NOVARTIS

Associate Director Biomedical Research Clinical Quality

Job ID
REQ-10065466
мар 02, 2026
Япония

Сводка

Provide strategic Quality oversight on the entire Clinical Trial Process (CTP) for the clinical trials under responsibility in order to ensure compliance with the Health Authorities requirements, the internal standards and a full adherence to patients' safety, rights and well-being.
Provides risk analysis to internal stakeholders to make critical decisions.
Dispense 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, 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 efforts for assigned programs.

Drive a culture of quality in NIBR by close business partnering to positively impact the business and implementing the quality strategy.

About the Role

Major Activities ：

- Proactively provide QA leadership for assigned franchise by ensuring considerable organization awareness (e.g. Interrelationship of departments and business priorities).
- Support implementation of quality strategy under the responsibility of Translational Medicine or Translational Clinical Oncology.
- Regularly monitor the implementation of the annual Quality Plan pertaining to the Clinical chapter and ensure that all delayed activities have a documented rational and appropriate escalation.
- Ensure adequate oversight of proactive quality risk management process in the overseen areas including quality risk assessments and submission/inspection readiness activities and ensure that Clinical Trial Processes are in control.
- Provide robust and clear quality oversight in the following areas of clinical development:
- Actively leverage audit/inspection outcomes/trends to sustain improvement in clinical trials conduct.
- Support continuous improvement initiatives and ensure that areas identified as weaknesses are properly being addressed and executed for sustainability
- Be QA point of contact for the assigned franchise and ensure quality is embedded in the decision taking processes.

Education(minimum/desirable):

Degree in Life Sciences, Pharmacy or Medicines. Advanced degree a plus.

Languages:

Fluency in English (oral and written)

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.

Why consider Novartis?

817million. That's how many lives our products touch. And while we're proud of that fact, in this world of digital and technological transformation, we must also ask ourselves this: how can we continue to improve and extend even more people's lives?

We believe the answers are found when curious, courageous and collaborative people like you are brought together in an inspiring environment. Where you're given opportunities to explore the power of digital and data. Where you're empowered to risk failure by taking smart risks, and where you're surrounded by people who share your determination to tackle the world's toughest medical challenges.

We are Novartis. Join us and help us reimagine medicine.

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Japan
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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
Quality
Место
Япония
Сайт
Toranomon (NPKK Head Office)
Company / Legal Entity
JP05 (FCRS = JP005) Novartis Pharma K.K.
Functional Area
Quality
Job Type
Full time
Employment Type
Regular
Shift Work
No

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

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