EU Regulatory Affairs, MSc

Target Group
This University course targets regulatory affairs professionals with about 3-5 years experience in regulatory affairs.

Admission criteria
> A university degree (at least bachelors) form an Austrian or other equivalent international University or

> For candidates with no University degree: A/Levels or other high school leaving certificate and at least 5 years work experience in regulatory affairs or a closely related discipline or

> For candidates with no University degree and no A/Level or other high school leaving certificate: Above 22 years of age, and at least 5 years work experience in regulatory affairs or a closely related discipline plus positive completion of a university admission interview.

Language
English

Locations
Vienna and Danube University Krems

Certificate
Certified Program
Duration: 2 terms, part-time
ECTS-Points: 39 ECTS
Admission fee: EUR 4.900,–*

Master of Science – MSc
Duration: 4 terms, part-time
ECTS-Points: 90 ECTS
Admission fee: EUR 8.900,–*

* The admission fee does not include the costs of the RAC certification and any extra courses offered by RAPS as preparation for the exam. Candidates taking the RAC exam offered by RAPS will have to register separately via the RAPS website: http://raps.org

www.donau-uni.ac.at/regulatoryaffairs

Danube University Krems specializes in part-time academic continuing education. As a public university for continuing education, it works with its expertise in teaching and research to overcome societal challenges and tailors its study programs to address them. The master programs and short programs cover nine fields of study and meet the specific requirements of working professionals. With 8,000 students coming from 85 countries, Danube University 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.

Danube University Krems. The University for Continuing Education.

Admission
Mag. (FH) Ariana Walzer
Danube University Krems
Center for Management in Healthcare
Dr.-Karl-Dorrek-Strasse 30, 3500 Krems, Austria
Phone +43 (0)2732 893-2820
ariana.walzer@donau-uni.ac.at

Information
DI Dr. Salma Michor, RAC
Michor Consulting e.U.
Schönbrunner Strasse 238/2/7, 1120 Vienna, Austria
Phone +43 (0)6991 952 16 62
smichor@michor-consulting.eu
www.michor-consulting.eu

Imprint
Editor: Danube University Krems, Center for Management in Healthcare
Images: Fotolia, Walter Skokanitsch, Hertha Hurnaus; Subject to alterations; Print: 12/2021
Find information on data processing and your rights regarding this at
https://www.donau-uni.ac.at/en/university/privacy-policy.html

EU Regulatory Affairs

Certified Program – 2 terms, part-time
Master of Science – 4 terms, part-time

www.donau-uni.ac.at/regulatoryaffairs

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. Regulatory Affairs is an emerging profession increasingly gaining in importance.

Students will receive a certificate from the Danube University Krems after successfully completing the first year or they can complete two years to obtain a Master's in EU Regulatory Affairs. In addition the first year covers the syllabus and can be used as a preparation for the Regulatory Affairs Certificate (RAC) offered by the Regulatory Affairs Professionals Society (RAPS).

Curriculum – Certified Progam

Compulsory courses
> Introduction to Regulatory Affairs
> Drug Regulatory Affairs
> Medical Device Regulatory Affairs
> Pharmaco-economics and Decision-Analytics

Electives
> Special Topics in Regulatory Affairs
> Quality Management and compliance
> Clinical Trial management
> Biotech, plasma and blood products

RAPS University Online Courses – Package Devices
> Medical Devices: US Regulations
> Medical Devices: EU Regulations
> Global Regulatory Strategy for Medical Devices
> Medical Devices: Compliance and Audits
> Ethics
> Role of the Regulatory Professional
> Medical Devices: Definition & Lifecycle
> Regulation of IVDs: US and Major Markets OUS
> Medical Devices: Postmarket Surveillance
> Medical Devices: Risk Management

or **RAPS University Online Courses – Package Drugs**
> Pharmaceuticals: US Regulations
> Pharmaceuticals: EU Regulations
> Global Regulatory Strategy for Pharmaceuticals
> Pharmaceuticals: Compliance and Audits
> Ethics
> Role of the Regulatory Professional
> Pharmaceuticals: Definition & Lifecycle
> Regulation of US and EU Biologics
> Chemistry, Manufactruing, and Controls (CMC)
> Pharmacovigilance

Curriculum – Master of Science

Specialization
> Pharmamanagement
> or eRegulatory Affairs

Master-Thesis

Lecturers (extract)
> Dr. Siegfried Schmitt, Parexel Consulting
> Dr. Wirthumer-Hoche, AGES (BMGF)

Project Manager/Lecturer
DI Dr. Salma Michor, MBA, RAC, Michor Consulting e.U.

Course Leader
Mag. Michael Ogertschnig, Danube University Krems

Aims of the Program
Participants will receive a thorough in depth training in all aspects of EU regulatory affairs covering both the pharmaceutical and medical device sectors.

Due to the growing importance of regulatory affairs and the real deficit of higher education courses on this topic in the EU, this course is expected to fill an important gap in the pharmaceutical/ medical device sector in Europe.

The course will be of special interest for regulatory affairs professionals from these sectors attracting students from all over EU. Due to current development in eCommerce and ICT this course will offer the possibility of specialization in eRegulatory Affairs.

In addition a specialization in pharma management will be offered to prepare students for strategic management positions within regulatory affairs.