

Director, Study Quality and Compliance - Nonclinical Safety/Toxicology

Job ID

REQ-10081566

Jul 09, 2026

LOC_US

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 click [here](#).

Role Requirements

Division

DIV_RE

Business Unit

Research

Location

LOC_US

Site

Cambridge (USA)

Company / Legal Entity

U175 (FCRS = US175) Novartis Institutes for BioMedical Research, Inc.

Functional Area

FCT_RD

Job Type

Full time

Employment Type

Regular

Shift Work

No

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