

HGRAC Specialist

Job ID
REQ-10075419
апр 09, 2026
Китай

Сводка

Responsible for HGRAC submission which focus on interpretation for HGRAC policies and document collection, submission, tracking and archiving.
Responsible for Clinical trial Registration (CTR) platform registration which focus on interpretation for CTR platform registration policies and document collection, submission, tracking and archiving.
Compliance with local regulations, GCP, Novartis SOP and applicable policies.

About the Role

Key responsibilities:

HGRAC Execution

- Act as key contact person to make sure local study teams can successful complete the preparation of HGRAC submission dossier, submit the HGRAC approval application and ensure all type of the HGRAC approval in line with HGRAC policies.
- Proactively negotiate with HGRAC and hospitals to ensure each permit application successful and each batch permit of trial samples to be exported successfully, per the trial plan.
- Maintain each type of HGRAC application related data tracking, as well as the relevant files archiving per the trial plan.
- Proactively work with local study teams to collect the data, address the issues and concerns to respond the internal/external environment change, and to proactively provide the inputs on the sample exportation application process optimization and issues resolution.

CTR platform registration

- Work as the registrant of CTR platform to make sure local study successful complete CTR platform registration in line with local regulations and Novartis SOP.
- Support line functions complete the registration form.
- Act as key contact person with CDE.

Essential requirements:

- Degree in scientific or healthcare is preferred, or equivalent working experience
- Fluent in local language
- Good English
- Minimum 2 years' pharmaceutical industry experience with 1 year strong experience in clinical research/HGRAC related work

Desirable requirements:

- Proven ability to manage teams and complex communication locally and in the global organization.
- Able to work in a matrix organization
- Ability to work under pressure
- Strong Interpersonal skills
- Strong leadership skills
- Working experience in a global team, team player
- Displays innovative ideas and solutions
- Highly proficient in negotiation skills
- Highly effective in influencing others

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>

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Дивизион
Development
Business Unit
Development
Место
Китай
Сайт
Beijing (Beijing)
Company / Legal Entity
CN14 (FCRS = CN014) China Novartis Institutes for BioMedical Research Co., Ltd.
Functional Area
Research & Development
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.

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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