NOVARTIS

GCP Compliance Manager (EMEA Hub)

Job ID
REQ-10072414
апр 17, 2026
Южноафриканская Республика

Сводка

The GCP Compliance Manager (EMEA Hub) is accountable for the compliance oversight and control of regulated GCO activities focusing on EMEA Hub & Country level delivery including country trial level conduct as per country assignment. This role contributes to all compliance activities supporting the three pillars of GCP Compliance, issue management, audits & inspections as per country assignment and GCO self-strategy delivery.

The GCP Compliance Manager (EMEA Hub) is the single point of contact for EMEA Hub & Country team members, providing day-to-day support and ongoing quality oversight. This role promotes a product quality culture within GCO supporting the GCP Compliance Head (EMEA hub), focusing on quality and compliance being increased and sustained and on active risk management.

About the Role

Major accountabilities:

- Accountable for the compliance oversight and control of regulated GCO activities focusing on EMEA Hub & Country level delivery including country trial level conduct as per country assignment.
- Single point of contact for EMEA Hub & Country team members for GCP Compliance.
- As per focus area and assignment, management and day-to-day support provided in program/trial level quality issues, deviations and quality events management.
- Coordination and support to program/trial delivery teams for audits and inspections based on trials' selection and audit/inspection scope.
- Delivery of the GCO self-assessment strategy related checks and controls.
- Support cross-functions risk assessments if program/trial/country level in scope and contribute to the monitoring of relevant indicators/metrics/thresholds.

Activities & Interfaces:

- Contribute to the execution of the GCO GCP Compliance strategy under the leadership of the GCP Compliance Head (EMEA Hub).
- Drive the compliance oversight and control of regulated GCO activities focusing on EMEA Hub & Country level delivery including country trial level conduct as per country assignment, working closely with the Hub & Country teams members, the relevant functions across GCO, involving and collaborating as required with GDD and the wider organization, such as Quality Assurance.
- Be the single point of contact for EMEA Hub & Country team members as per country assignment for GCP Compliance.
- Manage and provide day-to-day support to the EMEA Hub & Country team members in Hub & Country level quality issues, deviations and quality events management, providing expertise in investigation, RCA and CAPA development. Involve and collaborate as needed with the relevant functions across GCO, GDD and the wider organization, such as Quality Assurance.
- Coordinate and support Hub & Country related audits & inspections (e.g. Clinical Development Audit, Investigator Site Inspection) as per selection and scope, from preparation to CAPA & effectiveness checks completion, working closely with Quality Assurance. Support and conduct of inspection readiness as per scope.
- Deliver the GCO self-assessment strategy related checks and controls as assigned and share insights within the GCP Compliance team based on the day-to-day support provided.
- Support cross-functions risk assessments if program/trial/country level in scope, working with Hub & Country Teams and the relevant GCO functions.
- Contribute to the monitoring relevant indicators/ metrics/thresholds ensuring the detection of unreported issues, trends and early signals of risks at Hub & Country level.
- Participate in relevant GCO, PTC, GCP Compliance team meetings. May attend as needed or be delegated by the GCP Compliance Head (EMEA hub) to participate in relevant boards, committees and escalation meetings (e.g. GCO Quality Review Board; Issues Management & Escalations Triaging Meetings).
- Contribute to build a network of managers and other relevant stakeholders with other functions, compliance, process, training and risk groups across GCO, in GDD and within the wider organization, such as Quality Assurance.
- Promote a compliance culture within GCO, advocating the adherence to highest standards and ethical integrity.

Education:

- Advanced degree in science, engineering or relevant discipline.

Experience/Professional Requirement:

- 8+ years industry experience specifically in clinical operations and clinical site management with a strong understanding of clinical research international standards and regulatory requirements from Health Authorities. Audits and inspections experience highly desirable.
- Organizational and analytical skills associated with an aptitude in quality management and continuous improvement.
- Critical thinking ability and risk management and risk-based knowledge and mindset.
- Ability in partnering with a proactive and solution-oriented mindset.
- Strong skills to facilitate/optimize contribution of team members as individuals and members of a cohesive team.
- Ability to work effectively in a matrix cross-functional environment.
- Strong capacity for working independently with minimal guidance.
- Ability to make & communicate difficult decisions, associated with strong written and verbal communication skills.
- Self-awareness, willingness to further develop own strengths and explore opportunities for improvement.

Languages :

- English.

Novartis South Africa is committed to promoting equity (race, gender, and disability) through the filling of this post with a candidate whose

transfer/promotion/appointment will promote representivity in line with the numerical targets as contained in our Employment Equity plan. While we are prioritizing designated groups, our selection process will still be based on the most suitable candidate, with the necessary skills and experience, as outlined in the job description.

Why Novartis:

Our purpose is to reimagine medicine to improve and extend people's lives and our vision is to become the most valued and trusted medicines company in the world. How can we achieve this? With our people. It is our associates that drive us each day to reach our ambitions. Be a part of this mission and join us! Learn more here: https://www.novartis.com/about/strategy/people-and-culture

You'll receive: You can find everything you need to know about our benefits and rewards in the Novartis Life Handbookhttps://www.novartis.com/careers/benefits-rewards

Join our Novartis Network: If this role is not suitable to your experience or career goals but you wish to stay connected to hear more about Novartis and our career opportunities, join the Novartis Network here:
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)

Дивизион
Development
Business Unit
Development
Место
Южноафриканская Республика
Сайт
Midrand
Company / Legal Entity
ZA01 (FCRS = ZA001) Novartis SA (Pty) Ltd.
Functional Area
Research & Development
Job Type
Full time
Employment Type
Regular
Shift Work
No

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)

Novartis is committed to building an outstanding, inclusive work environment and diverse teams' representative of the patients and communities we serve.

Job ID
REQ-10072414

GCP Compliance Manager (EMEA Hub)

Apply to Job

Job ID
REQ-10072414

GCP Compliance Manager (EMEA Hub)

Apply to Job

Source URL: *https://novartis.ru/careers/career-search/job/details/req-10072414-gcp-compliance-manager-emea-hub*

List of links present in page

1. https://www.novartis.com/about/strategy/people-and-culture
2. https://www.novartis.com/careers/benefits-rewards
3. https://talentnetwork.novartis.com/network
4. https://www.novartis.com/about/strategy/people-and-culture
5. https://www.novartis.com/sites/novartis_com/files/novartis-life-handbook.pdf
6. https://www.novartis.com/about/strategy/people-and-culture
7. https://www.novartis.com/sites/novartis_com/files/novartis-life-handbook.pdf
8. https://novartis.wd3.myworkdayjobs.com/en-US/Novartis_Careers/job/Midrand/GCP-Compliance-Manager--EMEA-Hub-_REQ-10072414-1
9. https://novartis.wd3.myworkdayjobs.com/en-US/Novartis_Careers/job/Midrand/GCP-Compliance-Manager--EMEA-Hub-_REQ-10072414-1