

Global QMS RDQ Senior Specialist

Job ID
REQ-10024965
Oct 13, 2024
India

Summary

-Ensure and support overall GxP conformity and compliance with the Novartis Quality Manual, the law and other policies / procedures in processes like e.g. document management, change control system, training, escalation management, risk management, qualification / validation and CSV

About the Role

Global QMS RDQ Senior Specialist

About the Role:

As an experienced specialist drive efficiency and productivity gains through contributing to the implementation of new processes to administer a validated Global Learning Management System (LMS) covering multiple GxP areas in full alignment with Development and QA business goals and strategic objectives.

Management of GDD GxP Training content in LMS achieving full regulatory training compliance.

Key Responsibilities:

- Manage user accounts for global Development Global Learning Management System (LMS)
- Release training assignments in the LMS based on applicability's in STAR
- Update STAR and LMS as per LF Request (Applicability's Change Request process)
- Training systems document maintenance
- New/Remove/Update Roles in STAR and LMS
- Provide technical or administrative support for users
- Maintain access to LFRC and LFAR upon request
- Adhere to the global LMS Admin guidelines
- Ensure harmonization of LMS usage in global Development
- Perform validation activities – Validation Report, QC of releases, etc
- Brings up in a timely manner any Level 2 issues related to the LMS
- Be a role model for the Novartis values and behaviors and support the journey towards an inspired, curious, unbossed and self-aware organization
- Seek and implement opportunities for improving efficiency and effectiveness in our training system.

Essential Requirements:

- Significant relevant work experience (> 5 years) in the pharmaceutical industry or public health sector, in the area of Quality, Human Resources or Training.
- Demonstrated knowledge in implementing/managing robust Document management systems and

Learning Management Systems, setting global quality controls in a regulated area

- Sound understanding of regulated activities, health authority expectations, and GxP, paired with good business understanding.
- Role model for the Novartis values and behaviours and exemplary interpersonal skills
- Excellent leadership, interpersonal, communication, negotiation and problem solving skills
- Ability to innovative when faced with opportunities or challenges.
- Ability to influence and drive/facilitate change across the organization.

Desirable Requirements:

- Bachelor/Technical degree in Life Sciences or related fields. Advanced degree and/or MBA an advantage

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>

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>

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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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>

Division

Development

Business Unit

Innovative Medicines

Location

India

Site

Hyderabad (Office)

Company / Legal Entity

IN10 (FCRS = IN010) Novartis Healthcare Private Limited

Functional Area

Quality

Job Type

Full time

Employment Type

Regular
Shift Work
No
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Accessibility and accommodation

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

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

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