NOVARTIS

GCP Inspection Project Manager

Job ID
REQ-10013827
Oct 16, 2024
United Kingdom

Summary

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!

This role will be based in London, UK in a hybrid working approach

About the Role

Are you ready to become a GCP Inspection Project Manager? The successful applicant will have will be proficient in Microsoft Project as they will be tracking for visibility and transparency. This role is all about driving the management deliverables to support the execution a GCP inspection. Therefore, you will drive the collection for readiness, initiate discussion, stay on track and a show a strength of character to manage effectively. The individual will know that delays create problems, so keeping to a critical timeframe will mitigate risk.

Key requirements but not limited to:

- Define and provide Project Management support to assigned Development cross-functional program teams on inspection preparation, conduct and close out.
- Lead routine HA Inspection readiness project update meetings and tracking of line function deliverables.
- Support RDQ/CQA in the identification of potential risks, issues or gaps which may arise during GCP HA Inspection.
- Ensure risks are summarized and communicated to RDQ/CQA management, RDQ Heads, Global Program Heads, and other relevant line stakeholders, as needed.
- Maintain e-tools, systems and repositories required for HA Inspection deliverables.
- Collaborate with Development functions on content updates and enhancements.

- Support line functions in the identification, preparation and review of program specific documents prior to HA Inspections (i.e. develop storyboards, complete checklists).
- Plan and facilitate inspection preparation meetings, documentation of mitigation plans and ensure that inspection program teams are informed accordingly.

Your Experience:

- Bachelor's degree in life sciences / healthcare, or an advanced degree preferred.
- 6-8 years of pharmaceutical Quality Assurance experience.
- Solid experience of Microsoft Project
- Advanced understanding of the clinical drug development process and corresponding global clinical regulations. Experience in clinical development, submission and inspection activities preferred.
- Experience in Project Management and use of MS Project.
- Strong operational skills demonstrated excellence in execution.
- Proven matrix leadership skills: provides direction, vision and aligns team to deliver results.
- Excellent communication, negotiation, and interpersonal skills. Ability to successfully partner and communicate across all levels in the organization including GDD leadership as well as external stakeholders such as health authority inspectors.
- 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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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

Division
Development
Business Unit
Innovative Medicines
Location
United Kingdom
Site
London (The Westworks)
Company / Legal Entity
GB16 (FCRS = GB016) Novartis Pharmaceuticals UK Ltd.
Functional Area
Quality
Job Type
Full time
Employment Type
Regular
Shift Work
No
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2. https://talentnetwork.novartis.com/network
3. https://www.novartis.com/about/strategy/people-and-culture
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