Senior Expert or Associate Director CMC Statistics

Job ID
REQ-10052921

Jul 23, 2025

USA

Summary

Novartis is seeking a CMC statistical lead within the Quantitative Science and Statistics (QSS) function in Technical Research and Development (TRD). The CMC statistical lead will be providing statistical expertise in support for broad activities within CMC domain across cell and gene therapies for pipeline programs. Collaborate and provide statistical input on broad CMC activities including but not limited to analytical method development, method qualification/validation, technology transfer/bridging, product specification, product stability, process improvement, process validation, process control and quality by design. Apply statistical principles and techniques to provide strategies and solutions to a wide range of challenging problems in the drug development environment. Build effective relationships with peers and managements across functions and organizations. Participate in development of departmental process and infrastructure, as well as cross-functional team activities.

About the Role

#LI-Hybrid

*** Role will be filled at level commensurate with the experience of the candidate**

Key Responsibilities:

- Provide strategic statistical leadership and expertise to CMC functions and project teams on the development and implementation of proper study design, statistical analysis and data interpretation
- Lead statistical support for CMC projects and participate in reviewing and writing study protocol and technical reports
- Support regulatory strategy and preparation of regulatory submissions such as IND and BLA and participate in meetings with regulatory agencies
- Develop novel statistical methods to solve challenging issues in cell and gene therapies CMC domain
- Participate in development of intra- and inter-department process and infrastructure
- Design and conduct statistical trainings to non-statisticians

Essential Requirements:

- PhD in statistics or other related field with high statistical content.
- **Minimum of 7 years (for Associate Director) or 3 years (for Sr Expert)** of relevant industry experience in Biotech or Pharmaceutical drug development and manufacture environment
- Solid understanding in experimental design, statistical methodologies, modeling and simulations. Convey study results with statistical soundness and integrity. Experience in Bayesian statistics is a plus
- Excellent computational skills in statistical packages such as SAS, R, JMP and Minitab
- Familiar with regulatory guidance, US and international standards such as FDA, EMA, ICH and USP and experience in US and global regulatory submissions
- Exhibit superior oral and written communication skills
- Efficiently work and collaborate across teams and function areas
- Demonstrate mentorship and leadership skills

The pay range for this position at commencement of employment is expected to be between $132,300 and $245,700 /year (Senior Manager) & $145,6000 and $270,400/year (Associate Director); however, while salary ranges are effective from 1/1/25 through 12/31/2025, fluctuations in the job market may necessitate adjustments to pay ranges during this period. Further, final pay determinations will depend on various factors, including, but not limited to geographical location, experience level, knowledge, skills and abilities. The total compensation package for this position may also include other elements, including a sign-on bonus, restricted stock units, and discretionary awards in addition to a full range of medical, financial, and/or other benefits (including 401(k) eligibility and various paid time off benefits, such as vacation, sick time, and parental leave), dependent on the position offered. Details of participation in these benefit plans will be provided if an employee receives an offer of employment. If hired, employee will be in an “at-will position” and the Company reserves the right to modify base salary (as well as any other discretionary payment or compensation program) at any time, including for reasons related to individual performance, Company or individual department/team performance, and market factors.

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

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.

部門
Development

部門
Universal Hierarchy Node

国
USA

State
New Jersey

勤務地
East Hanover

Company / Legal Entity
U014 (FCRS = US014) Novartis Pharmaceuticals Corporation

Alternative Location 1
Durham, North Carolina, USA

Functional Area
Data and Digital

職種
Full time

雇用形態
Regular

Shift Work
No

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