

Submission Readiness Document Manager

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REQ-10081315
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Ирландия
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Сводка

Job Title: Submission Readiness Document Manager

#LI-Hybrid

Primary Location: Dublin, Ireland

Relocation Support: This role is based in Dublin, Ireland. Novartis is unable to offer relocation support: please only apply if accessible.

Ready to play a critical role in delivering life-changing medicines to patients worldwide? As a Submission Readiness Document Manager, you will ensure that clinical documents are technically compliant, and submission-ready—enabling timely and accurate regulatory submissions. You'll collaborate across global teams, drive process improvements to enhance clinical document management systems, processes and standards at Novartis. This role offers a unique opportunity to shape how clinical documents support regulatory success while strengthening operational excellence across a fast-paced, global environment.

About the Role

Key Responsibilities

- Manage submission-readiness of clinical documents, ensuring compliance with regulatory requirements and quality standards
- Oversee technical editorial and formatting of clinical documents for regulatory submissions
- Ensure clinical documentation meets Health Authority guidelines, Good Clinical Practice, and Novartis procedures
- Support implementation of submission readiness strategies and standardized document templates
- Collaborate with cross-functional teams to deliver high-quality documents within timelines
- Monitor vendor performance, track service metrics, and drive continuous improvement initiatives
- Act as escalation point for submission readiness issues and resolve operational challenges
- Identify risks, trends, and gaps in submission processes and implement appropriate mitigations
- Serve as Subject Matter Expert for submission readiness processes, tools, and training materials
- Support audits and inspections, including root cause analysis and corrective and preventive actions

Essential Requirements

- Bachelor's degree in life sciences, healthcare, pharmacy, or information management
- Proven experience in clinical development, clinical operations, or a similar environment (3–5 years)
- Strong expertise in clinical document management processes and regulatory requirements
- Advanced knowledge of documentation best practices, including data integrity and good documentation principles
- Experience working with document management systems and strong understanding of system structures and functionality
- Ability to manage projects in a global, cross-functional environment
- Strong organizational, tracking, and communication skills
- High level of independence with the ability to manage complex priorities effectively

Benefits & Rewards

At Novartis, we're committed to reimagining medicine together - and rewarding the people who make it happen.

Expected Annual Base Salary Range for role: 55,370 to 102,830 EURO

The base salary offered is determined based on gender-neutral objectives, such as relevant skills, competencies and experience in accordance with the Novartis pay setting policy and upon joining Novartis will be reviewed periodically.

In addition to your base salary, you may be eligible for a performance-based bonus depending on certain performance parameters.

The rewards of being part of our team go far beyond base pay and incentives. We also offer a variety of competitive benefits in kind to help you thrive personally and professionally, such as insurance plans, retirement plans, wellbeing resources and global recognition programs. In addition, we provide flexible and hybrid working options, where possible, and minimum 14 weeks paid parental leave.

Pay equity is a fundamental principle of our employment policy and reflects our commitment to create a diverse, equitable and inclusive environment that treats all employees with dignity and respect, as outlined in our Code of Ethics.

Read our brochure to learn more about our global total rewards offering:

https://www.novartis.com/sites/novartis_com/files/novartis-life-handbook.pdf

Note: Benefits and compensation may vary by country and are subject to local legal requirements, including provisions of collective bargaining agreements where applicable. A full overview of your compensation package, including any relevant collective bargaining agreement details applicable to your role based on your employment location and Novartis employer entity, will be communicated separately to you during the application process.

Commitment to Diversity and Inclusion / EEO paragraph

Novartis is committed to building an outstanding, inclusive work environment and diverse teams' representative of the patients and communities we serve.

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 \(PDF 30 MB\)](#)

Primary location salary range
€55,370.00 - €102,830.00
Дивизион
Development
Business Unit
Development
Место
Ирландия
Сайт
Dublin (NOCC)
Company / Legal Entity
IE02 (FCRS = IE002) Novartis Ireland Ltd
Functional Area
Research & Development
Job Type
Full time
Employment Type
Regular
Shift Work
No

Job ID
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