

RA CMC Senior Submission Coordinator

Job ID
REQ-10071289

2月 05, 2026

India

摘要

Independently drive end-to-end coordination of complex CMC submissions and project management activities. Provide advanced regulatory CMC operational, submission and compliance support to department in accordance to defined requirements to guarantee timely preparation of high quality CMC regulatory submissions and associated compliance information throughout the life cycle.

About the Role

Key Responsibilities:

- Independently, perform RA CMC compliance and operational support including QC check, DA checks, IND AR writing & coordination. CMC contact for some countries, compliance/regulatory database entry and reports and ensure appropriate eCTD operator attributes, module chapters
- Create CMC submission documentation such as folders structure, metadata forms, RA

request forms, populating RA CMC tracking sheets, letters, and various Health Authority forms. Act as super-user, business data owner and data steward in the applicable Regulatory Information Management System

- Proactively ensure CMC documentation is eCTD compliant and submission ready. Support eCTD compliance maintenance for the external documentation linked to the CMC submission modules, including third party documentation
- Independently support CMC project teams for document finalization, ancillary documents coordination and source documents management. Coordinate, prepare, compile and track CMC submissions for delivery to RA Operations
- Support RA CMC project teams to handle Country Organization (CO) request in the RA CMC ticketing system, organizing submission coordination activities like source documents and ancillary documents collection
- Perform super-user role of documentation system / support super-user for e.g. account requests / modifications as assigned
- Actively participate as a member of the global RA CMC project teams by contributing to the project operational and compliance strategy, identifying the potential compliance issues and sharing lessons learned
- Acquire and maintain GMP Certificates and Manufacturing Authorizations required for RA CMC submission in the Document Management System
- Coordinate preparation of declarations required for submission in RoW countries
- Support other team members in leading various operations, compliance, Data & Digital initiatives

Essential Requirements

- For Master 's in Pharmacy: Minimum 5 years of regulatory experience in Regulatory CMC operations, compliance, and project management. Internship experience during the degree program is not counted.
- For Other Scientific Master 's Degrees: Minimum 6 years of regulatory experience in Regulatory CMC operations, compliance, and project management. Internship experience during the degree program is not counted.
- Experience with: Regulatory project management, Pharmaceutical industry documentation systems, Regulatory Information Management Systems (RIMS), Data standards, data systems and data management tools
- Proven ability to work effectively with global, cross functional project teams and independently drive submission coordination activities
- Strong planning, organizational, and interpersonal skills
- Demonstrated ability to manage multiple priorities simultaneously (multitasking is essential)
- High level of computer literacy and competency with data driven and IT systems; strong data processing skills
- High level of digital and data fluency including familiarity with AI enabled tools and emerging IT technologies.

Commitment to Diversity and Inclusion:

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 individuals with disabilities. If, because of a medical condition or disability, you need a reasonable accommodation for any part of the recruitment process, or in order to perform the essential functions of a position, please send an e-mail to diversityandincl.india@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
India

站点
Hyderabad (Office)

Company / Legal Entity
IN10 (FCRS = IN010) Novartis Healthcare Private Limited

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("kalturaPlayer698467232da25132965549"); 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:
    "kalturaPlayer698467232da25132965549", 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: true, transcript: { position: "right", // Default: bottom; ('left', 'right', 'top', 'bottom')
      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

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