Country Head of Quality (Japan)

Job ID
REQ-10044041

Mar 12, 2025

Japan

Summary

-Stellt sicher, dass alle Produkte und Prozesse im globalen Gesch ä ftsbereich eine eingebaute Qualit ä t haben und alle internen und externen Anforderungen erf ü llen. Treiben Sie die Implementierung der Qualit ä tsorganisation voran, die Governance und Prozesse (global/Region) sicherstellt. Sicherstellen, dass die QS-Organisation in Ü bereinstimmung mit den aktuellen regulatorischen Anforderungen f ü r alle GxP-Bereiche (GMP, GDP, GCP, Pharmakovigilanz und GLP) und des Novartis Quality Manual and Policies sowie der Nichteinhaltung angemessen durch Korrektur- und Vorbeugungsma ß nahmen (CAPA), Behebungspl ä ne und/ oder Eskalation von Problemen behoben wird. F ü hrungskr ä fte einer bestimmten globalen Disziplin innerhalb einer Global Quality-Funktion.

About the Role

Drive the implementation of the Cross-Divisional Country Quality organization, ensuring governance and process oversight within Novartis Japan under NCQ responsibility. Implement all local regulatory

requirements for all GxP areas (i.e., GMP, GDP, GCP, PV) in compliance with Novartis Quality Manual and in alignment with Industry Best Practices. Drive cross-divisional standardization and efficiency gains through innovation and operational excellence projects. Continuously support the commercial performance and new product launches in Japan. Diligently implement the annual Quality Plan and prevent any non-compliance issues, ensuring that any deviation will be appropriately addressed through corrective and preventive actions (CAPA). Ensure the Escalation process is effectively managed and implemented in Japan to avoid any business disruption (stock outage, withdrawal, recall) or compromise to Novartis reputation.

Major Activities

1. Drive the creation and implementation of a consistent quality culture in the country organization together with all Country Quality units and QA associates.
2. Drive the implementation of the Cross Divisional Quality Organization in Japan, with a high focus on reducing complexity and simplification.
3. Actively drive operational excellence projects in line with global processes and country quality strategy to meet local saving targets according to budget.
4. Ensure the implementation of applicable Quality Standards and governance processes through the Novartis Quality Manual.
5. Establish effective Key Quality Indicators in the country to routinely monitor relevant processes, ensuring control and compliance.
6. Prevent potential compliance gaps and risks and ensure timely addressing of CAPAs.
7. Identify opportunities for continuous improvement and timely implementation of the annual Quality Plan at the country level.
8. Implement an adequate Escalation process in the country organization and support the effective and timely resolution of any Quality Event.
9. Provide quality oversight for Change Control and Deviations and ensure adequate implementation of CAPAs.
10. Liaise effectively in the country organization, GDD and NTO to ensure global processes implementation.
11. Ensure Quality oversight within the Country for third parties/vendors/outsourced activities in alignment with relevant stakeholders.
12. Ensure adequate regulatory inspection preparation, management, and follow-up in the country.
13. Improve and maintain effective communication with local Health Authorities and the country organization, ensuring all commitments are tracked and closed on time.
14. Ensure implementation of adequate GxP training within all relevant activities based on adequate planning.
15. Establish communication processes covering Regional and Headquarters interactions and implement any country-specific requirements for all GxP areas.
16. Ensure remediation activities for all existing gaps for ongoing compliance.
17. Lead talent development within the local country commercial organization Quality units. Develop adequate succession candidates for Quality organizations.
18. Ensure appropriate budget management in the country in compliance with company targets, identifying risks and opportunities.

KPI

1. Meet commercial targets including timely support for new product launches.

2. Meet efficiency targets as per predefined budget targets.
3. Ensure adequately resourced Quality Organization in all assigned country commercial organizations.
4. Implement all applicable Quality Modules from the Novartis Quality Manual and regulatory controls at relevant process steps.
5. Define, implement, and regularly review Key Quality Indicators by Management to monitor compliance and quality performance.
6. Effective implementation of the Annual Quality Plan.
7. Proactively identify and effectively mitigate risks.
8. Identify and manage GXP issues during internal and external audits properly.
9. Avoid stock-outs due to inefficient release procedures.
10. Ensure timely close-out of complaints and investigations.
11. Ensure an effective Change Control Process.
12. Manage the GxP Training program properly.
13. Ensure Vendor Oversight.
14. Support Talent development and ensure a Succession Plan.

Job Dimensions

1. Number of associates: Operational Quality oversight for approximately up to 25 FTEs in total.
2. Financial responsibility: Align with the Global NCQ Head. The Country QA Head is responsible for operating within all relevant Country QA, ensuring compliance with the approved budget.
3. Impact on the organization: Providing adequate Quality governance for the Country commercial organizations is critical for ongoing compliance with Health Authority requirements and expectations and is crucial to the overall compliance status throughout the Novartis Country QA.

Ideal Background

1. Education (minimum/desirable): Degree or PhD in Life Sciences, Pharmacy, or Medicine. Demonstrated success leading a high-impact organization or project.
2. Languages: Fluent in English (oral and written); knowledge of languages spoken in the respective region is a plus.
3. Experience/Professional requirement: 10+ years of Quality Assurance experience and involvement in regulated activities; a broad understanding of global expectations of Health Authorities in the GMP, GDP, GCP, PV regulated areas. Six or more years of demonstrated leadership and accomplishments in a global/matrix environment in the pharmaceutical industry. Three or more years of people management experience, including experience in a matrix environment. Strong management, interpersonal, communication, negotiation, and problem-solving skills. Strong project management skills, substantial organization awareness, including significant experience working cross-functionally and in global teams.

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

部門
Operations

部門
Universal Hierarchy Node

国
Japan

勤務地
Toranomon (NPKK Head Office)

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

Functional Area
Quality

職種
Full time

雇用形態
Regul ä r

Shift Work
No

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