

Quality Manager Pilot Plant

Job ID
REQ-10075309

4月 10, 2026

Austria

摘要

Location: Schafftenau, Austria #onsite

Role Purpose:

The Quality Manager Pilot Plant is responsible for managing all the quality and compliance activities within the Development GDPD (Global Device and Packaging Department) Pilot Plant Schafftenau AT which performs assembly of drug device combination products and GMP testing. Routine tasks focus on QA oversight of manufacturing, batch record review, failure investigations and deviation, change controls, and release activities. Ensure that compliance with cGMP/ GxP is maintained in TRD (Technical Research and Development).

About the Role

Major Accountabilities:

- Quality oversight of all GxP activities at the GDPD Pilot Plant, ensuring product quality and compliance with Novartis Quality standards.
- Ensure regulatory compliance to ISO 13485, 21 CFR 820, including health authority registrations and qualified state of facilities and utilities.
- Manage deviations, OOX, complaints, investigations, and CAPAs.
- Ensure Data Integrity and compliance with GxP, regulatory, and HSE requirements.
- Support internal and external audits
- Support transfer projects and qualification activities
- Participation in the compilation, revision and approval of validations, transfers, SOPs and other GxP related documents as applicable.

Minimum Requirements:

- Minimum Bachelor ' s (> 5 years ' pharma quality or operations) or Master ' s degree (> 3 years ' pharma quality or operations) in Pharmaceutical Sciences, Biotechnology, Engineering, or a related field.
- Experience: Drug Device combination products ISO 13485, 21 CFR 820
- Good knowledge of cGMP, working knowledge in technical development, production or QA.
- Sound scientific, technical and regulatory knowledge.
- Strong organizational and decision-making skills.
- Strong ability to analyze and evaluate cGMP compliance
- Knowledge of GxP requirements as well as experience with inspections.
- Flexibility to work in a fast-paced, quickly changing work environment.
- Knowledge of Manufacturing Process/ Product Expertise.

Required Language Skills: Fluent English and German required (oral & written).

Skills Desired: Communication Skills, Continuous Improvement mindset, Data integrity, Dealing with Ambiguity, Digital savviness, leadership, Problem Solving Skills, Regulatory Requirements knowledge, Collaboration

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.

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

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

Quality

地点

Austria

站点

Schaftenau

Company / Legal Entity

AT33 (FCRS = AT033) Novartis Pharmaceutical Manufacturing GmbH

Functional Area

Quality

Job Type

Full time

Employment Type

Regular

Shift Work

No

```
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"10m7rm1pm", partnerId: "2076321", uiConfId: "55802022" }, playback: { autoplay: false, autopause:
false, allowMutedAutoPlay: false, loop: false }, sources: { options: {}, startTime: 0 }, plugins: {},
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"]) {
config.plugins.preventSeek = { preventSeekForward: false, preventSeek: false }; }
config.plugins.floating = { disable: true }; if (KalturaPlayer.plugins["navigation"]) {
config.plugins.navigation = { position: "right", expandMode: "over", expandOnFirstPlay: false, visible:
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 } }; }
```

```
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"}); } catch (e) { console.error(e.message) }
```

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