

Associate Director, Regulatory Affairs CMC

Job ID
REQ-10071082

2月 03, 2026

Austria

摘要

#LI-Hybrid

Location: Schafenau, Austria

Novartis are seeking an Associate Director to lead regulatory activities related to Chemistry, Manufacturing and Controls (CMC). The role involves preparing and publishing CMC regulatory documentation for Health Authority submissions, as well as interacting with Health Authorities on CMC queries to support new product launches and post-marketing activities.

About the Role

Key Responsibilities:

- Formulate, lead and drive global CMC regulatory strategy for projects/products drawing on substantial regulatory expertise with a focus on innovation, maximizing the business benefit

balanced with regulatory risks and compliance.

- Lead and drive all global CMC submission activities (planning, authoring, reviewing, coordination, submission) for assigned projects/products, while applying the global strategy into submissions.
- Identify the required documentation and any content, quality and/or timeliness 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 Health Authority submissions, establishing and applying CMC global regulatory strategies, current regulatory trends and guidelines. Ensure technical congruency and regulatory compliance, meeting agreed upon timelines and e-publishing requirements.
- Represent Global Regulatory CMC on cross-functional project teams and maintain collaborative partnerships with stakeholders
- Initiate and lead Health Authority interactions and negotiations: setting objectives, preparing briefing books, coordinating and planning rehearsals and risk mitigation plans. Establish and maintain a single point of contact with FDA.
- Provide strategic advice and direction within the department and cross-functionally through specialized assignments.

Essential Requirements:

- Science degree (e.g. Chemistry, Pharmacy, Biochemistry, Molecular Biology, Biotechnology, Biology) or equivalent.
- Minimum 8 years regulatory experience and/or pharmaceutical industry experience.
- Substantial knowledge/experience in regulatory submission and approval processes and ability to deal with complex CMC regulatory issues and requirements.
- Proven 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 € 78,383.90/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.

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("kalturaPlayer6981f966cb023743796441"); 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: "kalturaPlayer6981f966cb023743796441", 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') to 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

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.

Job ID
REQ-10071082

Associate Director, Regulatory Affairs CMC

[Apply to Job](#)



Job ID
REQ-10071082

Associate Director, Regulatory Affairs CMC

[Apply to Job](#)

Source URL:
<https://prod1.novartis.com.cn/careers/career-search/job/details/req-10071082-associate-director-regulatory-affairs-cmc>

List of links present in page

1. <https://www.novartis.com/about/strategy/people-and-culture>
2. https://www.novartis.com/sites/novartis_com/files/novartis-life-handbook.pdf
3. <mailto:disabilities.austria@novartis.com>
4. <https://novartis.wd3.myworkdayjobs.com/en-US/NovartisCareers/job/Schaftenau/Associate-Director--Regulatory-Affairs-CMCREQ-10071082-1>
5. <https://novartis.wd3.myworkdayjobs.com/en-US/NovartisCareers/job/Schaftenau/Associate-Director--Regulatory-Affairs-CMCREQ-10071082-1>