NOVARTIS

Director, Study Quality and Compliance - Nonclinical Safety/Toxicology

Job ID
REQ-10081566
июл 09, 2026
США
Available in: English

Сводка

Location: Cambridge MA
Internal: Director
LI#-Hybrid

This role oversees the Study Quality and Compliance team within the Toxicology line function of Preclinical Safety (PCS). This team is responsible for: handling samples and data associated with both internally and externally conducted toxicology studies; maintaining departmental SOPs, and oversight of training records for departmental personnel; and interfacing with the archives function to ensure proper storage of toxicology-related materials and records. A major part of this role will be to identify and implement a software system that enables effective tracking and analytics of study-related information that this group is responsible for overseeing.

About the Role

Key Responsibilities:

- Lead and provide strategic oversight to the PCS Study Quality and Compliance team including responsibility for establishing long-term strategy and yearly goals which support it
- Modernize the group functionality leading the implementation of tracking, management, and data analytics software (eg, Smartsheet) across the toxicology line function to enhance quality and compliance oversight of toxicology studies
- Oversight of toxicology study data management from external and internal studies; this includes data suitability and availability for our internal toxicology study data warehouse
- Oversight and responsibility for ensuring SEND (Standard for Exchange of Nonclinical data) datasets are of high-quality and are ready in a timely manner for regulatory submissions, which includes SEND datasets from external CRO and de novo generation for internal non-GLP studies
- Oversight of SOPs and training records for PCS personnel to ensure compliance with GLP expectations, and serve as the management interface with the Archive Records Management team
- Oversight of support for biomarker and pathology with respect to shipment of study samples and data transfer of digital slides
- Support diligence acquisition and licensing deals through oversight and management of study-related data (including SEND) that need to be transferred

Essential Requirements:

- Advanced degree in biological-related sciences with at least 10 years of relevant pharmaceutical experience, or BS degree in biological-related science with 15 years of experience
- Previous experience working with GLP guidelines and pharmaceutical toxicology studies, and associated quality, compliance, and animal welfare attributes
- Previous people management or leadership experience
- Good communication skills, and excellent logistical/planning skills
- Fluent in English (spoken and written)

Desirable Requirements:

- Previous experience with software tools for data and/or program management is highly desired
- Previous experience with SEND, or at a minimum good general familiarity with its requirements is desired

The salary for this position is expected to range between: $185,500 and $344,500 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:

The Novartis Group of Companies are Equal Opportunity Employers. We do not discriminate in recruitment, hiring, training, promotion or other employment practices for reasons of race, color, religion, sex, national origin, age, sexual orientation, gender identity or expression, marital or veteran status, disability, or any other legally protected status.

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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