NOVARTIS

Senior Technical Steward Medical Devices

Job ID
REQ-10068590
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Индия

Сводка

The Senior Technical Steward Medical Devices provides his knowledge in medical device manufacturing and all related manufacturing activities like molding and device assembly to the global and local stakeholders. This role is pivotal in driving technical excellence, ensuring compliance, and advancing Novartis device strategy through deep process knowledge, supplier management, and cross-functional collaboration.

About the Role

Senior Technical Steward Medical Devices

Location – Hyderabad #LI Hybrid

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Key Responsibilities:

- Own and maintain deep knowledge of specific medical device manufacturing process technologies, including pilot scale operations, scale-up/down activities, and Design of Experiments (DoE).
- Act as an expert in molding of device constituent parts; oversee injection molding tool design, qualification, life-cycle management, and performance monitoring at external manufacturing sites.
- Provide expertise in autoinjector device and sub-assembly manufacturing processes to ensure robust and compliant operations.
- Support Technical Steward in device development projects by assessing scalability of new devices transitioning from development to commercial manufacturing phases.
- Advise Technical Stewards on initial qualification and life-cycle maintenance of injection molding machine toolsets and related activities to advance Novartis' Device Strategy. Ensure accurate and thorough review of technical documentation packages during development handover by applying your technical expertise.
- Ensure adherence to current industry practices, regulatory and quality guidelines, and standards for injection molding and component assembly; apply this knowledge in line qualification and product validation activities.
- Leverage understanding of the molding and assembly supplier landscape to maintain and transform it into a future-ready, robust supplier network.
- Deliver fundamental technical knowledge through regular training and education programs for Process Experts and Operators. Spearhead process and operational excellence initiatives to enhance combination product quality, reliability, and reduce risks and costs.
- Collaborate with technical development teams, other sites, and the global MS&T network to enable effective transfer of technical knowledge. Conduct technical feasibility trials to support process improvements and implementation of new manufacturing technologies.

Commitment to Diversity & Inclusion:

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

Essential Requirements

- Exposure to ISO 13485, 21 CFR Part 4 and FDA validation guidelines.
- Bachelor's or Master's degree in Mechanical Engineering, Chemical Engineering, or a related discipline.
- Approximately 10 years of experience in combination products development or operations.
- Previous experience in pharmaceutical, biotechnology or engineering environments.

Strong working knowledge of GMP manufacturing principles.

Desirable Requirements

- Proven experience in outsourcing and managing strategic device partners.
- Demonstrated project management experience in combination products.
- Fluency in English (written and spoken) is essential.
- Advanced understanding of mechanical design principles, assembly process expertise and design standards, including proficiency in CAD software (e.g., SolidWorks) for e.g. injection device development and manufacturing).

- Strong interpersonal and negotiation skills, with a proven ability to build effective relationships and influence outcomes.

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

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

Benefits and Rewards: Learn about all the ways we'll help you thrive personally and professionally.
Read our handbook (PDF 30 MB)

Дивизион
Operations
Business Unit
Other
Место
Индия
Сайт
Hyderabad (Office)
Company / Legal Entity
IN10 (FCRS = IN010) Novartis Healthcare Private Limited
Alternative Location 1
Ljubljana, Словения
Alternative Location 2
Schaftenau, Австрия
Functional Area
Technical Operations
Job Type
Full time
Employment Type
Regular
Shift Work
No

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 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.

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