NOVARTIS

Regulatory Diagnostics Manager/ Senior Regulatory Diagnostics Manager

Job ID
REQ-10046815
Apr 14, 2025
USA

Summary

The Regulatory Diagnostics Manager (RDM) 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 RDM 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 RDM 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

Key Responsibilities:

Regulatory Strategy and Implementation

- Supports the diagnostics regulatory strategy for precision IVDs and CDx (e.g. US, EU, Japan, China).
- With support of the RA TA and Diagnostics Lead, 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
- With oversight of the RA TA and Diagnostics Lead, 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
- As needed, partner with RA country organizations to align on local regulatory requirements for precision IVDs and CDx and deliver timely submissions as appropriate including annual reports and notifications
- 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.
- Member of RA subteam and Biomarker Development Subteam (BDST) as appropriate

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 Help ensure regulatory compliance of Partner companies for CDx development and IVD deliverables related to our portfolio, as appropriate and elevate to RA Diagnostic Lead where appropriate Support roll-out of new procedures, SOPs and working practices and training related to IVD and CDx development

Performance Indicators

- Successful implementation of regulatory diagnostics strategies with timely submissions for precision IVDs and CDx Full compliance with IVD and LDT rules for our clinical trials Identification of precision IVD and CDx needs for Novartis programs Strong partnership with RA Diagnostics Team members and the RA community Adherence to Novartis Policies and guidelines.

Essential Requirements:

- Science based BS or MS with requisite experience and demonstrated capability. Advanced degree (MS, Ph D, PharmD) considered a plus.
- Minimum 2-4 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) and/or submission
    - 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 skills

Senior Manager:

- 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 skills

The pay range for this position at commencement of employment is expected to be between $114,100 and $211,900 (Manager) & $145,600 and $270,400 (Sr. Manager)/year; 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

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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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

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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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