

EU Regulatory Affairs

Certified Program – 2 terms, part-time

Master of Science – 4 terms, part-time

Danube University Krems. Center for Management in Healthcare.

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 EU Regulatory Affairs Certification (RAC) offered by the Regulatory Affairs Professionals Society (RAPS).

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.

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) from 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

Certificate

Certified Program

Duration: 2 terms, part-time

ECTS-Points: 39 ECTS

Admission fee: EUR 4.500,-*

Master of Science – MSc

Duration: 4 terms, part-time

ECTS-Points: 90 ECTS

Admission fee: EUR 7.900,-

* The tuition of EUR 4.500,- 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/EU exam offered by RAPS will have to register separately via the RAPS website:

www.raps.org/certification/application-information.aspx

Admission

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Danube University Krems. The University for Continuing Education.