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