

## Regulatory Affairs Associate Director, CMC

Job ID  
REQ-10078161

5月 29, 2026

Switzerland

### 摘要

#LI-Hybrid  
Location: Basel, Switzerland

We are looking for a Regulatory Affairs Associate Director, CMC to contribute to the development and delivery of global Chemistry, Manufacturing and Controls (CMC) regulatory strategies across a portfolio of products.

In this role, you will support regulatory activities across development and lifecycle stages, ensuring high-quality submission content and alignment with global regulatory requirements. Working closely with cross-functional partners, you will help enable timely approvals and maintain compliant, consistent product information across markets.

About the Role

## Major Accountabilities

- Contribute to the development and implementation of global CMC regulatory strategies for assigned projects and products.
- Plan, coordinate, and support CMC submission activities, including authoring, review, and submission of documentation.
- Identify documentation requirements and manage alignment on content, quality, and timelines across stakeholders.
- Author and review high-quality CMC regulatory documentation, ensuring compliance with applicable guidelines and standards.
- Communicate regulatory considerations, risks, and updates to cross-functional project teams and stakeholders.
- Contribute to and support Health Authority interactions, including preparation of briefing materials and responses.
- Collaborate across functions to support consistent delivery and alignment on regulatory activities.
- Contribute to continuous improvement initiatives and support knowledge sharing within the regulatory community.

## Essential Requirements

- Fluency in English (written and spoken).
- Degree in a scientific discipline (e.g. Chemistry, Pharmacy, Biochemistry, Biotechnology, Biology) or equivalent experience.
- Demonstrated capability in CMC Regulatory Affairs, including regulatory submission and approval processes.
- Strong understanding of CMC regulatory requirements, with the ability to navigate complex regulatory topics and contribute to regulatory strategy.
- Ability to evaluate scientific data across multiple disciplines and translate insights into regulatory decision-making and documentation.
- Working knowledge of pharmaceutical development, manufacturing, or related scientific areas.
- Ability to collaborate effectively and influence within cross-functional, global matrix teams while managing multiple priorities.
- Strong planning, organisational, and interpersonal skills, with a focus on quality, delivery, and continuous improvement.

## Commitment to Diversity and Inclusion / EEO paragraph

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

## Accessibility and Accommodation

Novartis is committed to working with and providing reasonable accommodation to all individuals. If,

because of a medical condition or disability, you need a reasonable accommodation for any part of the recruitment process, or in order to receive more detailed information about the essential functions of a position, please send an e-mail to [inclusion.switzerland@novartis.com](mailto:inclusion.switzerland@novartis.com) and let us know the nature of your request and your contact information. Please include the job requisition number in your message.

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

Switzerland

站点

Basel (City)

Company / Legal Entity

C028 (FCRS = CH028) Novartis Pharma AG

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 }; }
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(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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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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