ATMP Quality Assurance Lead

Job ID
REQ-10038258

Jan 27, 2025

Spain

Summary

The ATMP QA is responsible for the management of ATMP QA Batch Preparation Hub team to leverage preparation process for ATMP products, ensuring compliance with cGxP and Marketing Authorization Holders (MAHs). In this role the QA Lead ensures that release preparation activities, executed by team, are performed in a timely and proper manner to reach customer satisfaction and drives innovation and operational excellence projects that will yield standardization and efficiency gains within ATMP QA team and with stakeholders, NCQ, Supply Chain Management.

About the Role

Major accountabilities:

- Support of the Qualified Person(s) in the field of ATMPs (commercial goods and clinical investigational preparations) as well as in the supervision of clinical trainees in accordance with §3 of the Licensing Regulations for Pharmacists

- Compilation and preliminary review of documents from databases
- Execution of the batch record review of the manufacturing documentation
- Compliance with GxP requirements and other legal regulations in EU as well as participation or implementation of GxP training / SOP training
- Contacts/exchange of information with national and international functions (including CGT US, CGT CH, QA, supply chain, responsible persons in the countries, depot)
- Archiving of documents for clinical investigational medicinal products
- Creation & updating of standard operating procedures (SOPs)
- Evaluation of pharmaceutical product complaints, documentation and evaluation of deviations
- Preparation and maintenance of quality accrual agreements
- Regular contacts with Novartis manufacturing companies and third-party manufacturers
- Participation in audits and inspections
- Ensure that the EU Release Preparation HUB team operates in an efficient and innovative manner. Drive implementation of productivity improvement and implementation of best practices and efficiency projects.

Minimum Requirements:

- Degree in Pharmacy preferred, or related Health Care degree.
- At least 5 years of demonstrated experience in pharmaceutical industry, in manufacturing, QA and QC. Preferable certified as Advanced Therapy Medicinal Products (Cell & Gene Therapy) Qualified Person.
- Analytical thinking, flexibility in cooperation with other functions, national organizations, as well as the ability to solve problems.
- Fluent English, written and spoken.

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Commitment to Diversity and Inclusion: 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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部門
Operations

部門
Innovative Medicines

国
Spain

勤務地
Barcelona Gran V í a

Company / Legal Entity
ES06 (FCRS = ES006) Novartis Farmac é utica, S.A.

Functional Area
Quality

職種
Full time

雇用形態
Regular

Shift Work
No

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