
UNIVERSITY OF COPENHAGEN
FACULTY OF HEALTH AND MEDICAL SCIENCES
MASTER OF MEDICINES REGULATORY AFFAIRS
Innovate and strengthen the regulatory process
atrium

MASTER OF MEDICINES REGULATORY AFFAIRS

The Master of Medicines Regulatory Affairs uniquely combines practice-based competencies from industry and/or medicines agencies with the latest research and knowledge in regulatory science.

This practice-based continuing education provides in-depth knowledge and understanding of the regulatory work.

The scientific approach facilitates sound and transparent regulatory decision-making and will enable you to challenge specialists and argue for clinical relevance and scientific legitimacy to ensure a strong, reliable and quality-based storyline. The Master of Medicines Regulatory Affairs combines aspects from the classic safety, clinical and quality disciplines to meet the broader responsibilities of lead regulatory affairs specialists.

OUTCOME

The programme will provide you with a mix of practice-based competencies, in-depth scientific knowledge, and effective negotiation skills.

A comprehensive understanding of the regulatory process enables a more strategic and tactic approach to be taken to ensure innovation progress while maintaining product safety in order to obtain a sound and speedy marketing authorisation.

Enrol in the master's programme and:

- Achieve a thorough insight into the regulatory process at all stages during drug development and life cycle.
- Become competent in analysing, predicting and advising on drug regulations and directives.
- Learn to critically examine legislation in regulatory science.
- Get an overview of the differences in regulatory demands globally.
- Understand how to organise the regulatory work across the classic safety, clinical and quality disciplines to prevent delays in the innovation process.

PARTICIPANTS

This master's programme is designed for ambitious regulatory affairs specialists employed in industry, regulatory agencies, or consulting. Enrolment requires an academic degree and at least two years' work experience with regulatory affairs. You can sign up for the full programme or individual courses.

"I chose this master's programme because I want to be able to help advise government and regulatory bodies in Rwanda on how to optimize regulatory affairs without compromising the outcome on access to medicines. For that, I needed a specialized education, and I found that at University of Copenhagen."

- Moses Kasigazi, Master's graduate. Vaccines Supply Chain and Logistics Manager, partnering with Rwanda Ministry of Health.

STUDY PART-TIME

The master's programme consists of intense courses, combining lectures, seminars and/or individual assignments. For the individual assignments, you will work independently often on a topic of your own choice, preferably relevant to both you and the company you work for. You will be taught by leading experts from both academia and industry.

This programme must be completed within 2 to 6 years, which allows you to work full-time and study part-time concurrently.

Compulsory courses	ECTS
Clinical Development and Documentation	4
Discovery and Development of Medicines	5
Drug Regulatory Science	3
Global Pharmaceutical Policy – Rationales and Stakeholders	4
Labelling as a Driver for Regulatory Strategy	3
Safety of Medicines - from Non-clinical Development to Pharmacovigilance	4
The EU Regulatory Environment – Procedures and Applications	4
The US Regulatory Environment	4
Transparency and Trustworthiness in Drug Development	3
Fixed elective courses – choose one	
Biopharmaceuticals – Quality Development and Documentation	4
Quality – Drug Substance and Drug Product	4
Elective courses	**10**
Master's project	**12**

"One of the reasons I chose the programme is because it allows me to continue my regular work during my studies, and I can take it at my own pace.

I definitely recommend the Master of Medicines Regulatory Affairs to others. The lecturers have a high standard and broad knowledge, and the other students are very experienced. This combination creates a wide perspective, interesting discussions, and a great network. It has been a really positive experience so far."

- Ewa Törnqvist, Master's student. Owner of R-Track Consulting, Sweden.

COLLABORATION
The University of Copenhagen and Atrium have co-created the Master of Medicines Regulatory Affairs.

Atrium
Atrium is an international educational academy established in 1972. As an independent part of the Danish Association of the Pharmaceutical Industries, Atrium has a close connection to the experts in the pharmaceutical industry and medicines agencies. Atrium is one of Europe's leading private course providers of practice-based courses in regulatory affairs.

Copenhagen Centre for Regulatory Science
Copenhagen Centre for Regulatory Science (CORS) was established to meet the University of Copenhagen's strategic commitment to become internationally influential in the field of research and education in regulatory science. This strategic centre includes interdisciplinary research in regulatory science.

APPLICATION DEADLINE
Programme application deadline:
1 November every year.
Course application deadline:
6-8 weeks prior to course start.

FOR FURTHER INFORMATION
Visit **mra.ku.dk** or contact **master@sund.ku.dk**.

Photos: Shutterstock, iStock, Christoffer Regild, University of Copenhagen and Atrium | Print: Printfoparitas | Design: Kliborg Design | 2023