NOVARTIS

MS&T Specialist (Medical Device)

Job ID
REQ-10080475
Jun 12, 2026
LOC_IN

About the Role

Major accountabilities:

- Support technology transfer, prepare & maintain Novartis medical device's technical documents including Design History Files (DHF), Risk Assessment, Post-Market Surveillance (PMS) documents.
- Prepare & maintain Device Master Record (DMR), identify the gaps using manufacturing expertise, provide recommendations in compliance with the applicable standards (ISO, FDA, MDR, etc.,).
- Prepare and update post market surveillance (PMS) plan, related activities & report for medical devices.
- Collect, analyses and present data using appropriate visualization tool (e.g., Power BI) to support report preparation.
- Perform Data Administrator (DA) and Data Integrity (DI) check as per requirements.
- Initiate, manage and contribute to the Change Control process in management tools.
- Handling of SaMD activities. Maintaining documents related to SaMD (Distribution file, impact assessment of changes to SaMD distribution.). Collecting information related to regulatory compliances and co-ordinating with third-party manufacturer and business owner.
- Create and review GxP documents including SOPs, working procedures, trend reports, qualification reports and technical investigations, as and when needed.
- Provide active support during internal and external audits by collecting and presenting the requested process/data and reports.
- Support implementing service quality and process improvement projects, CAPA management within global operations Centers.
- Ensure compliance with the Novartis internal quality standards, relevant regulatory requirements, filed product quality standards and service level agreements.

Essential requirements:

- Scientific degree.
- Previous experience within the Medical Device/Pharmaceutical environment in a multinational organization.
- Data analysis/business intelligence expertise (e.g. Power BI, Excel, Minitab).
- Fluent in English.

Commitment to Diversity and Inclusion

Novartis is committed to building an outstanding, inclusive work environment and diverse team 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.

Role Requirements

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)

Division
DIV_TO
Business Unit
Production / Manufacturing
Location
LOC_IN
Site
Hyderabad (Office)
Company / Legal Entity
IN10 (FCRS = IN010) Novartis Healthcare Private Limited
Functional Area
FCT_TO
Job Type
Full time
Employment Type
Regular
Shift Work
No
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