

Head of US Risk Management & Product Safety (Risk Evaluation and Mitigation Strategies-REMS)

Job ID
REQ-10070450

2月 04, 2026

USA

摘要

The Head of US Risk Management & Product Safety (REMS) provides strategic leadership, oversight, and execution of US Risk Evaluation and Mitigation Strategies (REMS) and local product safety activities across the product lifecycle. This role ensures high quality implementation of risk management programs, operational excellence, regulatory compliance, and optimal patient safety outcomes. The position partners cross functionally with Medical, Regulatory, Commercial, Quality, and Global Safety teams, and serves as the primary US authority on REMS and product safety.

About the Role

#LI-Hybrid

Location: East Hanover, NJ

Key Responsibilities:

1. REMS Strategy & Leadership

- Lead the design, regulatory development, and launch execution of innovative REMS programs, ensuring operational feasibility and alignment with commercial strategy through collaboration with cross functional leaders
- Design, execute, and continuous improvement of REMS programs that minimize stakeholder burden while enhancing patient safety
- Lead cross functional project and product teams across the lifecycle to develop and operationalize evidence based risk management solutions, including enhanced pharmacovigilance and risk minimization activities.

2. REMS Operational Oversight

- Oversee performance and governance of REMS vendors to ensure quality execution, compliance, and data integrity.
- Ensure accurate, timely compliant execution of REMS commitments and assessments, including monitoring of KPIs and escalation of risks.

3. US Local Product Safety Management

- Serve as the primary US authority for product safety inquiries, escalations, and Health Authority interactions across the lifecycle.
- Oversee safety related US labeling (USPI, Medication Guides, REMS language) and ensure timely submission of required US aggregate reports.

4. Regulatory Compliance & Quality Oversight

- Ensure inspection and audit readiness for all REMS and US product safety operations; lead response management, corrective actions, and CAPA implementation through closure.
- Maintain deep expertise in evolving US regulatory and REMS requirements; translate regulatory expectations into operational guidance
- Represent the company in FDA interactions, REMS negotiations, advisory committee discussions, and relevant industry forums to advocate for science based, patient centric risk management approaches.

Essential Requirements:

- A Bachelor 's degree required. An advanced degree preferred (PharmD, M.D, PHD)
- 10+ years' experience in risk management operations, including risk management planning and leadership experience in the pharmaceutical industry required

- 5+ years of leading REMS programs a matrix role that encompasses managing cross-functional teams across all areas of an organization
- Strong knowledge of FDA REMS requirements, US PV regulations, risk minimization strategies, and audit/inspection management.
- Proven leadership in cross-functional settings; excellent communication, influencing, collaboration, and decision-making skills
- Strong executive presence with excellent interpersonal, verbal, and written communication abilities, organizational acumen, and the capability to manage multiple high priority projects simultaneously
- Proven expertise leading large-scale, strategic initiatives related to drug development, risk management and regulatory requirement
- Deep understanding of risk management principles and best practices for REMS development implementers, and experience implementing risk management practices and/or managing risk in complex and/or conflict related environments

Desirable Requirements:

- Familiarity with safety databases, REMS platforms, and data analytics tools.

The salary for this position is expected to range between \$176,400 and \$327,600 per year.

The final salary offered is determined based on factors like, but not limited to, relevant skills and experience, and upon joining Novartis will be reviewed periodically. Novartis may change the published salary range based on company and market factors.

Your compensation will include a performance-based cash incentive and, depending on the level of the role, eligibility to be considered for annual equity awards.

US-based eligible employees will receive a comprehensive benefits package that includes health, life and disability benefits, a 401(k) with company contribution and match, and a variety of other benefits. In addition, employees are eligible for a generous time off package including vacation, personal days, holidays and other leaves.

To learn more about the culture, rewards and benefits we offer our people click [here](#).

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 \(PDF 30 MB\)](#)

EEO Statement:

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Accessibility & Reasonable Accommodations

The Novartis Group of Companies are 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 application process, or to perform the essential functions of a position, please send an e-mail to us.reasonableaccommodations@novartis.com or call +1(877)395-2339 and let us know the nature of your request and your contact information. Please include the job requisition number in your message.

部门
Development

Business Unit
Development

地点
USA

状态
New Jersey

站点
East Hanover

Company / Legal Entity
U014 (FCRS = US014) Novartis Pharmaceuticals Corporation

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("kulturaplayer69835f8ee8676740679863"); 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:
"kulturaplayer69835f8ee8676740679863", provider: { widgetId: "10m7rm1pm", partnerId:
"2076321", uiConfd: "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

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