

ATMP QA Release Officer

Job ID
REQ-10038249
jan 28, 2025
Espagne

Résumé

The ATMP QA Release Officer assists the Qualified Person in maintaining and developing the quality assurance system and is responsible for the preparation and review of relevant documents in the context of the release of medicinal products by the Qualified Person.

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.
- 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.

Minimum Requirements:

- Education: Degree in Pharmacy preferred, or related Health Care degree.
- At least 2 years of demonstrated experience in pharmaceutical industry, in manufacturing, QA and QC. Preferable experience in Advanced Therapy Medicinal Products.
- Analytical thinking, flexibility in working with other functions, country organizations, as well as the ability to solve problems.
- Organizational talent, persuasiveness and the ability to communicate across departments (also internationally).
- Fluent English and Spanish, 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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Division

Operations

Business Unit

Innovative Medicines

Emplacement

Espagne

Site

Barcelona Gran Vía

Company / Legal Entity

ES06 (FCRS = ES006) Novartis Farmacéutica, S.A.

Functional Area

Qualité

Job Type

Full time

Employment Type

Regular

Shift Work

No

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