

Associate, Country QA Compliance

Job ID
REQ-10070053

1月 23, 2026

Japan

摘要

新たな専門性を磨きながらキャリアの幅を広げたい方にとって、本ポジションは大きな成長機会となります。新製品開発プロジェクトへの参画や、多様なステークホルダーとの協働を通じて、品質・薬事・製造に関する知見を横断的に積み重ねることができます。また、国内外の製造所や当局とのコミュニケーションを通じて、視野をさらに広げられる役割です。新薬の上市を支える重要な一員として、専門性を継続的に高めながらインパクトを発揮できるポジションです。

Country QA Complianceは、品質統括部門の中で新製品開発への参画と、製造所に関するGMP適合性調査を担当する部署です。本Roleでは、新製品開発プロジェクトの一員として、薬事部門、国内外の製造所、サプライグループなどと連携しながら、新薬の発売に貢献できます。

GMP適合性調査業務においては、新規申請・一変申請に伴う調査、ならびに5年ごとに実施する定期調査における、申請から結果通知の受領までの当局対応を行います。海外製造所や、グループ会社である篠山工場を含む国内製造所とのコミュニケーションを通じ、申請に必要な資料の入手・確認、当局への申請および照会対応を担います。

新薬申請から市販後の品質管理まで、知識と経験の幅を広げたい方、GMP適合性調査の経験をお持ちの方、あるいはQA業務に新たに挑戦したい方からのご応募をお待ちしています

This position offers an exceptional opportunity for individuals who want to expand their expertise while taking on new challenges in the pharmaceutical quality field. By contributing to new product development projects and collaborating with a wide range of internal and external stakeholders, you will build cross-functional experience across quality, regulatory, and manufacturing domains. Through regular communication with domestic and global manufacturing sites as well as health authorities, you will broaden your perspective and strengthen your professional impact. As a key member supporting the launch of new medicines, you will play a central role in securing high-quality products for patients while continuously elevating your technical proficiency.

Country QA Compliance is a department within the Quality organization responsible for participating in new product development and conducting Good Manufacturing Practice (GMP) compliance activities related to manufacturing sites. In this role, you will contribute to new product launches by working closely with regulatory affairs, domestic and global manufacturing sites, and supply teams. For GMP compliance activities, you will lead end-to-end processes for new registration applications, post-approval variations, and periodic GMP inspections conducted every five years—including preparation, submission, communication with authorities, and coordination with manufacturing sites in Japan and overseas. Through this role, you will gain broad exposure from new drug applications to post-marketing quality management.

We welcome applicants with experience in GMP inspections, those eager to expand their quality knowledge, and those motivated to take on new challenges within Quality Assurance.

About the Role

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Key Responsibilities:

- 日本およびグローバルの品質基準に沿った薬事コンプライアンス活動をリードする
- PMDAによるGMP適合性調査に向けた資料準備から完了までの対応を実施する
- 新製品導入プロジェクトを支えるため、関係部門と連携し品質観点で貢献する
- 日常的な品質関連業務を支援し、継続的な品質維持とプロセスの一貫性を確保する

Essential Requirements:

- 大学卒業または同等以上の学歴を有していること
- 医薬品業界における品質管理業務の経験を3年以上有していること
- 新規およびGMP適合性調査の実務経験をお持ちであると尚よい
- 母国語レベルの日本語力と、英語でのビジネス会話およびメールでのコミュニケーションがスムーズに可能であること
- 多部門と連携しながら複数タスクを円滑に進められる組織力と調整力を備えていること

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Key Responsibilities

- Lead regulatory compliance activities aligned with both Japan and global quality standards
- Prepare documentation and manage end-to-end activities for GMP compliance inspections conducted by PMDA
- Collaborate with cross-functional teams to support new product introduction from a quality perspective
- Support daily quality operations to ensure consistent processes and sustainable quality performance

• Essential Requirements

- Bachelor ' s degree or higher, or equivalent academic background
- Minimum three years of experience in pharmaceutical quality-related roles
- Experience with new product registration or GMP compliance inspections is an advantage
- Native-level Japanese proficiency and business-level communication skills in English (spoken and written)
- Strong organizational and coordination skills to manage multiple tasks collaboratively across functions

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.

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>

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>

Benefits and Rewards: Read our handbook to learn about all the ways we'll help you thrive personally and professionally: <https://www.novartis.com/careers/benefits-rewards>

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

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。

現在の求人情報はすべて[こちら](#)

に掲載されています。詐欺の可能性がある求人広告や採用オファーに遭遇した場合は、返信したり、金銭や個人情報を送ったりしないよう強くおすすめします。

ノバルティスでキャリアを築く魅力: 病気と向き合う人々やそのご家族を支えるには、革新的な科学だけでは不十分です。それには、あなたのような情熱と知性を持った仲間が必要です。

互いに協力し、支え合い、刺激し合うことで、患者さんの人生を変えるようなブレイクスルーを生み出すことができます。さ

あ、一緒により明るい未来を創りませんか? <https://www.novartis.com/about/strategy/people-and-culture>

ノバルティス・タレントネットワーク:

今のノバルティスの募集職種がご希望に合わない場合でも、ぜひタレントコミュニティにご登録ください。あな

たに合ったキャリアの機会

が見つかり次第、いち早くご案内いたします。 <https://talentnetwork.novartis.com/network>

福利厚生:

ノバルティスの福利厚生と報奨について必要な情報は、ノバルティスライフハンドブックに記載されています。 <https://www.novartis.com/careers/benefits-rewards>

多様性と包括性へのコミットメント:

ノバルティスは患者さんや地域社会などに対して、包括的かつ優れた職場環境、および多様なチームを構築するよう取り組んでいます。

合理的配慮:

ノバルティスは障害を持つ個々人に対して、合理的配慮を提供し協働することをお約束します。健康状態や障害に関して、採用プロセスあるいは必須の職務を満たすために合理的配慮が必要な場合は midcareer-r.japan@novartis.com 宛てに電子メールをお送りください。その際ご依頼内容、ご連絡先、求人票の番号を明記してください。

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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

Operations

Business Unit
Quality

地点
Japan

站点
Toranomom (NPKK Head Office)

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

Functional Area
Quality

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("kalturaplayer697aace30898d200354144"); 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:
"kalturaplayer697aace30898d200354144", provider: { widgetId: "10m7rm1pm", 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 } };
```

```
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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