

Associate Director Medical Writer

Job ID
REQ-10070371

2月 04, 2026

Spain

摘要

The Associate Director Medical Writer champions preparation of high standard global Aggregate Reports (i.e. periodic safety reports (PSUR), development safety update reports (DSUR) and risk management plans (RMP) for critical portfolio with high priority in close collaboration with global, cross functional product responsible teams. They'll Identify and lead process improvement initiatives for efficiency gain, act as Subject Matter Expert (SME) in assessing impact on aggregate reports and risk management plans for process proposals. Organize and lead workshops ensuring Novartis addresses the Health Authority (HA) comments adequately for the department 's deliverables across portfolio.

About the Role

#LI-Hybrid

This position is based in Barcelona, Spain. Please apply only if this location is accessible to you, as

relocation support is not available.

Key responsibilities but not limited to:

- Lead the authoring, review, and independent management of Safety Concerns and other critical content in Aggregate Reports and RMPs.
- Review and ensures HA comments are addressed in all relevant department 's deliverables for a product / class across the TAs in collaboration with Medical function, QPPV office and other global stakeholders.
- Lead preparation of Aggregate Reports for newly launched and acquired products as well as for first risk management plans for initial submissions and new indications.
- Develop and implements strategies for data analysis and presentation across global Aggregate Reports, RMPs, and other departmental deliverables; actively contributes to planning and reviewing statistical analysis plans, ensuring clarity, accuracy, in all submissions
- Contribute to complex cross functional global projects focusing on quality improvement and contribute to projects on process improvement initiatives including IT projects/systems (including AI) which are of high priority/ criticality to the business.
- Provide expert opinion in the development of safety document templates and Standard Operating Procedures pertaining the department 's deliverables to comply with emerging worldwide regulations.
- Provide impact assessment on the department 's deliverables for any new process proposals, process improvement proposals etc.
- Identifies knowledge gap, develops training materials and conducts workshops.
- Mentors associates to enhance their skills and contributions.
- Leads capability building initiatives for medical safety writing and future projects.
- Collaborates with process owner on process simplification and improvement initiatives Business interface with key stakeholders within and outside Novartis including HAs.
- Ensures team awareness and assess impact of updates to global PV regulatory requirements for department 's deliverables.
- Works jointly with Compliance & Quality and Process compliance & Risk Mitigation functions to support trend analyses, knowledge generation and mitigation of any identified risks.
- Deputize Team Lead / Group Head and assists with the recruitment of new staff.
- Work predominately in the field of medical writing and can contribute to RMP Management after appropriate training.

Essential requirements:

- Education and/or professional experience: Graduate/Postgraduate/Doctorate degree in Life Sciences/Pharmacy/Medical Sciences or equivalent degree
- Fluent English (oral and written)
- At least 7 years ' experience in drug safety / development or closely related areas of responsibility, with a minimum of 5 years ' experience in safety writing.

Desirable requirements:

- Excellent understanding of the disease area

- Sound expertise in data analysis and presentation
- Strong project management and communication skills.
- Ability to lead global and cross-functional work groups.
- Excellent understanding of drug development process, GCP and medical terminology
- Ability to mentor and guide

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
Development

Business Unit
Development

地点
Spain

站点
Barcelona Gran V í a

Company / Legal Entity
ES06 (FCRS = ES006) Novartis Farmac é utica, S.A.

Functional Area
Research & Development

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("kalturaplayer69872c2525695139072885"); 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:
"kalturaplayer69872c2525695139072885", 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 } };
```

```
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: "1dgfvmafo"}); 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.

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