

Senior Expert - Medical Device Analytical Representative (m/f/d)

Job ID
REQ-10071217

3月 31, 2026

Austria

摘要

#LI-Hybrid

Internal job title: Senior Expert - Science & Technology

Location: Schafftenau, Austria

With the increasing diversity of Novartis' portfolio, the need for drug-device combination product analytical data packages is also increasing. As such, we are searching for a Senior Expert - Medical Device Analytical Representative with combination product development experience to lead the creation of strong analytical data-packages.

As a member of the global Chemistry Manufacturing Control (CMC) analytical sub team and device sub team for your project(s) you will be the main contact & coordinator for all project-specific analytical tasks related to functional attributes of drug-device combination products at all levels (from component to drug product to final product), especially for injectables like Biologics, Ribonucleic Acids, Radio-Ligands (peptides).

About the Role

Key Responsibilities:

- As a member of global CMC analytical subteam and device subteam for your project(s), you are the contact person & coordinator for all project-specific analytical tasks related to functional/mechanical attributes of drug-device combination products at all levels (from component to drug product to final product); plan resource & budget for your project(s).
- Select testing laboratory inline with resource availability, capability and in/outsourcing strategy, e.g. GDPD, QC, CRO; lead outsourced analytical project activities at CROs and contribute to manage external partnership.
- Own drug-specific analytical methods (AMs) / parameter sheets (PSs) for functional attributes like activation and injection force, time, volume, sound, as well as (needle) safety features, organize and align x-functional inputs (e.g. with Device/Pack Tech); define, organize, document AM/PS validation and transfer.
- Co-shape and co-author x-functional analytical CMC strategies and documents, e.g. drug product and final product stability strategy, protocols and reports, method validation and transfer status summaries, Analytical Specifications (AS); organize input to Justification of Specification JoS (from Device/PackTech and HFE).
- Contribute to and review regulatory documents, support product registrations incl. present at inspections with minimal support by Leader or assigned to moderately complex projects.

Essential Requirements:

- Master or PhD in engineering or chemical/bio analytics or equivalent and some working experience in pharmaceutical industry in combination product development.
- Proven knowledge in late phase parenteral analytical development; leadership experience in managing development projects, ideally in a global matrix environment, understanding and awareness of regulatory guidelines for combination. product analytics, experience with cGMP and relevant ISOs
- Collaborative spirit, self-driven attitude, high level of learning agility.
- Proficiency in English (written and spoken).

You ' ll receive

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 € 65,605.54/year (on a full-time basis). In most cases, the actual salary will be higher, as we strive to maintain a competitive position in the market and consider your previous experience, qualifications and individual competencies.

We are open for part-time and job-sharing models and support flexible and remote working where possible.

Commitment to Diversity & Inclusion:

Novartis is committed to building an outstanding, inclusive work environment and diverse teams representative of the patients and communities we serve.

Adjustments for Applicants with Disabilities

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 \(PDF 30 MB\)](#)

部门

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

```
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sources: { options: {}, startTime: 0 }, ui: { showCCButton: false, settings: { showQualityMenu: true,
showSpeedMenu: false }, css : "/modules/custom/arcticnckalturaaddon/css/kalturavideo.css",
components: { fullscreen: { disableDoubleClick: false } }, uiComponents: [ { presets: ['Playback',
'Live'], area: 'BottomBarRightControls', replaceComponent: 'Fullscreen', get:
KalturaPlayer.ui.components.Remove } ] } }; // Check and add plugins only if they exist if
(KalturaPlayer.plugins["download"]) { config.plugins.download = { disable: true }; } if
(KalturaPlayer.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 (KalturaPlayer.plugins["preventSeek"]) {
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config.plugins.floating = { disable: true }; if (KalturaPlayer.plugins["navigation"]) {
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false }; } if (KalturaPlayer.plugins["hotspots"]) { config.plugins['playkit-js-hotspots'] = { disable: true }; }
if (KalturaPlayer.plugins["moderation"]) { config.plugins['playkit-js-moderation'] = { disable: true }; } if
(KalturaPlayer.plugins["info"]) { config.plugins['playkit-js-info'] = { disable: true }; } if
(KalturaPlayer.plugins["share"]) { config.plugins.share = { disable: true }; } config.ui.uiComponents =
[]; if (KalturaPlayer.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 } }; }
```

```
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```

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