NOVARTIS

Principal Scientist I/II, Study Quality and Compliance - Nonclinical Safety/Toxicology

Job ID
REQ-10081568
июл 09, 2026
США
Available in: English

Сводка

Location: Cambridge MA
Internal: Principal Scientist I/II
LI#-Hybrid

The individual will provide scientific and operational support to Study Quality and Compliance group within the Toxicology line function of Preclinical Safety (PCS). Key areas of responsibility or oversight include ensuring training records, CVs, Job Descriptions (JDs) for all of PCS are appropriately maintained and on file, as well as periodic review and maintenance of departmental SOPs. With respect to these items, provide support to health authority inspections and internal inspection-readiness audits. This person will also be responsible for coordinating with the Archive Records Management function for the transfer of GLP and non-GLP study records and materials from one archive location to another. The ideal candidate would also have experience with SEND (Standard for Exchange of Nonclinical Data) packages to provide support for both creation and QC of these datasets.

About the Role

Key Responsibilities:

- Oversee periodic review and maintenance of PCS SOPs, garnering necessary stakeholder input and having good working knowledge of any company SOPs that influence or impact the PCS SOPs.
- Be responsible for ensuring PCS compliance with training records CV, and JDs, and ensure the process for doing so is consistent with GLP requirements.
- Support Archives Record Management (ARM) function, by collating a listing of all studies that have records and materials archived at CRO study site. Coordinate the ARM transfers to permanent archiving locations.
- Support SEND package creation and quality review for FDA submissions
- Support the Study Quality and Compliance team's effort for tracking and managing study-related information through input of information types from the areas of responsibility above and generally support the effort in various workstreams or initiatives.

Essential Requirements:

- Degree in biological related sciences
- 8+ years of relevant experience working in a pharmaceutical setting
- Experience working in GLP setting, and general regulatory compliance and animal welfare knowledge related to conduct of toxicology studies
- Good communication skills, and excellent logistical/planning skills
- Fluent in English (spoken and written)

Desirable Requirements:

- Previous experience with SEND packages is desirable
- Previous experience with software for online information and program management is a plus

This is a dual level posting. The final level & title of the offer role would be determined by the hiring team based on the skills, experience & capabilities required to perform the role at the level the role has been offered.

The salary for this position is expected to range between:

Principal Scientist I: $119,700 and $222,300 per year.
Principal Scientist II: $126,000 and $234,000 per year.

The final salary offered is determined based on factors like, but not limited to, relevant skills and experience, and upon joining Novartis will be reviewed periodically. Novartis may change the published salary range based on company and market factors. Your compensation will include a performance-based cash incentive and, depending on the level of the role, eligibility to be considered for annual equity awards.

US-based eligible employees will receive a comprehensive benefits package that includes health, life and disability benefits, a 401(k) with company contribution and match, and a variety of other benefits. In addition, employees are eligible for a generous time off package including vacation, personal days, holidays and other leaves.

To learn more about the culture, rewards and benefits we offer our people clickhere.

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)

EEO Statement:

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Accessibility & Reasonable Accommodations

The Novartis Group of Companies are 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 application process, or to perform the essential functions of a position, please send an e-mail to us.reasonableaccommodations@novartis.com or call +1(877)395-2339 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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Functional Area
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Job Type
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Employment Type
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Shift Work
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