University for Continuing Education Krems

Curriculum

Core Curriculum

> Introduction to Regulatory Affairs

> Drug Regulatory Affairs I
(Pre-market requirements, types of applications, types of registration procedures, data requirements)

> Drug Regulatory Affairs II
(Medicinal Product post marketing & compliance)

> Medical Device Regulatory Affairs
(Medical device pre-market requirements, Conformity Assessment and Notified Bodies)

> Medical Device Regulatory Affairs II (Medical device post marketing & compliance)

> Pharmaco-economics and Decision-Analytics
(Benefit of drugs, Cost-Benefit Analysis, Value Dossiers, Market Access, Efficiency and Effectiveness, Admission Strategies)

Elective courses (choose two of the options)

> Special Topics in Regulatory Affairs
(Generics, Orphan drugs, Cosmetic products, Food supplements, Veterinary medicinal products, OTC products, advertising & Promotion)

> Quality management and compliance
(Quality systems, enforcement and national authorities)

> Clinical Trial management
(Drugs and devices)

> Biotech, plasma and blood products
Biotech products, Human tissue regulation, Products from human blood/plasma, biosimilars

RAPS Online Courses (choose one package)

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, Manufacturing, and Controls (CMC)

> Pharmacovigilance

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