NOVARTIS

Head GCP Inspection Management

Job ID
REQ-10013826
Juli 10, 2024
Schweiz

Zusammenfassung

Our Development Team is guided by our purpose: to reimagine medicine to improve and extend people's lives. To do this, we are optimizing and strengthening our processes and ways of working. We are investing in new technologies and building specific therapeutic areas and platform depth and capabilities – all to bring our medicines to patients even faster. We are seeking key talent, like you, to join us and help give people with disease and their families a brighter future to look forward to. Apply today – we will thrive together!

About the Role

Purpose

Are you ready to become the Head, Good Clinical Practice Inspection Management? If Quality Assurance runs through your veins, then please read on. You will be accountable for the GCP Inspection strategy development and execution is. The successful applicant will oversee all the processes when it comes to an inspection. A good inspection is knowing that before it starts, we know how it ends. Therefore, if all elements are completed in the planning phase then this truly defines the success of this role. This is a extremely exciting time to join Novartis at a leadership level, driving quality compliance, success, innovation and nurturing development.

Key requirements but not limited to:

- **Drive and maintain quality strategic oversight - governance and processes - for global and key market pre-approval and global supervisory GCP HA Inspections, including global supplemental submissions, through maintaining a centralized inspection readiness model within RDQ/CQA**
- **Provide leadership and direction to subject matter experts in Development and RDQ prior, during and after relevant GCP Inspections to ensure a well-maintained inspection readiness culture; provide training and coaching to colleagues as appropriate and required.**
- **Guide and oversee Project Management for pre-approval and global supervisory GCP HA Inspections incl. tactical action tracking during the end-to-end process of inspection preparation, conduct and close out.**

- **Guide and oversee pre-approval and global supervisory GCP HA Inspection risk assessments in collaboration with the business stakeholders, provide input to the RDQ risk management team, and updates to senior management.**
- **Maintain GCP Inspection knowledge and inspection intelligence (external trends, industry benchmarks) and ensure that learnings are shared across Development and RDQ; analyse internal and external inspection findings and develop inspection risk mitigation strategies.**

Your Experience:

- **Master's degree in life sciences / healthcare, M.D, Ph.D or MBA is desired.**
- **At least 15 years of experience in the pharmaceutical drug development industry**
- **A minimum of 10 years managing and hosting global health authority inspections (e.g., with FDA, EMA, MHRA, BfArM, PMDA, or other major health authorities).**
- **Strong focus of quality and compliance, with very good knowledge of relevant European, US and local regulations.**
- **Proven track record as a leader of global and cross-functional teams and being a role model for the Novartis values and behaviours and exemplary interpersonal skills.**
- **Project management experience including use of MS Project.**
- **High learning agility, mentally quick, comfortable with complexity and diversity, and highly interested in continuous improvement.**
- **Excellent communication, negotiation and change management skills.**
- **Proficient English language skills.**

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

Commitment to Diversity & Inclusion:

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

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

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Abteilung
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Business Unit
Innovative Medicines
Ort
Schweiz
Website
Basel (City)
Company / Legal Entity
C028 (FCRS = CH028) Novartis Pharma AG
Functional Area
Quality
Job Type
Full time
Employment Type
Regular
Shift Work
No
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