EU RLT Drug Product Compliance Lead

Job ID
REQ-10003277
Mai 15, 2024
Espagne

Résumé

~ Liderar la función de control de calidad, asegurando así que todos los procesos y procedimientos, tareas, responsabilidades y proyectos cumplan con todas las leyes farmacéuticas, el Manual de Calidad y las Políticas de Novartis, así como las Mejores Prácticas de la Industria. Este rol comprende requisitos especiales de GxP y debe ejecutarse de acuerdo con estos. Asegurar que todos los procesos relevantes para la calidad sean conformes y que el incumplimiento se aborde adecuadamente a través de acciones correctivas y preventivas (CAPA) y / o escalamiento de problemas.

About the Role

Major Accountabilities

- Ensure implementation of applicable Quality Standards and governance processes through the implementation of the Novartis Quality Manual and Policies.
- Ensure that regulatory controls are in place in relevant process steps -Ensures adherence to GxP, any further legal and company internal regulations for manufacturing, control and distribution operations and to HSE guidelines and requirements -Ensure implementation of defined Key Quality Indicators in the area of responsibility to monitor on an on-going basis that relevant processes are in control and compliant.
- Ensure regularly review and assessment of KQIs at the Leadership Team level.
- Ensure adequate escalation of issues and support their timely resolution and provide quality oversight for deviations and ensure that adequate corrective and preventive actions (CAPA's) are implemented.
- Provide quality oversight for planned changes.
- Ensure adequate regulatory inspection preparation, management and follow-up in the area of responsibility.
- Ensure communication with local Health Authorities is adequately shared within the organization and commitments tracked and closed on time.
- Ensure implementation of adequate training within the area of responsibility for all GXP activities by defining, planning and supporting training activities.
- Ensure that processes are in place to communicate country specific requirements to the Region and headquarter organizations for all GXP areas and assess their implications for the compliance of existing processes and systems.
- Initiate remediation activities, as necessary, to ensure ongoing compliance.
- Ensures adequate processing of complaints.
- Establishes an efficient recall organization as well as ensure development of talent within the local Quality unit.
- Develop adequate succession candidates for the Quality organizations.

Essential requirements:

- Education: Bachelors of Science in related field
- 5-7 years of experience in Quality Assurance and and Management
- Excellent project management skills and operations management/execution
- Solid leadership skills
- Fluent English, written and spoken, other languages are a plus.

Why Novartis:Our purpose is to re-imagine 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

Novartis is focused on delivering high-value medicines that address society's most pressing disease burdens. Our aim is to create long-term value by contributing to advances in human health, delivering returns to shareholders, and benefiting society.

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