Senior Process and Compliance Manager

Job ID
REQ-10065574

10月 27, 2025

India

摘要

Responsible for ensuring operational excellence related to clinical trial activities within Translational Clinical Oncology (TCO). Track progress to key quality indicators (KQIs), Quality Plan and overall compliance to applicable processes and regulations. Lead and assist in the development and implementation of process improvement initiatives within the function; ensure changes are adequately communicated and managed. Work collaboratively with clinical QA (CQA) and appropriate line functions to ensure that TCO upholds high quality standards.

About the Role

Major accountabilities:

- Accurate and timely execution of process improvement and quality initiatives as measured by meeting key milestones effectively.
- Successful implementation of process improvements as measured by sustainable changes and improved efficiency.
- Increased compliance with relevant processes.

- Establish business partnerships with all relevant TCO functional groups, CQA, training and other LFs as required.
- Training programs implemented in a timely fashion, and tracked to ensure compliance and maintenance

Impact on the Organization:

- Improved quality of outputs
- Increased compliance with SOP, GCP and training
- Decreased audit/inspection findings
- Efficient use of resources through operational effectiveness

Additional Details

- KQIs - Responsible to track, report and reinforce adherence to applicable performance measures. Support in recommending corrective actions based upon report outputs and root cause analysis; and support implementing training/communication as applicable to ensure remediation (preventative actions). Support Clinical Trial Quality Risk Management (CTQRM) review by evaluating studies to ensure adherence to CTQRM SOP and follow-up with respective study leads.
- SOPs - provide input into new SOPs/WPs on behalf of TCO as applicable, may serve as subject matter expert. Contribute to identifying training opportunities and ensuring compliance with new SOPs and Working Practices. Track quality issues and ensure their documentation within the quality event management system and implementation of corrective actions. Support the implementation and tracking of compliance to the clinical trial processes.
- Quality Plan - Ensure that actions required of TCO are appropriately tracked. Support the conduct of self-assessments for TCO in conjunction with CQA. Proactively ensure procedural deficiencies within TCO are corrected and prevented. Liaise with BR TM and CS&I and appropriate Development LFs to ensure quality outcomes.
- Process Expertise - identify or support the identification of procedural gaps and their correction with process improvements where applicable. Represent TCO/BR in cross-functional initiatives aiming for continual process improvement and ensuring a compliance focused environment either by direct involvement or by ensuring appropriate TCO/BR representation. May serve as Managed Access Program Champion.
- Training -Support training/communications to assure understanding of new processes or findings. Assure remediation. Identify gaps and assign action where needed to promptly gain compliance. Assist with change management activities related to new processes or organizational changes. Support/organize timely Lessons Learned sessions.
- Compliance - As applicable based on assignment, ensure Corrective Actions Preventative Actions (CAPA) commitments are adequate, submitted and completed in a timely manner. Initiate and document root cause investigations of critical issues. Support inspection preparation and inspection readiness. Ensure the timely submission and completion of adequate Corrective Actions Preventative Actions (CAPA). Ensure audit and inspection outcomes requiring corrective action are managed.
- Act as TCO Protocol Review Committee Manager, as assigned: run PRC Office independently (meetings and agenda planning, uploading of documents in review system), maintain the PRC SharePoint site, system owner of the TCO PRC submission tracker, providing training and access and working with IT on system updates; maintain revisions to the PRC charter.
- Act as BR-DOC Manager, as assigned - manage end-to-end document QC function with BR Translational Medicine - BR Doc function. Provide vendor management, track submissions and provide guidance to TCO teams.
- As assigned, participate as a reviewer on the TCO Protocol Review Committee or assist with quality checks of documents (protocols, ICFs, etc) as appropriate per TCO process.
- Escalate issues to TCO management and CQA in a timely manner.

Minimum Requirements:
Work Experience:

- A minimum of 5 years of relevant pharmaceutical clinical development experience
- Extensive knowledge of clinical development process, GCP and clinical quality management; including strong understanding of regulation and guidance for clinical studies
- Proficiency/Fluency in English
- Experience working in matrix environment and in global teams.
- Excellent interpersonal, problem-solving, negotiation and conflict resolution skills
- Excellent organizational skills, as well as predisposition to quality management and process improvement

- Excellent communicator and presenter (oral and written).

Education:

- Bachelor of Science (BS) or advanced degree in scientific discipline or equivalent education in life science/healthcare required

Languages :

- English.

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

部门
Biomedical Research

Business Unit
Pharma Research

地点
India

站点
Hyderabad (Office)

Company / Legal Entity
IN10 (FCRS = IN010) Novartis Healthcare Private Limited

Functional Area
Research & Development

Job Type
Full time

Employment Type
Regular

Shift Work
No

Apply to Job

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.india@novartis.com and let us know the nature of your request and your contact information. Please include the job requisition number in your message.

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

Job ID
REQ-10065574

Senior Process and Compliance Manager

Apply to Job

Source URL:
https://www.novartis.com.cn/careers/career-search/job/details/req-10065574-senior-process-and-compliance-manager

List of links present in page

1. https://www.novartis.com/about/strategy/people-and-culture
2. https://talentnetwork.novartis.com/network
3. https://www.novartis.com/careers/benefits-rewards
4. https://novartis.wd3.myworkdayjobs.com/en-US/NovartisCareers/job/Hyderabad-Office/Senior-Process-and-Compliance-ManagerREQ-10065574
5. mailto:diversityandincl.india@novartis.com
6. https://novartis.wd3.myworkdayjobs.com/en-US/NovartisCareers/job/Hyderabad-Office/Senior-Process-and-Compliance-ManagerREQ-10065574