



POSTGRADUATE CERTIFICATE IN REGULATORY MEDICAL WRITING



Regulatory Medical Writing Postgraduate Certification Course provides a possibility to learn strategies, tricks, action plans to become confident in collaboration within a clinical and regulatory environment to create accurate, clearly worded documents.

The Regulatory Medical Writing Course at Ladavius Academy provides a unique opportunity to delve deeply into the intricacies of regulatory writing, offering a blend of theoretical knowledge, hands-on practice, and real-world examples.

WHO IS THE PROGRAMME FOR?

This programme is designed for those wishing to achieve regulatory medical writer qualification and to further develop their regulatory affairs or clinical trials career.

Upon graduation, participants will achieve a highly prestigious sought after academic qualification plus the knowledge and skills.

Duration:

Theory 3 hours; Practice 6 hours.

Learning Mode:

Online. Part-time at your own path. Lifetime access to the materials.

Credits:

200 LAI credits, 3 Continuing Education Credits

NFQ Level:

Level 9



TEACHING & LEARNING METHODS

- Case Studies
- Live Cases
- Terminology
- Documents Templates
- Lectures from industry practitioners



BENEFITS

- **In-Depth Understanding:** Gain a profound understanding of the regulatory landscape, guidelines, and requirements governing medical writing in clinical and nonclinical contexts.
- **Document Types and Structure:** Explore various regulatory documents such as Investigator's Brochures, Clinical Study Reports, and Common Technical Documents (CTD), understanding their structure, purpose, and the critical information they convey.
- **Writing Techniques and Best Practices:** Hone your writing skills through practical sessions focused on developing clear, concise, and compliant regulatory documents. Learn industry best practices and techniques to effectively communicate complex scientific information.
- **Practical Examples and Case Studies:** Dive into real-world examples and case studies, dissecting successful submissions and identifying key elements that contribute to their approval.
- **Actual Submission Documents:** Gain exclusive access to actual submission documents, providing a hands-on experience in working with the materials encountered in regulatory processes.
- **Tips from Industry Experts:** Learn from experienced professional in the field who will share insights, tips, and strategies to navigate the regulatory writing landscape successfully.
- **Career Development:** Receive guidance on advancing your career in regulatory medical writing, exploring job opportunities, and understanding the evolving role of regulatory writers in the pharmaceutical and healthcare industries.

- **Practical Application:** Apply your knowledge by working on your own regulatory writing projects, whether you are a beginner crafting your first document or an experienced professional seeking to refine your skills.
- **Networking Opportunities:** Connect with fellow participants, industry experts, and potential employers through networking sessions, fostering a supportive community of regulatory medical writers.

This programme is tailored for professionals at various career stages, including researchers, medical writers, regulatory affairs specialists, and professionals transitioning into regulatory medical writing. Whether you're looking to enhance your skills, explore a new career path, or stay current with industry trends, our Regulatory Medical Writing Course provides the tools and knowledge needed for success in this critical and evolving field.

APPLICATIONS & FEES

Applications to the programme are made via the website:

www.ladavius.com/courses/medical-regulatory-writing/

Regular Fee: € 950

Spring Enrolment Fee until 31May2024: € 450

