University for Continuing Education Krems

Master

EU Regulatory Affairs

Master of Science – MSc (CE)
4 semesters, part time

donau-uni.ac.at/regulatoryaffairs-msc





EU Regulatory Affairs

The pharmaceutical and medical device sectors are one of the most highly regulated in the world second only to the nuclear and aerospace industries. In order to keep abreast of current trends it is necessary for professionals working in those industries to be well acquainted with current and future trends and regulations.

The continuing education program therefore responds to a steadily growing and strategically important need for specialized competencies in sectors shaped by regulatory complexity, digital transformation, and rising security requirements.



"The program is ideal for regulatory professionals looking to advance their career in the field covering EU pharmaceutical and medical device registration and includes current topics such as AI and Digital Transformation, Combination Products, the New EU Pharmaceutical Legislation and Software as a Medical Device."

— Salma Michor PhD, RAC,
C-Level Pharma and MedTech, entrepreneur,
non – executive and executive board member, strategist

Modular Structure

Compulsory Modules
(63 ECTS)

> Introduction to Regulatory Affairs
> Drug Regulatory Affairs
> Medical Device Regulatory Affairs
> Pharmaco-economics and Decision-Analytics
> Biologics, Plasma and Blood Products
> Special Topics in Regulatory Affairs
> Quality Management and Compliance
> Clinical Trail Management
> Artificial Intelligence in Regulatory Affairs
> Research Methods and Academic Writing
> Strategy and Management
> Commercial and Financial Management

Specialization Modules (students select one)
(9 ECTS)

> Specialization EU Drug Regulatory Affairs
> Specialization EU Medical Device Regulatory Affairs
> Specialization Middle East Drug Regulatory Affairs

Master's Thesis Colloquium
(3 ECTS)

Master's Thesis
(15 ECTS)



Aims of the Program

The continuing education program provides an advanced understanding of the European and international regulatory frameworks governing pharmaceuticals, medical devices, and related healthcare products. Students acquire the knowledge and skills required to professionally plan, evaluate, and support regulatory documentation, market authorization strategies, and compliance requirements. They are enabled to identify changes in legislation and regulatory guidelines at an early stage and to assess their implications for products, processes, and organizations. The program also fosters the ability to communicate complex regulatory matters effectively to diverse stakeholders and to coordinate interdisciplinary teams with confidence.

Furthermore, students develop the capability to identify regulatory risks, assess them based on evidence, and derive appropriate measures to ensure quality, transparency, and compliance. Another key focus is the development of a strategic understanding of the role of Regulatory Affairs in innovation, market access, and sustainable corporate governance.

Qualification Profile

Graduates of this Master's Program are enabled to:

> explain the key regulatory frameworks for medicinal products, medical devices, and related healthcare products at European and international level

> analyse regulatory requirements throughout the product lifecycle

> develop structured approaches for the preparation, review, and maintenance of regulatory documentation and dossiers

> discuss the impact of new legal and normative requirements on organisations, processes, and products

> develop appropriate measures to minimise regulatory risks

> communicate regulatory matters effectively to internal and external stakeholders in a manner appropriate to the target audience

> design regulatory decision-making processes, taking into account economic considerations, time management, and strategic objectives

> identify potential gender and diversity aspects in regulatory assessments, processes, and decision-making

> discuss the role of Regulatory Affairs as a strategic function in order to ensure compliance, market access, and sustainable business development

Study Program

The modules of this part-time program which combine online learning and face-to-face sessions (online and/or on campus) are taught in English language.

In addition to the modules scheduled according to a timely predefined schedule, the program also includes selfdirected learning units that are not bound to fixed dates and may be completed flexibly.

The evaluation of the students' learning process will be based on written online exams after each module and/or students' participation in group works, homeworks, discussions and presentations.

It is possible to finalize the Certificate Program first. Completed modules can then be credited towards the MSc continuing education program.



EU Regulatory Affairs

Target Group
Professionals in the pharmaceutical and medical technology sectors working in Regulatory Affairs, Quality Assurance, Clinical Research, Product Development, or Market Access who seek to deepen their knowledge and expertise in regulatory affairs.

Admission Requirements
> A degree in a relevant field of study at a minimum of Bachelor's level (180 ECTS credits) from a recognised national or international post-secondary educational institution
AND
> Several years of relevant professional experience
AND
> A positive completion of the selection procedure at University Krems
> English language skills

Program Director
Mag. Michael Ogertschnig, MBA
Department for Economy and Health

Quick Facts

Graduation
Master of Science (Continuing Education) – MSc (CE)

ECTS-Points
90

Learning Format
Distance Learning

Duration
4 semesters, part time

Locations
University for Continuing Education Krems, another venue abroad and online

Costs
EUR 14,900 (the fees do not include any taxes, travel or accommodation costs, RAC exam from RAPS)

Language
English

Cooperation Partner

RAPS REGULATORY AFFAIRS PROFESSIONALS SOCIETY

University for Continuing Education Krems



The University for Continuing Education Krems specializes in academic continuing education for working professionals. As a public university for continuing education, it works with its expertise in research and teaching to overcome societal challenges and tailors its study programs to address them. The continuing education study programs cover ten fields of study and meet the specific requirements of students with work experience. With approximately 6,500 students coming from more than 100 countries, the University for Continuing Education Krems combines its many years of experience in university-based continuing education with innovation to provide outstanding quality in research and teaching at an international level. The University holds the AQ Austria quality seal. Situated 60 km from Vienna in the alluring world heritage region Wachau, Campus Krems is a highly attractive location.

Information and Registration

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Published by University for Continuing Education Krems,
Department for Economics and Health
Photos: Adobe Stock – Generated by AI, Walter Skokanitsch, Michor/Privat
Status: 10/2026
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