

Specialist - MS&T (Medical Devices)

Job ID
REQ-10072784

3月 02, 2026

India

摘要

The purpose of the role is to be responsible for managing medical device service aspects focused to ensure accurate and timely preparation and maintenance of medical device technical documents, in accordance with cGMP (Current Good Manufacturing Practices), the Quality Assurance Agreement, regulatory requirements, the Novartis Quality Manual and is conducted according to the relevant Standard Operating Procedures and agreed between MS&T NOCC and business partners within Operations network.

About the Role

Key Responsibilities:

- 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.
- Assist the department to any other ad hoc activities/ requests to meet the business requirements
- 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:

- Quality / Accuracy / Right First Time
- Timeliness
- Deviations / Escalations

Specific Professional Competencies

- Good Documentation Practices
- Risk Analysis
- Post-market Surveillance
- Technical Documentation maintenance for medical devices
- Gap assessment
- Technology Transfer
- Report writing
- Data Analytics

- Change Control Management
- Project Management Skills

Desirable Requirements:

Subordinate Functions:

N/A

Number of Associates:

Direct: N/A

Indirect: N/A

Financial responsibility (where appropriate):

N/A

Impact on the organization (where appropriate):

N/A

Ideal Background:

Education:

Pharmacy/ Science/ MBA / Engineering/ equivalent from a reputed institute

Languages:

Fluent in English (written and spoken)

Experiences:

- Min 6 years of experience in MS&T, medical devices, Quality Assurance, Regulatory or in the manufacturing of pharmaceutical drug products
- GxP knowledge, Broad IT knowledge and Proficient in MS-Office
- Excellent communication, presentation, interpersonal and analytical skills
- Experience of working closely with the global stakeholders
- Project Management skills

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 \(PDF 30 MB\)](#)

部门

Operations

Business Unit

Production / Manufacturing

地点

India

站点

Hyderabad (Office)

Company / Legal Entity
IN10 (FCRS = IN010) Novartis Healthcare Private Limited

Functional Area
Technical Operations

Job Type
Full time

Employment Type
Regular

Shift Work
No

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function adjustKalturaPlayer() { var deviceWidth = window.innerWidth ||
document.documentElement.clientWidth || document.body.clientWidth; var mediaElement =
document.getElementById("kalturaplayer69a567c5a08bd137200980"); var mediaContainer =
mediaElement.closest('.nc-kaltura-media'); var originalWidth = "1200px"; var originalHeight = "674px";
var originalWidthValue = parseFloat(originalWidth); var originalHeightValue =
parseFloat(originalHeight); var mediaType = "video"; var isResponsive = false; // Get computed styles
of the container element. var parentStyles = window.getComputedStyle(mediaContainer); var
finalWidth = parseFloat(parentStyles.width); if (finalWidth  var config = { targetId:
"kalturaplayer69a567c5a08bd137200980", provider: { widgetId: "10m7rm1pm", partnerId:
"2076321", uiConfId: "55802022" }, playback: { autoplay: false, autopause: false,
allowMutedAutoPlay: false, loop: false }, sources: { options: {}, startTime: 0 }, plugins: { download: {
disable: true }, "playkit-js-transcript":{ position: "right", // Default: bottom;( ' left ', ' right', ' top ', 'bottom' ) to
enable transcript. expandMode: "over", // Default: alongside;( ' alongside', ' hidden ', 'over' )
expandOnFirstPlay: false, showTime: true, downloadDisabled: false, printDisabled: false, disable:
true } }, ui: { showCCButton: false, settings: { showQualityMenu: true, showSpeedMenu: false },
components: { fullscreen: { disableDoubleClick: false } }, uiComponents: [ { presets: ['Playback',
'Live'], area: 'BottomBarRightControls', replaceComponent: 'Fullscreen', get:
KalturaPlayer.ui.components.Remove } ] } }; config.plugins.preventSeek = { preventSeekForward:
false, preventSeek: false }; config.plugins.floating = { disable: true }; config.plugins.navigation = {
position: "right", expandMode: "over", expandOnFirstPlay: false, visible: false }; config.plugins['playkit-
js-hotspots'] = { disable: true }; config.plugins['playkit-js-moderation'] = { disable: true };
config.plugins['playkit-js-info'] = { disable: true }; config.plugins.share = { disable: true };
config.ui.uiComponents = []; config.plugins.googleTagManager = {};
config.plugins.googleTagManager.customEventsTracking = {};
config.plugins.googleTagManager.containerId = 'GTM-57RJQ5';
config.plugins.googleTagManager.customEventsTracking.custom = [];
config.plugins.googleTagManager.customEventsTracking = { preset: { coreEvents: true, UIEvents:
false, playlistEvents: false, castEvents: false } };
```

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try { var kalturaPlayer = KalturaPlayer.setup(config); // Add the player to the global array. if (typeof kalturaPlayerVideos !== 'undefined') { kalturaPlayerVideos.push(kalturaPlayer); } else { var kalturaPlayerVideos = []; kalturaPlayerVideos.push(kalturaPlayer); } // Load the Player for other media. kalturaPlayer.loadMedia({entryId: "1_dgfvmafo"}); setTimeout(() => { setupAutoPause(kalturaPlayerVideos); }, 500); function setupAutoPause(players) { players.forEach((currentPlayer) => { currentPlayer.addEventListener('play', () => { players.forEach((otherPlayer) => { if (otherPlayer !== currentPlayer && typeof otherPlayer.pause === 'function') { otherPlayer.pause(); } })); }); }); } catch (e) { console.error(e.message) }
```



VIDEO

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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