NOVARTIS

Development Regulatory Affaires (開発薬事) - Neuroscience, Gene Therapy & Precision Diagnostics

Job ID
REQ-10080994

六月 22, 2026

Japan

摘要

シニアGPRM-Jとして、医薬品の開発段階から市販後に至るまでの薬事戦略を主導・支援し、日本における最適な承認取得および製品維持を実現する。日本およびグローバルの規制環境に精通した専門性を活かし、PMDA等の規制当局との信頼関係を構築するとともに、クロスファンクショナルおよびグローバルチームと連携し、ノバルティスの事業価値最大化に貢献する。また、業界活動や後進の育成を通じて、ノバルティス・ジャパンのリーディングカンパニーとしての地位確立を支える。

About the Role

業務内容：

- **医薬品の初期開発段階からプロジェクトチームに参画し、承認取得**

までの期間を通し、薬事戦略の立案、それに基づく開発プランの作成について中心的な役割を果たし薬事的リスクマネジメントを行う。

- 規制当局P(MDA, MHLW) 対応をリードし、プロジェクトチームの代表として関係当局との交渉に責任を持つ。例：開発プロジェクトの承認申請チームのリード
- Globalと協同し、世界同時開発・同時申請・同時承認の達成をドライブする。
- 各部門の担当者等と協働し、Product Life Cycle Planの最大化に貢献する。

業務のやりがい：

- 開発早期から承認取得、市販後まで薬の一生に幅広く関わることができる
- 規制や業界の流れを正しく読み取り、将来的な変化を見越した薬事戦略の立案/実行をリードできる
- 社内外の顧客や海外の開発関連部署など多くのメンバーと多岐にわたる仕事に携われる
- 個人としての作業に加えて、チームメンバーとの協働を通じて、申請・承認などの大きなマイルストーンも経験できる
- 社内外や規制当局も巻き込んで、AIやITテクノロジーを活用した先進的な医薬品開発を推進していくイノベーティブな活動にも参画できる

求められる主なスキル・経験：

1.開発薬事に関わる知識, 経験

-医薬品開発, 薬事規制に関する全般的な知識経験

-規制当局との折衝経験

2.コミュニケーション・ネゴシエーション・プレゼンテーション

-社内の他部門との調整

-規制当局との折衝・交渉

-マネジメントへの報告

3.プロジェクトマネジメント

-進捗管理, 会議運営, 記録作成等

4.リーダーシップ

-規制当局対応, 承認申請チームのリード

5.英語

-マネジメントへのレポートの作成・説明, global memberとの電話会議等の機会があるため, 業務に支障が出ない程度の英語力が必要になります。

<ENG>

Major Accountabilities

- Assist developing innovative and high quality regulatory strategies to facilitate regulatory processes in development and ensure registration with optimized labels that contribute to health and welfare of the Japanese nation.
- Contribute to the regulatory activities in day-to-day operations for assigned TA area.
- Lead cross functional communication for preparing and finalizing Japanese labeling for new drugs.
- Take regulatory related actions to maintain post marketing products in Japan.
- Establish goodrelationship with the Japanese HA in responsible projects
- Contribute to the adherence to regulations, guidelines and global/internal procedures.
- Ensure adequate reporting of adverse events / technical complaint / compliance issue in accordance with company procedures
- 100% timely delivery of all training requirements including compliance

Education:

- Degree in pharmacy, medicines, science, agriculture and/or pharmaceutical engineering discipline required. Advanced degree (Master Degree, PhD, etc.) prefered.
- Pharmacist license preferred.

Experience/Professional requirement:

- Demonstrate good presentation skills in delivering clear messages to audience and modifying language and style to meet the needs from audience.

- Understand the drug development/maintenance processes, milestones in the assigned disease area and Novartis procedures for decision board review and approval.
- Understand basic knowledge of Japan regulation
- Possess basic knowledge of global regulatory environment, and contribute to elaborating the project specific development/regulatory strategy and plan.
- Report and summarize discussions in which RA plays an important role. Good in writing and reading English (e.g. exchange of scientific and technical information by e-mail and generation of scientific and technical documentation).
- Proactively communicate issues and potential solutions.
- Provide updates on current situation, and ensure that the same information is disseminated throughout the organization as needed. Network with others and share information.
- Demonstrate cultural awareness and work in cross cultural environment.

English Skill:

Fluent English as business 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: Read our handbook to learn about all the ways we ' ll help you thrive personally and professionally: https://www.novartis.com/sites/novartiscom/files/novartis-life-handbook.pdf

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.

Join our Novartis Network: Not the right Novartis role for you? Sign up to our talent community to stay connected and learn about suitable career opportunities as soon as they come up: https://talentnetwork.novartis.com/network. You can follow us via Novartis Recruitment WeChat Official Account and Novartis Recruitment WeChat Video Account.

Be aware of fake job advertisements and job offers

Novartis is aware of employment scams which make false use of our company name or leader ' s names to defraud job seekers. Novartis does not make job offers without interview and never asks candidates for money.

All our current job openings are displayed here. If you have encountered a job posting or been approached with a job offer that you suspect may be fraudulent, we strongly recommend you do not respond, send money or personal information.

偽の求人広告や採用オファーにご注意ください

ノバルティスでは、当社名や幹部の名前を不正に使用して求職者をだます「採用詐欺」が発生していることを認識しています。

ノバルティスでは、面接なしに採用オファーを出すことはなく、候補者に金銭を要求することも決してありません。

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Benefits and Rewards: Learn about all the ways we ' ll help you thrive personally and professionally. Read our handbook (PDF 30 MB)

部門
Development

Business Unit
Development

地点
Japan

站点
本社

Company / Legal Entity
JP05 (FCRS = JP005) Novartis Pharma K.K.

Functional Area
Research & Development

Job Type
Full time

Employment Type
Regular

Shift Work
No

var kPlayer = KalturaPlayer55802022 || KalturaPlayer; var config = { targetId: "kalturaplayer6af2831b5cc51477312572", 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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