirements across multiple health authorities.
- Experience in executing process validation and reviewing and writing technical reports.
- Proven project management experience in a cross-functional environment (e.g. multi-site, technical development, other functions).
- Fundamental understanding of standard pharmaceutical analytical testing.
- Fluent in English and Spanish, written and spoken.

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部门

Operations

Business Unit

Innovative Medicines

地点

Spain

站点

Zaragoza

Company / Legal Entity

ES45 (FCRS = ES045) AAA Ib é rica S.L.U.

Functional Area

Technical Operations

Job Type

Full time

Employment Type
Regular

Shift Work
No

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