

Quality Assurance Specialist

Job ID
REQ-10013347
Jun 27, 2024
Spain

Summary

The Quality Assurance Specialist manages Quality aspects and projects within area of responsibility. Ensures and supports overall GxP conformity and Compliance with the Novartis Quality Management Systems. The QA Specialist also ensures that product arrives to market in conformity of MA and GMP requirements.

About the Role

Major accountabilities:

- Conduct GxP monitoring on all sections, conduct QA investigation for noncompliance, Follow up the corrective actions. Archive relative documentations.
- Ensure that a local Quality System and Standard Operating Procedures are in place for all cGMP/GDP related activities and that compliance with cGMP/GDP regulations is maintained through training and internal audits.
- Ensure that all aspects of the handling and distribution of pharmaceutical products in the country comply with the requirements of the Novartis Quality Manual and Policies and meet all relevant cGMP regulatory and legislative requirements. Evaluation of the transport of commercial medication and assessment in case of temperature excursions.
- Ensure that all incoming drug products are inspected prior to release to the market in accordance with the current in place procedures, registered specifications and with local/international regulations.
- Perform DoCC according to current PPMS as well as review of batch documentation from plant and other associated documents (deviations, notifications, etc.). Initiation and obtaining and approval of the EU Batch Certificate for corresponding registered QP.
- Perform the oversight of complaints, recalls, counterfeits and product tampering according to the Novartis Corporate Quality Manual and local written procedures.
- Management and prioritization of emergencies and releases. Ensure SLC implementation in conjunction with Supply, DRA and other related departments.
- Management of the repackaging of commercial batches according to GMPs.

Obligatory requirements:

- Education: Pharmacy, Biotechnologist, or any other health care degree.
- 2-3 years of experience in Quality Assurance, Quality Control and/or Manufacturing Operations,
- Solid knowledge of GMP regulations.
- Fluent English and Spanish, written and spoken.

Why Novartis:

Our purpose is to reimagine medicine to improve and extend people's lives and our vision is to become the

most valued and trusted medicines company in the world. How can we achieve this? With our people. It is our associates that drive us each day to reach our ambitions. Be a part of this mission and join us! Learn more here: [https://www.novartis.com/about/strategy/people and culture](https://www.novartis.com/about/strategy/people-and-culture)

You'll receive: You can find everything you need to know about our benefits and rewards in the Novartis Life Handbook. [https://www.novartis.com/careers/benefits rewards](https://www.novartis.com/careers/benefits-rewards)

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.

Join our Novartis Network:

If this role is not suitable to your experience or career goals but you wish to stay connected to hear more about Novartis and our career opportunities, join the Novartis Network here:
<https://talentnetwork.novartis.com/network>

Why Novartis: Helping people with disease and their families takes more than innovative science. It takes a community of smart, passionate people like you. Collaborating, supporting and inspiring each other. Combining to achieve breakthroughs that change patients' lives. Ready to create a brighter future together?
<https://www.novartis.com/about/strategy/people-and-culture>

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<https://talentnetwork.novartis.com/network>

Division

Operations

Business Unit

Innovative Medicines

Location

Spain

Site

Barcelona Gran Vía

Company / Legal Entity

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

Functional Area

Quality

Job Type

Full time

Employment Type

Regular

Shift Work

No

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