

Manager, Regulatory Affairs CMC

Job ID
REQ-10071157

2月 03, 2026

Austria

摘要

#LI-Hybrid

Location: Schafenau, Austria

Novartis are seeking a Manager to be responsible for regulatory activities related to Chemistry, Manufacturing and Controls (CMC), including the preparation and publication of CMC regulatory documentation for Health Authority submissions. The role also involves engaging with Health Authorities on CMC related questions to support both new product launches and post marketing activities.

About the Role

Key Responsibilities:

- Formulate and lead global CMC regulatory strategy with a focus on innovation, balancing

business benefit with regulatory compliance.

- Lead and implement global CMC submission activities (planning, authoring, reviewing, coordination, submission) for assigned projects/products.
- Identify the required documentation and any content, quality and/or timelines issues for global submissions and negotiate the delivery of approved technical source documents in accordance with project timelines.
- Author and/or review high-quality CMC documentation for HA submission, applying agreed CMC global regulatory strategies, current regulatory trends and guidelines. Ensure technical congruency and regulatory compliance, meeting agreed upon timelines and e-publishing requirements.
- Proactively communicate CMC regulatory strategies, risks and key issues throughout the life cycle in a timely manner to project teams and other stakeholders. Represent department in cross-functional project teams.
- Prepare and communicate CMC risk management assessments and lessons learned on major submissions.
- Initiate and lead Health Authority interactions and negotiations.

Essential Requirements:

- Science degree (e.g. Chemistry, Pharmacy, Biochemistry, Molecular Biology, Biotechnology, Biology) or equivalent.
- At least 2 years ' experience in regulatory CMC experience and/or pharmaceutical industry experience.
- Demonstrated working knowledge of chemistry/biotechnology, analytics or pharmaceutical technology. Knowledge/experience of regulations, guidelines and product life cycle maintenance.
- Ability to critically evaluate data from a broad range of scientific disciplines.

Benefits & Rewards:

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

Commitment to Diversity and Inclusion / EEO:

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

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 \(PDF 30 MB\)](#)

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

```
function adjustKalturaPlayer() { var deviceWidth = window.innerWidth ||
document.documentElement.clientWidth || document.body.clientWidth; var mediaElement =
document.getElementById("kulturaplayer69820781d3b39049396665"); 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 < originalWidthValue) {
  var config = { targetId:
    "kulturaplayer69820781d3b39049396665", 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')
    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 } };

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: "1dgfvmafo"}); 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

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

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