

## ATMP QA Release Officer

Job ID  
REQ-10045356

3月 21, 2025

Spain

### 摘要

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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部门  
Operations

Business Unit  
Universal Hierarchy Node

地点  
Spain

站点  
Barcelona Gran V í a

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

Functional Area  
Quality

Job Type  
Full time

Employment Type  
Regular

Shift Work  
No

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