

Associate, Country QA Operations, Core Products

Job ID
REQ-10072899

3月 03, 2026

Japan

摘要

あなたの品質判断が、患者さんに届く医薬品の安全と信頼を守ります。Good Practice(適正基準)への適合とノバルティス品質管理システムへの準拠をリードし、変更管理から監査・是正対応、苦情・リコール対応まで、国レベルの品質オペレーションを一気通貫で推進していただくポジションです。規制当局やサプライチェーン、薬事・メディカルなど多様なステークホルダーと協働しながら、「正しく作り、正しく記録し、正しく届ける」仕組みを強化し、日々の業務改善とリスク低減を実現します。品質を通じて事業と患者さんの両方にインパクトを出したい方に最適な環境です。Your quality decisions directly protect the safety and trust of patients. You will lead compliance with Good Practice (GxP) requirements and the Novartis Quality Management System, overseeing end to end national quality operations—from change management and audits to CAPA, complaints, and recall management. By collaborating closely with regulatory authorities, supply chain, regulatory affairs, medical, and other key stakeholders, you will strengthen systems that ensure products are “made right, documented right, and delivered right,” driving operational excellence, risk reduction, and continuous improvement. This is an ideal opportunity for professionals who want to create tangible impact for both patients and the business through quality

About the Role

Key Responsibilities:

- 製品の安定供給を確保するため、製造拠点およびCMOと品質面で密に連携する
- 製品に変更が発生した場合、品質手順および体制の構築・準備を実行する
- 国内外ステークホルダーと連携し、上市後製品における品質課題や変更管理に対応し、安定供給を支える
- 逸脱、品質情報の管理および是正・予防措置の実行を推進する
- GQPに基づく規制対応を行い、承認書内容と実運用との整合性を維持する
- 内部および外部からのGQP/GMP/GCTP監査に対応し、指摘事項の是正およびフォローアップを実施する

Experience and Skills:

- 大学卒業または同等以上の学歴を有していること(薬学部、化学、理工学部が望ましい)
- 医薬品に関わる品質保証、品質管理、または製造関連業務において約3年程度、もしくはそれ以上の実務経験を有すること
- 薬機法、GQP省令等の規制要件に基づいた業務運用に関する基本的な理解を有すること
- 変更管理、逸脱管理、是正・予防措置のいずれかのプロセス運用経験を有すること
- 国内外の関係部門および外部パートナーと協働し、品質課題の調整・解決に携わった経験を有すること
- 文章および会議において、業務遂行に必要なレベルの英語でのコミュニケーション能力を有すること
- 複数の業務を並行して進め、期限を意識しながら正確に遂行できる業務遂行能力を有すること

Key Responsibilities

- Collaborate closely with manufacturing sites and Contract Manufacturing Organizations (CMOs) to ensure stable product supply from a quality perspective
- Establish and prepare quality procedures and organizational readiness in response to product changes
- Work with domestic and global stakeholders to address post-launch quality issues and manage changes, supporting stable supply
- Drive deviation management, quality event handling, and implementation of corrective and preventive actions (CAPA)
- Ensure regulatory compliance under GQP requirements and maintain alignment between approved dossiers and actual operations
- Lead and support internal and external GQP/GMP/GCTP audits, including remediation and follow-up of audit findings

Experience and Skills

- Bachelor's degree or higher (Pharmacy, Chemistry, Science, Engineering, or related field preferred)
- Approximately 3 years or more of hands-on experience in Quality Assurance, Quality Control, or manufacturing-related roles within the pharmaceutical industry
- Basic understanding of Japanese regulatory requirements, including the PMD Act and GQP ordinance
- Practical experience in at least one of the following processes: change management, deviation management, or CAPA
- Experience collaborating with internal cross-functional teams and external partners to coordinate and resolve quality issues
- Business-level English communication skills, both written and verbal, sufficient for documentation and meetings
- Strong ability to manage multiple tasks simultaneously, meet deadlines, and execute work accurately

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。詐欺の可能性の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ー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

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.

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

Quality

地点

Japan

站点

Toranomon (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("kalturaplayer69bfcc35a728a248595240"); 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 < deviceWidth) { var config = { targetId:
"kalturaplayer69bfcc35a728a248595240", 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: "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

利便性と合理的配慮

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