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

Job ID
REQ-10025784
Ene 21, 2025
España

Resumen

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

Location: Barcelona Gran Vía, 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.

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

División
Development
Business Unit
Innovative Medicines
Ubicación
España
Sitio
Barcelona Gran Vía
Company / Legal Entity
ES06 (FCRS = ES006) Novartis Farmacéutica, S.A.
Functional Area
Quality
Job Type
Full time
Employment Type
Regular
Shift Work
No

Apply to Job

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

Job ID
REQ-10025784

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

Apply to Job

Source URL: *https://prod1.adacap.com/careers/career-search/job/details/req-10025784-associate-director-clinical-qa-program-lead-mfd*

List of links present in page

1. https://www.novartis.com/sites/novartis_com/files/novartis-life-handbook.pdf
2. https://www.novartis.com/about/strategy/people-and-culture
3. https://talentnetwork.novartis.com/network
4. https://www.novartis.com/careers/benefits-rewards
5. https://novartis.wd3.myworkdayjobs.com/en-US/Novartis_Careers/job/Barcelona-Gran-Va/Associate-Director--Clinical-QA-Program-Lead--m-f-d-_REQ-10025784-1
6. https://novartis.wd3.myworkdayjobs.com/en-US/Novartis_Careers/job/Barcelona-Gran-Va/Associate-Director--Clinical-QA-Program-Lead--m-f-d-_REQ-10025784-1