NOVARTIS

Quality Manager Pilot Plant - Medical Devices

Job ID
REQ-10092747

十一月 18, 2026

Austria

摘要

Location: Schaftenau, Austria #onsite

Role Purpose:
The Quality Manager Pilot Plant is responsible for managing the quality and compliance activities within the Development GDPD (Global Device and Packaging Department) Pilot Plant Schaftenau 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.
- undefined

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).

Benefits & Rewards

At Novartis, we ' re committed to reimagining medicine together - and rewarding the people who make it happen.

Expected Annual Base Salary Range for role: € 66,918 to € 105,200

The base salary offered is determined based on gender-neutral objectives, such as relevant skills, competencies and experience in accordance with the Novartis pay setting policy and upon joining Novartis will be reviewed periodically.

In addition to your base salary, you may be eligible for a performance-based bonus depending on certain performance parameters.

The rewards of being part of our team go far beyond base pay and incentives. We also offer a variety of competitive benefits in kind to help you thrive personally and professionally, such as insurance plans, retirement plans, wellbeing resources and global recognition programs. In addition, we provide flexible and hybrid working options, where possible, and minimum 14 weeks paid parental leave.

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)

Primary location salary range
€ 66,918.00 - € 105,200.00

部门
Development

Business Unit
Development

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
Regul ä r

Shift Work
No

var kPlayer = KalturaPlayer55802022 || KalturaPlayer; var config = { targetId: "kalturaplayer6afd9c64b0cfd659561082", 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

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// Ensure the global player registry array always exists, regardless of embed type. window.kalturaPlayerVideos = window.kalturaPlayerVideos || []; try { var thumbEmbedPromise = thumbnailEmbed({config, mediaInfo: {entryId: "1dgfvmafo"}}); // thumbnailEmbed() 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 kaltura datalayer.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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