NOVARTIS

Associate Director, Clinical Quality Assurance

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Китай

Сводка

Provide strategic end-to-end Quality oversight on the clinical trials to ensure compliance with the Health Authorities' requirements, the internal standards and a full adherence to patients' safety, rights, well-being and data integrity.
Provide QA insights into risk analysis and participate in decision making together with internal stakeholders, to assure that clinical trials have no delays whilst maintaining high quality level data.
Provide QA expertise and guidance to Translational Medicine and Translational Clinical Oncology and collaborate with other QA functions in order to ensure that high priority programs and Quality initiatives driven by the business meet defined expectations.
Takes full ownership of the quality aspects of the assigned clinical trials
Lead/ participate in due diligence and integration activities for assigned programs.
Drive a culture of quality in BR by partnering to positively impact the business and implement the quality strategy.

About the Role

Major Accountabilities:

1.Provide robust and clear quality oversight in the following areas of clinical development:

- Collaborating with key stakeholders to detect, prevent, and remediate risks and to ensure that clinical trial processes and operations are in control (e.g. Risk-based Quality Management). Work effectively in a matrix environment with stakeholders to prioritize, develop, and implement plans to address gaps and ensure sustained compliance.
- Support identification and management of quality issues/incidents pertinent to BR clinical areas, ensuring timely escalation when required.
- Provide QA oversight to ensure interactions with Health Authorities are consistent with regulatory requirements, Novartis standards, and HA expectations through CSR review, audit planning, submission readiness, and inspection preparation & facilitation in collaboration with other QA functions.
- Supporting/leading inspection/audit follow-up activities including CAPA preparation, review, effectiveness and closeout activities and lessons learned
- Proactively reviewing outcomes/trends to sustain improvement in clinical processes and trial conduct in collaboration with other QA functions.
- Support implementation of Quality Plan actions as assigned and ensure that any delayed activities have a documented rational and appropriate escalation.
- Support continuous improvement initiatives and ensure that areas identified as weaknesses are properly being addressed and executed for sustainability
- Coach and advise new clinical Quality associates, student interns, fellows, and job shadow/sabbatical participants in the team as assigned by manager
- Act as CQA expert for process/systems as assigned (e.g. 1QEM system, FIRST, NCV, Andromeda, Sense)

2. Provides expert knowledge and skills for the wide range of Research & Development activities to ensure compliance to regulatory requirements and interdependence with the GCP areas for the fast-changing research environment, including:

- Research Collaborations
- Mergers and acquisitions (e.g. Due diligence or Integration SME as assigned)
- Non/low intervention studies

3.Support implementation of Quality Plan actions as assigned and ensure that any delayed activities have a documented rational and appropriate escalation.

4.Support continuous improvement initiatives and ensure that areas identified as weaknesses are properly being addressed and executed for sustainability

5.Coach and advise new clinical Quality associates, student interns, fellows, and job shadow/sabbatical participants in the team as assigned by manager

6.Act as CQA expert for process/systems as assigned (e.g. 1QEM system, FIRST, NCV, Andromeda, Sense)

Experience/Professional requirement:

- +7 years of involvement in regulated activities (GCP/PV), clinical development and/or QA positions.
- Broad understanding of global expectations of Health Authorities in the area of Clinical Development and profound understanding of the science of product development.
- Ability to work independently and in a global/matrix environment.
- 3 or more years' experience in managing projects.
- Ability to effectively interact with and present to senior management at all levels, as well as to external audiences and inspectors.
- Strong skills in GCP, quality and/or clinical development.
- Strong interpersonal, communication, negotiation, and problem-solving skills.
- Strong office IT skills including MS Office suite.
- A clear sense of personal accountability, an ability to empower people, ability to drive quality culture with partners and a high degree of mutual respect and integrity are essential factors to succeed.

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

Biomedical Research
Business Unit
Research
Место
Китай
Сайт
Shanghai (Shanghai)
Company / Legal Entity
CN14 (FCRS = CN014) China Novartis Institutes for BioMedical Research Co., Ltd.
Functional Area
Quality
Job Type
Full time
Employment Type
Regular
Shift Work
No

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.

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