Global Head TRD QA Drug Delivery Systems

Job ID
REQ-10062143

9月 15, 2025

Switzerland

摘要

Location: Basel, Switzerland OR Schaftenau, Austria

Role Purpose:
Leads the global TRD QA Drug Delivery Systems organization ensuring optimal execution of assigned business deliverables and the development and implementation of TRD QA overall strategic vision.

Drives quality and compliance across the respective TRD functions to ensure on-going compliance with all relevant regulations for medicinal products and Novartis policies & standards. Ensures close alignment with partners in TRD, RDQ and Novartis Operations. Holds GMP standards high, while supporting GDP (Good Development Practices) concepts and workflows in the TRD GDPD labs and plants.

The Global Head Quality Drug Delivery is accountable for the quality oversight of activities associated with technical development and commercialization of drug delivery systems including Medical Devices and Software as Medical Devises (SaMDs) for all New Biological Entities (NBEs), New Chemical Entities (NCEs) and Biosimilars (BS).

Is accountable for all Medical Device activities associated with ISO certification and CE marking of devices within the responsibility of Novartis Pharma AG, according to the definition of ISO 13485 and the EU Medical Device Regulation. Responsible for setting directions, coordinating functional objectives and monitoring processes in all GDD and NTO Novartis groups.

Leads different groups within different legal entities and on different global locations (CH, AT, IN) to ensure technical development and manufacturing operations (end to end) of strategic Drug Delivery Systems are conducted in accordance with Novartis Quality System requirements, ensuring high product quality, regulatory compliance and operational efficiency.

About the Role

Main Responsibilities:

- Direct operational & functional leadership of the TRD QA DDS platform supporting over 100 development projects from early phase until commercialization. Ensuring all development projects are in line with regulatory and internal design control standards as well with applicable quality requirements.
- Responsible for the deployment and execution of the Quality and Compliance operational strategy related to Drug Delivery System regulations, and is accountable for effective use of resources within the sub functional areas on multiple locations to ensure uninterrupted development and supply of strategic products. He/she contributes to function leadership and / or site leadership team providing quality governance in compliance with national and international GxP device regulations.
- Accountable for cross-division Medical Device Quality Governance to ensure alignment in the implementation of the medical device quality strategy for Novartis. Accountable for GMP oversight in the TRD device analytical labs and the TRD assembly pilot plant in AT
- Ensure implementation and maintenance of all required Medical Device Management Reviews for all development products in accordance with cGMP, legal & regulatory requirements and the Novartis Corporate Quality Manual.
- Manage quality problems and technical matters for the assigned DDS product portfolio to ensure they are resolved consistently and in accordance with global standards and policies.
- Responsible for Drug Delivery System quality risk management, through proactive risk management tools and approaches, to minimize impact on global launches, supplies and patients.
- Ensure successful inspections and audits outcome at development sites and support regulatory inspections of manufacturing sites involved in DDS manufacturing, testing and assembly.
- Accountable for the escalation of quality & compliance issue associated with Drug Delivery Systems to management in accordance to Novartis global requirements and drive the implementation of remediation actions in a timely and robust manner.
- Responsible for product assessments, Medical Device Reporting and recall activities per the global standards and policies. Manage communication and interface with external contacts were appropriate: Industry, Novartis, and Health Authorities. External interaction with national and national regulatory bodies (e.g. European Medicines Agency (EMA), Food and Drug Administration (FDA) and Notified Bodies (NBs) mainly require interpretation of complex

information; internal interaction requires negotiation with and persuasion of function leadership and site management team.
- Participate in external working groups or standards setting organizations to influence the global regulatory and/or technical requirements affecting Drug Delivery Systems.
- Survey the industry through benchmarking efforts, internal surveys, and best-practice networks to identify emerging trends and best quality practices, in order to drive implementation within GDQ and NTO Quality.
- Support and ensure compliance for major Due Diligence and Integration projects for Drug Delivery Systems

Education (minimum/desirable):

Bachelor (> 10 years ' pharma quality or operations)

Masters (> 5 years ' pharma quality or operations)

Languages:

Fluent English required (oral & written). Good skills in site (local) language desired (oral).

Experience/Professional requirement:

- > 15 years broad experience in Pharmaceutical Industry and/or Health Authority experience.
- Expert knowledge of Drug Delivery System quality requirements.
- Operational experience in manufacturing, QA/QC management, technical development or other relevant experience.
- High expertise in development / manufacturing and Health Authority interaction, i.e. Swissmedic, EMA, FDA, Notified Body. Strong interpersonal skills, including diplomacy and persuasion, used in obtaining cooperation and consensus with Novartis stakeholders and external partners.
- Sound practical judgement in the interpretation and application of regulations and standards.

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.

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 inclusion.switzerland@novartis.com and let us know the nature of your request and your contact information. Please include the job requisition number in your message.

For Austrian applicants:

Adjustments for Applicants with Disabilities: If because of a medical condition, physical disability or a neurodiverse condition you require an adjustment during the recruitment process, please reach out to disabilities.austria@novartis.com and let us know the nature of your request as well as your contact information. The support which we can provide will include advice on suitable positions as well as guidance at all stages of the application process. Austrian law provides candidates the opportunity to involve the local disability representative, Behindertenvertrauensperson (BVP), in the application process. If you would like to request this, please let us know in advance as a note on your CV.

In accordance with Austrian law, we are obliged to disclose the minimum salary as stated in the collective bargaining agreement. For this position the minimum salary is €85,704.64 EUR/year (on a full time basis). The actual salary will be significantly higher, as we strive to maintain a competitive position in the market and consider your previous experience, qualifications and individual competencies

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

Benefits and Rewards: Read our handbook to learn about all the ways we ' ll help you thrive personally and professionally: https://www.novartis.com/careers/benefits-rewards

部门
Development

Business Unit
Innovative Medicines

地点
Switzerland

站点
Basel (City)

Company / Legal Entity
C028 (FCRS = CH028) Novartis Pharma AG

Alternative Location 1
Schaftenau, Austria

Functional Area
Quality

Job Type
Full time

Employment Type
Regular

Shift Work
No

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