Regulatory Diagnostics Associate Director

Job ID
REQ-10067179

11月 24, 2025

USA

摘要

The Regulatory Diagnostics Associate Director (RDAD) for Precision Diagnostics is responsible for implementation of strategic plans for development of diagnostics, including Companion Diagnostics (CDx), as they pertain to the Novartis innovative medicines portfolio, including its marketed products. The RD Associate Director works with oversight of senior members of the Regulatory Affairs Precision Diagnostics Team including the TA and Diagnostics Lead on strategies and submissions including companion diagnostics, in close collaboration with internal RA Disease Unit associates, associates of Digital, Data and Clinical Innovation (DDCI) at Novartis as well as Partner Companies that develop diagnostics and ensures adherence to regulatory requirements. The RD Associate Director will also provide regulatory support including tactical and technical regulatory direction for clinical trial assays to ensure compliance with regulations on diagnostics.

About the Role

#LI-Hybrid

Key Responsibilities:

Regulatory Strategy and Implementation

- Supports the diagnostics regulatory strategy for precision IVDs (In Vitro Diagnostic) and CDx (e.g. US, EU, Japan, China).
- Responsible for submissions in the premarket as well as post-market space including investigational Device Exemptions (IDE), Significant Risk Determinations, Performance Study Applications (PsA) and pre-market authorization submissions.
- Works to ensure diagnostic regulatory input for early development and late- stage programs is incorporated into the overall drug development strategy to ensure regulatory requirements pertaining to IVD, CDx and LDT regulations are met.
- Facilitates preparation, filing, finalization of briefing books including coordination and planning for pre-Submission or other meetings with HAs related to precision diagnostics and CDx development. Participation in HA meetings as appropriate.
- Develops, manages, and implements plans for timely response to HA requests and coordinates of any applicable follow-up activities.

Training and Compliance

- Support compliance activities for Novartis clinical trials as they relate to global regulations on precision diagnostics and CDx, such as European IVDR (In Vitro Diagnostic Regulation).

Performance Indicators

- Successful implementation of regulatory diagnostics strategies with timely submissions for precision IVDs and CDx and identification of precision IVD and CDx needs for Novartis programs.
- Full compliance with IVD and LDT rules for our clinical trials.

Essential Requirements:

- Science based BS or MS with requisite experience and demonstrated capability. Advanced degree (MS, Ph D, PharmD) considered a plus.
- Minimum 4-6 years of experience in pharmaceutical industry with relevant experience related to diagnostics, IVD or CDx development
    - Demonstrated experience of successfully contributions to a IVD/CDx regulatory project(s)
    - Experience in the diagnostic, IVD and/or CDx industry
    - Understanding of IDE, MAA, NDA/BLA, 510(k), PMA submission(s)
    - Understanding of assay validation and CLIA
    - Understanding of clinical trials
    - Strong interpersonal, communication and, negotiation skill

The salary for this position is expected to range between $145,600 and $270,400 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.

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: Read our handbook to learn about all the ways we ' ll help you thrive personally and professionally: https://www.novartis.com/careers/benefits-rewards

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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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Development

Business Unit
Development

地点
USA

状态
Massachusetts

站点
Cambridge (USA)

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

Alternative Location 1
East Hanover, New Jersey, USA

Functional Area
Research & Development

Job Type
Full time

Employment Type
Regular

Shift Work
No

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REQ-10067179

Regulatory Diagnostics Associate Director

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