Associate Director, Clinical QA Program Lead (m/f/d)

Job ID
REQ-10025784

12月 19, 2024

Spain

摘要

Associate Director, Clinical QA Program Lead (m/f/d)

Location: Barcelona Gran V í a, Spain #LI-Hybrid

The Associate Director, Clinical QA Program Lead will provide Quality oversight for the end-to end clinical process for the clinical trials under responsibility to ensure compliance with the Health Authorities requirements, the internal standards and a full adherence to patients ' safety, rights and well-being.

About the Role

Major accountabilities:

Your responsibilities will be but are not limited to:

- Proactively provide QA leadership to the business strategy for assigned programs/trials by ensuring considerable organization awareness (e.g. Interrelationship of departments and business priorities).
- Drive implementation of quality strategy within GCT/CTT under responsibility and monitor the implementation of the annual Quality Plan pertaining to the assigned programs/studies.
- 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 CTP processes are in control.
- Provide robust and clear quality oversight in different areas of clinical development such as collaboration with key stakeholders to ensure that risks are detected and remediated, support core governance for quality incident management for major deviations and ensure timely escalation when required, provide GCP guidance to day-to-day questions arising from Clinical trials deliverables, etc.
- Support inspections preparation and facilitation, also for audits and inspections follow-up activities including CAPA preparation.
- Active participation in continuous improvement initiatives (including Work streams).

Minimum requirements:

- Bachelors ' degree in life science or healthcare field required. Advanced degree or equivalent education/degree in life sciences/healthcare preferred (PhD/MD/ PharmD/Masters).
- Sound experience of involvement in regulated activities (GCP/PV), clinical development, and/or QA positions, as well as in project management.
- Broad understanding of global expectations of Health Authorities in the area of Clinical Development and profound understanding of the science of product development.
- Strong skills in GCP, quality and/or clinical development.
- Ability to work independently and in a global/matrix environment.

Desirable requirements:

- Prior experience in RLT strongly preferred.

Benefits & Rewards:

Read our handbook to learn about all the ways we ' ll help you thrive personally and professionally: Novartis Life Handbook

Benefits in Spain include Company Pension plan; Life and Accidental Insurance; Meals; Allowance or Canteen in the office; Flexible working hours.

Commitment to Diversity & Inclusion:

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 all individuals. If, because of a medical condition or disability, you need a reasonable accommodation for any part of the recruitment process, or in any order to receive more detailed information about essential functions of a position, please send an e-mail to inclusion.spain@novartis.com and let us know the nature of your request and your contact information. Please include the job requisition number in your message.

You will receive:

Competitive salary, Annual bonus, Pension scheme, Share scheme, Health insurance, 27 days annual leave, Flexible working arrangements, subsidized dining facilities, Employee recognition scheme, learning and development opportunities.

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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部门
Development

Business Unit
Innovative Medicines

地点
Spain

站点
Barcelona Gran V í a

Company / Legal Entity
ES06 (FCRS = ES006) Novartis Farmac é utica, S.A.

Functional Area
Quality

Job Type
Full time

Employment Type
Regular

Shift Work
No

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