

Validation Lead

Job ID
REQ-10066763

12月 15, 2025

USA

摘要

Bring your expertise to a role where your decisions directly safeguard product quality, patient safety, and regulatory trust. As our Validation Lead in Indianapolis, you will shape and own the site 's end to end validation strategy—process, cleaning, primary packaging, and ongoing process verification—so manufacturing stays inspection ready and continuously compliant with current Good Manufacturing Practice. You ' ll partner closely with Manufacturing Science and Technology, Engineering, Information Technology, Quality Control, and Analytical Science and Technology to orchestrate the Validation Master Plan, monitor meaningful performance indicators, and proactively manage risk. Your work will also enable smooth product transfers and launches by generating robust, data driven evidence for registration dossiers. If you thrive on building clear standards, coaching teams, and turning complex technical challenges into practical, reliable solutions, this role gives you the platform to make an impact that matters.

#LI-Onsite

Location: Indianapolis, IN

Relocation Support: Yes

About the Role

Key Responsibilities:

- Develop and implement site validation strategies for process, cleaning, packaging, and ongoing process verification.
- Oversee the Validation Master Plan, ensuring timely execution and audit readiness.
- Provide technical expertise and guidance for risk assessments and validation documentation.
- Lead validation activities, ensuring compliance with Novartis and regulatory requirements.
- Partner with cross-functional teams to support equipment, utilities, and analytical method qualification.
- Facilitate product transfers and launches by aligning validation approaches and generating registration data.
- Monitor validation performance indicators and proactively address challenges to maintain continuous compliance.

The salary for this position is expected to range between \$114,100 and \$211,900 per year.

The final salary offered is determined based on factors like, but not limited to, relevant skills and experience, and upon joining Novartis will be reviewed periodically. Novartis may change the published salary range based on company and market factors.

Your compensation will include a performance-based cash incentive and, depending on the level of the role, eligibility to be considered for annual equity awards.

US-based eligible employees will receive a comprehensive benefits package that includes health, life and disability benefits, a 401(k) with company contribution and match, and a variety of other benefits. In addition, employees are eligible for a generous time off package including vacation, personal days, holidays and other leaves.

Essential Requirements:

- Bachelor's degree in Biomedical Engineering, Chemistry, Pharmacy, Chemical Engineering, or Pharmaceutical Technology.
- Minimum 5 years' experience in manufacturing, technical development, or quality within the pharmaceutical industry.
- Hands-on experience leading and managing validation projects.
- Strong knowledge of manufacturing processes, process equipment, and applied statistics.
- Proven ability to write and review technical reports and validation documentation.
- Fluent in English and proficient in the local site language.

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 \(PDF 30 MB\)](#)

EEO Statement:

The Novartis Group of Companies are Equal Opportunity Employers. We do not discriminate in recruitment, hiring, training, promotion or other employment practices for reasons of race, color, religion, sex, national origin, age, sexual orientation, gender identity or expression, marital or veteran status, disability, or any other legally protected status.

Accessibility & Reasonable Accommodations

The Novartis Group of Companies are 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 application process, or to perform the essential functions of a position, please send an e-mail to us.reasonableaccommodations@novartis.com or call +1(877)395-2339 and let us know the nature of your request and your contact information. Please include the job requisition number in your message.

部门
Operations

Business Unit
Production / Manufacturing

地点
USA

状态
Indiana

站点
Indianapolis

Company / Legal Entity
U469 (FCRS = US469) AAA USA Inc.

Functional Area
Technical Operations

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("kaltura_player_697c2870ef980100509760"); 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:  
"kaltura_player_697c2870ef980100509760", 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: "1_dgfvmafo"}); 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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