NOVARTIS

Development Quality Assurance Manager/Expert

Job ID
REQ-10087291
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Япония

Сводка

The Development Quality Assurance Manager is responsible for assuring quality over-sight for activities undertaken in all Novartis entities in a country to assure compliance with relevant Good Clinical Practice (GCP) and Good Pharmacovigilance Practice (GPvP) regulations and guidelines to assure the execution of high quality research and activities within a country(ies). Activities in scope include but may not be limited to assuring ade-quate systems are in place for the protection of patient safety, rights and well-being, data integrity, and quality oversight of Clinical and Pharmacovigilance activities as needed in both pre- and post- market settings in assigned country(ies) in all Novartis entities.
The Development Quality Assurance Manager is responsible for assuring the quality and compliance of Development, Global and local Medical Affairs (MA) & Commercial patient-facing projects, products and programs. Operates in direct collaboration with local De-velopment colleagues (Study and Site Operations, Patient Safety and Regulatory Affairs), Medical Affairs and Novartis Country Quality (NCQ) to ensure compliance to Novartis en-tities requirements and relevant HA regulations and guidance. Ensures implementation of the Novartis Quality Manual and Quality Management System in assigned country(ies) to achieve a high level of quality and compliance.
-Manage projects, including Quality Plan initiatives, and processes that support quality objectives to assure their compliance with GxP regulations.

About the Role

Major Accountabilities

Local Quality System: Oversee implementation, maintenance, and monitoring of the local Quality System and written procedures to ensure GCP and Pharmacovigilance related processes and tasks are compliant with Novartis global requirements and applicable regulations and guidelines. This includes ensuring adherence to ICH GCP and GPvP guidance documents, Novartis written processes, acting as the QA subject matter expert for the approval of local GCP/PV procedures and supporting local IMP release process such that it is done according to global and local requirements.

Quality Plan and Continuous Improvement: Support and monitor implementation of the local Quality Plan (QP) deliverables related to GCP and PV areas, ensuring alignment with the applicable global QP chapters where ever possible. Utilize lessons learned from audits, inspections, KQI reviews and day-to-day oversight of quality performance to recommend and initiate continuous improvement efforts.

Training systems: Ensure adequate training systems are in place in assigned country(ies) for GCP, GPvP and other relevant Development activities in compliance with Novartis global and local requirements. Assure that relevant business areas are maintaining inspection-ready documentation to support reviews of training compliance.

Quality Issue Management: Drive Clinical/PV QA investigation activities at the country level as appropriate and ensure implementation of robust CAPA plans where applicable. Take accountability for escalation of GCP/GPvP process non-compliance as needed.

Risk Identification and Management: Monitor local Quality System, processes and Key Quality Indicators (KQIs) to proactively identify potential quality risk. Collaborate with business partners to ensure that risks are reviewed for root cause, impact, and recurrence and assure that relevant line function owners put in place mitigation plans to address. Ensure adequate and timely escalation of issues to relevant functions as needed.

Inspection Management and Support: Provide leadership and/or support as needed for GCP and GPvP HA inspections of activities in assigned country(ies). Assure support prior to, during and post inspection for the country organization, investigational sites and/or external service providers, as applicable, in collaboration with the assigned inspection lead. Ensure that responses to local Health Authorities are submitted on-time, commitments are agreed internally and can be met and relevant CAPAs have been completed/closed according to agreed timelines.

Audit Management: Partner with local and global Development teams, PS, NCQ and other internal stakeholders in the execution, where QA processes are subject to the audit, and follow-up of audits on clinical development and PV activities. Collaborate with the business, and auditees as appropriate to determine root cause for identified audit and inspection observations (any audits and inspections related to clinical/medical, PV related areas) and verify robust and sustainable corrective and preventive actions are implemented.

CAPA management: Act as local approver for the documentation and management of local CAPAs to support appropriate review and closure of each corrective and preventive action. Assure local line functions take appropriate ownership of duties as required by the CAPA processes.

ESP/Supplier Management: Responsible for the execution of QA activities required for the qualification/requalification of ESPs supporting activities with a clinical or PV component. Ensure the ESP selection, PV / QA agreements and oversight processes are properly followed at the CO for ESPs supporting Development activities with a clinical/medical or PV component.

Data integrity: Ensure that there is a process in place to maintain local quality and compliance with requirements for digital governance platforms and computerized systems with GCP and/or GPvP impact.

Governance/Communication: Lead/co-lead local quality review board meetings (ex: Quality committee), and ensure any identified trends/risks related to PV or GCP are communicated and addressed in a timely manner. Ensure a process is in place to update local functions on the possible impact of changes to local and/or global requirements and regulations. Ensure there is an appropriate interface with internal/external stakeholders for any GCP/PV related activity (e.g. local Health Authority, clinical and PV related changes/initiatives). Partner with local NCQ team to ensure the analysis, assessment and resolution of issues with common interfaces (GCP/PV and GMP). Coordinate and analyze clinical and PV section of the AQMR. Ensure business continuity plan is maintained and resulting measures are implemented in GCP and GPvP areas

Education (minimum/desirable):

Degree in Life Sciences or related fields

Languages:

English fluent in speaking and writing.

Experience:

Typically more than 5 years experience in the pharmaceutical industry in a relevant field such as quality assurance, regulatory affairs, pharmacovigilance or a directly related area, preferably with a minimum of 3 years experience in clinical development. Experience in leading projects

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/novartis_com/files/novartis-life-handbook.pdf

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 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.

Additional Information

Be aware of fake job advertisements and job offers. Novartis does not make job offers without interviews 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 provide personal information.

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

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)

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Audit & Compliance
Место
Япония
Сайт
本社
Company / Legal Entity
JP05 (FCRS = JP005) Novartis Pharma K.K.
Functional Area
Quality
Job Type
Full time
Employment Type
Regular
Shift Work
No

利便性と合理的配慮

ノバルティス は 障害 を 持 つ 個人 と 協力 し、 合理的配慮 を 提供 することをお 約束 します。健康状態 や 障害 を 理由 に 採用 プロセス のいかなる 部分 においても、あるいは 職務 の 必須事項 を 果 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 してください。

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