NOVARTIS

Project Team Lead

Job ID
REQ-10087963

九月 16, 2026

China

摘要

Technical Transfer Lead
Lead the Launch and Product Transfer Project Teams. Direct and monitor the project activities for the assigned Drug product manufacturing and packaging projects, until submission and handover to operations. Responsible for successful transfers of manufacturing and packaging process from Development to Tech-Ops and for availability of launch supplies on time and quality.
Responsible for technology transfer activities at ESO (within, inbound and outbound), including any scale-up or other process adaptations.
Leads technical transfer project team at ESO and liaises efficiently with involved functions (e.g. Technical Development, Supply Chain, Production Unit, Quality Control, HSE, other site

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.

Design, plan, perform, interpret and report scientific experiments under the lead of the department head to contribute to overall Project Management strategies and objectives.

About the Role

Major accountabilities:

Technical Transfer Lead

1. Take end-to-end responsibility for launch and transfer projects from assignment to submission.

2. Form and lead the project team consisting of Novartis and CMO team members, manage the team and set priorities for project and project team meetings.

3. Manage project team activities necessary for project success.

4. Support the evaluation of new CMOs and external suppliers for launch and transfer projects. Prepare project plans including activities at Novartis and CMOs and ensure adherence to the plan.

5. Ensure that all project activities at Novartis and CMOs follow global and local GMP regulations and adequate HSE standards.

6. Ensure timely availability of manufacturing processes, analytical methods, validation documents, source data and documents for registration.

7. Provide input into overall ESO strategy.

8. Assess resource requirements at Novartis and CMOs and request additional resources if applicable (e.g. personnel and investments). Proactively communicate critical issues to project stakeholders at Novartis and CMOs.

9. Highlight potential impacts on overall project timelines, demand and supply. Make sure that

issues are investigated, solutions are found and implemented.

10. Ensure the documents being part of the project documentation are prepared, approved, stored and archived according to current Novartis processes and in high quality.

11. Support preparation, review and approval of relevant registration documents.

12. Initiate (transfers) and support the pre-approval inspection (PAI) process together with QA.

13. Attend project governance and project meetings (e.g. PRM, DMC, TRD Sub team Meetings) and present the project status, or project issues, if appropriate.

14. Contribute to process improvement and optimization initiatives (TLCM projects).

15. Ensure that the API and Drug Product manufacturing and Drug Product packing produced after successful launch or the pharmaceutical manufacturers to produce drug products can use transfer.

16. Lead and support resolution of technical issues at CMOs and external suppliers.

17. Supports Launch Site decisions (CPIC) by providing analysis of technology, capacity, skills through inter-functional evaluations.

Key performance indicators:

1. Technical transfers activities are executed on time and products meet quality requirements.

2. Products and processes at assigned CMOs are in control and capable and maintained in a validated state. Completes remediation activities in accordance with project timelines.

3. Defines and delivers product quality improvements.

4. Ensures key projects such as Launches or Finished Dosage Form (FDF) changes are delivered on time, on budget and meet the target success criteria. Recognized as an excellent collaborator and partner by the CMOs, SRTs, QA and others partner functions (R&D).

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
Product Supply Chain

地点
China

站点
Changshu (Jiangsu Province)

Company / Legal Entity
CN06 (FCRS = CN006) Beijing Novartis Pharma Co., Ltd

Functional Area
Technical Operations

Job Type
Full time

Employment Type
Regular

Shift Work
No

var kPlayer = KalturaPlayer55802022 || KalturaPlayer; var config = { targetId: "kalturaplayer6ae414e089a3d331136189", provider: { widgetId: "10m7rm1pm", partnerId: "2076321", uiConfId: "55802022" }, playback: { autoplay: false, autopause: false, muted: false, loop: false }, sources: { options: {}, startTime: 0 }, disableUserCache: "true", plugins: {}, sources: { options: {}, startTime: 0 }, ui: { showCCButton: false, settings: { showQualityMenu: true, showSpeedMenu: false }, components: { fullscreen: { disableDoubleClick: false } }, uiComponents: [{ presets: ['Playback', 'Live'], area: 'BottomBarRightControls', replaceComponent: 'Fullscreen', get: kPlayer.ui.components.Remove }] } }; // Check and add plugins only if they exist if (kPlayer.plugins["download"]) { config.plugins.download = { disable: true }; } if

(kPlayer.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 (kPlayer.plugins["preventSeek"]) { config.plugins.preventSeek = { preventSeekForward: false, preventSeek: false }; } config.plugins.floating = { disable: true }; if (kPlayer.plugins["navigation"]) { config.plugins.navigation = { position: "right", expandMode: "over", expandOnFirstPlay: false, visible: false }; } if (kPlayer.plugins["hotspots"]) { config.plugins['playkit-js-hotspots'] = { disable: true }; } if (kPlayer.plugins["moderation"]) { config.plugins['playkit-js-moderation'] = { disable: true }; } if (kPlayer.plugins["info"]) { config.plugins['playkit-js-info'] = { disable: true }; } if (kPlayer.plugins["share"]) { config.plugins.share = { disable: true }; } config.ui.uiComponents = []; if (kPlayer.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 } }; }

// Ensure the global player registry array always exists, regardless of embed type. window.kalturaPlayerVideos = window.kalturaPlayerVideos || []; try { var thumbEmbedPromise = thumbnailEmbed({config, mediaInfo: {entryId: "1dgfvmafo"}}); // thumbnailEmbed() returns a Promise that resolves with the player instance // when the user clicks the thumbnail. Use .then() to capture the player directly. thumbEmbedPromise .then(function(player) { window.kalturaPlayerVideos.push(player); // Notify kaltura datalayer.js that a new player is ready so it can // attach custom event listeners immediately, regardless of when // the user clicked the thumbnail relative to page load. document.dispatchEvent(new CustomEvent('kalturaPlayerReady', { detail: { player: player } })); }) .catch(function(error) { console.error(error); }); } catch (e) { console.error(e.message) }

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