NOVARTIS

Sr. Process Expert

Job ID
REQ-10071928

3月 05, 2026

China

摘要

Technical Transfer Lead
Responsible for technology transfer activities at site level (within, inbound and outbound), including any scale-up or other process adaptations. Leads technical transfer project team at site and liaises efficiently with involved functions (e.g. Technical Development, Supply Chain, Production Unit, Quality Control, HSE, other sites.).
Product Steward
Owns the process knowledge of the product(s) assigned throughout the commercial lifecycle, maintains the oversight on process capability, through data trending and statistical analysis of critical variables, ensuring process(es) are robust, in continued state of validation and continuously improving.Ensures seamless flow of knowledge and information across functions, and with other Sites when applicable, with focus on the assigned product(s). Provides second line technical/scientific process support.
Technical Steward
Provides to the Site the specialist knowledge and expertise, as Subject Matter Expert (SME), of specific pharmaceutical processes or process technologies (e.g. Technical Steward for galenics, for film coating, biologics - upstream or downstream, etc.).Oversees processes and standards to maintain and improve existing and to implement new innovative manufacturing technologies.

Validation Lead
Responsible for developing, implementing and managing the site process validation, primary packaging validation, cleaning validation and revalidation strategies to meet cGMP and quality requirements on time and on budget to ensure that programs are compliant with Regulatory Authorities ' expectations and related SOPs.
Senior Scientist MS&T
Design, plan, perform, interpret and report scientific experiments under the lead of the department head to contribute to overall MS&T strategies and objectives.

About the Role

Job Purpose:

The Senior Process Expert can work with shopfloor technicians and provide direct front line support to production activities using technical understanding and knowledge of cGMPS, SOPs, and process steps. He is also responsible to oversees processes and standards to maintain and improve existing and to implement new innovative manufacturing technologies.

This individual is accountable to support Manufacturing activities, develop training materials for production operators, train production staff, support process issues, protocol generation, general documentation support, deviation investigations, CAPA ownership, change record ownership, and continuous improvement of the process. The Senior Process Expert role can work with the production shift lead to coordinate the on shift management and other routine shopfloor team management.

Major accountabilities:

Stewardship - for technology assigned

- As the SPOC of PU Process SME to be interface with global MS&T network and with technical development organization, for the corresponding global activities, to define and implement new technical standards for existing and new technologies and equipment.
- Owns the knowledge of specific pharmaceutical manufacturing process technologies, locally, including any pilot scale, scale up or down, and Design of Experiments (DoE).
- Participate in the definition and selection of pharmaceutical equipment, through providing input to User Requirements.
- Collaborate with technical development, other sites and global MS&T network to facilitate transfer of technical knowledge.
- Assure that the necessary benchmark is done internally in Novartis, and externally in the scientific and academic environment, in order to stimulate and to extend the knowledge, increasing the know-how of the associates and

expanding it to the rest of the organization.
- Be a recognized scientific expert internally and externally by reporting and presenting scientific/technical work at internal/external meetings/conferences and publish in peer reviewed international scientific journals including patents.
- Maintain their work in inspection readiness level.
- Support Product Stewards in creation of Quality Risk Assessments.
- Support creation of SOPs for Process Unit.
- Provide technical expertise to Engineering for design activities in Capex projects around technologies within area of responsibility.
- Provide technical expertise for equipment qualification around technologies within area of responsibility.

Manufacturing Excellence- for the technology(ies) assigned

- Support a culture of safety, quality, diversity, and inclusion.
- Can work with shopfloor technicians and provide front line support to manufacturing shifts to ensure safe, quality, and timely completion of product batches.
- Manage and maintain manufacturing documentation including Master Batch Record, applicable SOPs, risk assessments, protocols, and other documentation as needed.
- Track and trend critical process parameters and in process checks as the lead for ongoing process verification (OPV) and identify CAPAs to address any trends.
- Identify, assess, and own technical changes through GMP change control processes.
- Investigate deviations and determine root causes and identify CAPA.
- Act as Subject Matter Expert (SME) for the product and process knowledge and provide input to the Annual Product Review.
- Ensure processes are inspection ready at all times.
- Support continuous improvement through identification of opportunities, technologies, and owning changes to implement improvements.
- Support validation protocol generation and execution.
- Support on going self-learning and ensuring training is up to date.
- Provide guidance and support to production team through training and knowledge sharing.
- This position will involve wearing protective clothing and working in a Manufacturing Grade C clean room environment.
- This position may require shift work including weekends and off hours support.
- Strong interpersonal, written, communication skills along with problem solving and follow-up skills.
- Well organized, flexible and work with minimal supervision.
- Harmonize and optimize technical processes across the site. Benchmark new technologies and equipment relevant for site.
- Designs and controls optimization projects.
- Trouble shooting / root cause investigation by providing second level of specialist expertise as SME and by harmonising and optimising related technical processes across the units.
- Perform technical feasibility trials related to process improvement and implementation of new manufacturing technologies.

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
Operations

Business Unit
Production / Manufacturing

地点
China

站点
Haiyan (Zhejiang Province)

Company / Legal Entity
CN27 (FCRS = CN027) Novartis Pharmaceutical Technology Zhejiang Co., Ltd.

Functional Area
Technical Operations

Job Type
Full time

Employment Type
Regular

Shift Work
No

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function adjustKalturaPlayer() { var deviceWidth = window.innerWidth || document.documentElement.clientWidth || document.body.clientWidth; var mediaElement = document.getElementById("kalturaplayer69c0367f9dea0122225188"); 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  var config = { targetId: "kalturaplayer69c0367f9dea0122225188", provider: { widgetId: "1_0m7rm1pm", partnerId: "2076321", uiConfId: "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 } };
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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) }
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VIDEO

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.china@novartis.com and let us know the nature of your request and your contact information. Please include the job requisition number in your message.

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