PART-TIME Quality Manager & Qualified Person GMP

Job ID
392597BR
Abr 24, 2024
Czech Republic

About the Role

Quality Manager/Qualified Person GMP
Location: Novartis, Prague, Czech Republic #LI-Hybrid
PART-TIME role

About the Role:
• Assurance that the product quality conforms with specifications and that production activity is compliant with Novartis quality policy and GxP requirements.
• Ensure that relevant documentation is up-to-date and archived correctly. Ensure “state of the art” GxP know-how and future trends in the field of GxP
• Perform role of local Qualified Person listed on Novartis GMP license namely in scope of performance of batch confirmation for all imported batches in compliance with requirements arising from the Act No. 378/2007 of Coll., §66, as amended and oversighting batch certification by EU QP after importation to the Country

Key Responsibilities:
• Ensure that all aspects of the handling, manufacturing and distribution of biopharmaceutical / pharmaceutical products are in compliance with the Novartis Quality Manual, the effective Quality Agreement that they meet relevant GxP regulatory requirements and are conducted according to local SOPs.
• Review and check the batch documentation for correctness, completeness and safely archive the original documents for the prescribed period and plan, conduct and monitor self-Inspection schemes for all sections. Monitor actions and corrections accordingly.
• Conduct GxP monitoring on all sections, conduct QA investigation for noncompliance, follow up the corrective actions. Archive relative documentations and manage/Approve critical quality issues (deviations, complaints, recalls, counterfeits and product tampering, stability failures, etc.) according to the Quality Agreement and the Novartis Quality Manual. Ensure investigations are correctly executed. Ensure all required actions are taken appropriately and in a timely fashion.
• Escalate any issues or instances of instability per the Novartis escalation policy, and initiate any market action that is required. Decide escalation to Senior Management Level and lead Global Quality Assessments and manage filing accordingly as well as ensure that Change requests, are managed according to the Novartis SOPs from receipt, through to the implementation and closure.
• Responsible for assessing quality trends and driving continuous improvement for processes and product quality performance and maintain access to regulatory and Health authorities in respect to up-dated GxP Provide latest know how in the field of GxP and other quality related fields. Identify repetitive activities and regulatory areas for which SOPs are required. Initiate the introduction of SOPs.
• Plan, initiate and monitor basic GxP-training for all employees in regular intervals. Be responsible for

annually training program and implementation.
• Establish and maintain cross-functional contacts with peer organization and authorities and, follow-up quality related developments in the field of Pharmaceutical products.
• Support launches of product in close collaboration with Business and/ or development organization.
• Ensure that all drug products are released to the market in accordance with local/international regulations.
• Ensure that coordinated contact is maintained with all parties (the Regulatory Authorities, the local partners and stakeholders and Global QA.)
• Reporting of technical complaints / adverse events / special case scenarios related to Novartis products within 24 hours of receipt.
• The Qualified Person of a manufacturer of medicinal products for human use (QP GMP) shall ensure that the requirements arising from the Act No. 378 / 2007 of Coll., § 66, as amended, are fulfilled namely in scope of importation as per Novartis set up.
- The Qualified Person of a manufacturer of medicinal products for human use is responsible for routine check of documentation related to product inspection in the warehouse, check of artwork compliance, the temperature records and performance of batch confirmation prior to certification by EU QP in a register or equivalent IT system suitable for that purpose and keep up-to-date with the activities carried out and appropriately archived.
- Professional services of Qualified Person GMP are performed in the premises of Novartis s.r.o., Gemini, budova B, Na Pankráci 1724/129, 140 00 Praha 4 and Novartis warehousing facility at Movianto Česká republika s.r.o., Podolí 78e, 664 03 Podolí.

Diversity & Inclusion / EEO

We are committed to building an outstanding, inclusive work environment and diverse teams representative of the patients and communities we serve.

Role Requirements

Essential Requirements:

1. Minimum acceptable degree: according to requirements of the Act on Pharmaceuticals No. 378/2007 of Coll., §65, i.e. regularly completed academic study which provides academic education including at least 4 years of theoretical and practical education in one of the following fields of education:
• pharmacy – field of study: pharmacy,
• general medicine, dentistry, or stomatology,
• veterinary medicine or veterinary hygiene and ecology,
• chemistry, or
• biology.

2. GMP qualified person should have completed at least a two-year practice at one or more manufacturers of medicinal products in the following fields:
• qualitative analyses of medicinal products,
• quantitative analyses of medicinal products and
• testing and control required for quality assurance of medicinal products.

Desirable Requirements:

• Experience in pharmaceutical company (e.g. QA, RA, SCM, R&D) on top of above mentioned minimum two-years practice at one or more manufacturers of medicinal products is an advantage.

• Fluent in local and English language
• Collaborating across boundaries Functional Breadth; Operations Management and Execution
• Being resilient Operational Excellence; Project Excellence; Flexibility
• Product Release Quality Assurance Quality Change; Control Quality Management; Regulations & Guidelines; Risk Management

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

Join our Novartis Network:

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

Accessibility and accommodation:

Novartis is committed to working with and providing reasonable accommodation to all individuals. If, because of a medical condition or disability, you need a reasonable accommodation for any part of the recruitment process, or in order to receive more detailed information about the essential functions of a position, please send an e-mail to and let us know the nature of your request and your contact information. Please include the job requisition number in your message.

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

Join our Novartis Network: Not the right Novartis role for you? Sign up to our talent community to stay connected and learn about suitable career opportunities as soon as they come up: https://talentnetwork.novartis.com/network

División
Operations
Business Unit
QUALITY
Ubicación
Czech Republic
Sitio
Prague
Company / Legal Entity
NOV CZE
Functional Area
Quality
Job Type

Part Time
Part Time percentage
50
Employment Type
Temporary
Shift Work
No
Apply to Job Access Job Account
Job ID
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PART-TIME Quality Manager & Qualified Person GMP

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