

Senior Expert Engineering RMCS

Job ID
REQ-10088387

十月 05, 2026

Austria

摘要

With the increasing diversity and complexity of Novartis' drug delivery device and drug-device combination product portfolio, robust and harmonized risk management and control strategies are critical to ensure patient safety, regulatory compliance, and sustainable product quality.

As Senior Expert Risk Management & Control Strategy, you will act as a technical and strategic authority within the RMCS team, shaping how risks are identified, assessed, controlled, and documented across the device development lifecycle. You will work at the interface of design, quality, regulatory, manufacturing, and suppliers, enabling defensible decisions and fit-for-purpose control strategies for global development programs.

This is a high-impact individual contributor role, ideal for an expert who enjoys solving complex problems, influencing without authority, and raising the overall maturity of risk management practices across a portfolio.

About the Role

Location: Schafftenau, Austria

Work Pattern: Hybrid

Please note that this position does not include relocation support. Candidates should therefore already be based in, or able to work from, the advertised location.

Key responsibilities:

- Act as **senior subject matter expert** for device and combination product risk management in accordance with ISO 14971, MDR, FDA expectations, and Novartis internal standards.
- Define, assess, and challenge **technical/design, manufacturing, and use-related risks**, ensuring risks are adequately mitigated and justified.
- Develop and strengthen **control strategies** (e.g. testing vs. not testing, process controls, verification strategies) across development and lifecycle stages.
- Drive **consistency and quality** of Risk Management Files (RMF), Risk Management Plans, and Risk Management Reports across projects and platforms.
- Provide expert guidance to project teams on **risk acceptability, residual risk justification, and benefit-risk considerations**.
- Support **health authority submissions and interactions**, including inspection readiness and responses related to risk management and control strategy.
- Contribute to methodologies, templates, guidance documents, and training materials.
- Coach and mentor junior experts and project team members, strengthening risk management capability and culture across the organization.
- Proactively engage stakeholders to **pre-align on risk positions** and avoid late-stage surprises.

Essential Requirements:

- Advanced degree in engineering, life sciences, or a related technical discipline.
- Fluent English - both spoken and written.
- Extensive hands-on experience in **medical device and/or drug-device combination product risk management**.
- Strong working knowledge of **ISO 14971**, EU MDR, FDA device expectations, and Quality-by-Design principles.
- Proven ability to translate complex technical risks into **clear, defensible, and regulator-ready documentation**.
- Track record of influencing cross-functional stakeholders without direct authority.
- Structured, analytical mindset with strong judgment and decision-making capability.

Desirable:

- Experience across multiple device platforms (e.g. autoinjectors, inhalers, pumps).
- Exposure to **combination products** within pharmaceutical development.
- Experience supporting regulatory submissions, audits, or inspections.

- Ability to act as a reference point for best practices and emerging regulatory trends.
- German language is not required but would be an advantage.

Salary & Benefits:

In addition to a market-competitive base salary, we offer an attractive incentive program, a modern company pension scheme, childcare facilities, learning and development opportunities as well as worldwide career possibilities within the Novartis group.

In accordance with Austrian law, we are obliged to disclose the minimum salary as stated in the collective bargaining agreement. For this position the minimum salary is € 65,504/year (on a full-time basis). The actual salary will be significantly higher, as we strive to maintain a competitive position in the market and consider your previous experience, qualifications and individual competencies.

Accessibility and accommodation:

If because of a medical condition, physical disability or a neurodiverse condition you require an adjustment during the recruitment process, please reach out to disabilities.austria@novartis.com and let us know the nature of your request as well as your contact information. The support which we can provide will include advice on suitable positions as well as guidance at all stages of the application process. Austrian law provides candidates the opportunity to involve the local disability representative, Behindertenvertrauensperson (BVP), in the application process. If you would like to request this, please let us know in advance as a note on your CV.

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 \(PDF 30 MB\)](#)

Primary location salary range
€ 66,918.00 - € 117,800.00

部門
Development

Business Unit
Development

地点
Austria

站点
Schaftenau

Company / Legal Entity
AT33 (FCRS = AT033) Novartis Pharmaceutical Manufacturing GmbH

Functional Area
Research & Development

Job Type
Full time

Employment Type
Regular

Shift Work
No

```
var kPlayer = KalturaPlayer55802022 || KalturaPlayer; var config = { targetId:
"kalturaplayer6acca43f4a052515235157", provider: { widgetId: "10m7rm1pm", partnerId:
"2076321", uiConfId: "55802022" }, playback: { autoplay: false, autopause: false, muted: false, loop:
false }, sources: { options: {}, startTime: 0 }, disableUserCache: "true", plugins: {}, sources: { options:
{}}, startTime: 0 }, ui: { showCCButton: false, settings: { showQualityMenu: true, showSpeedMenu:
false }, components: { fullscreen: { disableDoubleClick: false } }, uiComponents: [ { presets:
['Playback', 'Live'], area: 'BottomBarRightControls', replaceComponent: 'Fullscreen', get:
kPlayer.ui.components.Remove } ] } }; // Check and add plugins only if they exist if
(kPlayer.plugins["download"]) { config.plugins.download = { disable: true }; } if
(kPlayer.plugins["transcript"]) { config.plugins["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 }; } if (kPlayer.plugins["preventSeek"]) {
config.plugins.preventSeek = { preventSeekForward: false, preventSeek: false }; }
config.plugins.floating = { disable: true }; if (kPlayer.plugins["navigation"]) { config.plugins.navigation =
```

```
{ position: "right", expandMode: "over", expandOnFirstPlay: false, visible: false }; } if
(kPlayer.plugins["hotspots"]) { config.plugins['playkit-js-hotspots'] = { disable: true }; } if
(kPlayer.plugins["moderation"]) { config.plugins['playkit-js-moderation'] = { disable: true }; } if
(kPlayer.plugins["info"]) { config.plugins['playkit-js-info'] = { disable: true }; } if
(kPlayer.plugins["share"]) { config.plugins.share = { disable: true }; } config.ui.uiComponents = []; if
(kPlayer.plugins["googleAnalytics"]) { 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 } }; }
```

```
// Ensure the global player registry array always exists, regardless of embed type.
window.kalturaPlayerVideos = window.kalturaPlayerVideos || []; try { var thumbEmbedPromise =
thumbEmbed({config, mediaInfo: {entryId: "1dgfvmafo"}}); // thumbEmbed() returns a
Promise that resolves with the player instance // when the user clicks the thumbnail. Use .then() to
capture the player directly. thumbEmbedPromise .then(function(player) {
window.kalturaPlayerVideos.push(player); // Notify kalturadatalayer.js that a new player is ready so
it can // attach custom event listeners immediately, regardless of when // the user clicked the
thumbnail relative to page load. document.dispatchEvent(new CustomEvent('kalturaPlayerReady', {
detail: { player: player } })); }) .catch(function(error) { console.error(error); }); } catch (e) {
console.error(e.message) }
```

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