STARS Core Curriculum in Regulatory Science

European Regulatory System

- EU Regulatory bodies and their roles / activities
- Pharmaceutical and legal framework
- Pharmacovigilance in the EU
- Regulatory activities of EMA and NCAs in support of innovation, research and product development
- Phases of clinical trials and the level of quality / non-clinical / clinical evidence required
- EU marketing authorisation procedures
- Early access tools
- Post-marketing phase
- Medicines and medical devices

STARS Comprehensive Curriculum in Regulatory Science

Module ‘Quality‘

- Principles and guidelines applying to the pharmaceutical development
- The specific regulatory framework to address quality requirements in the relevant field of study, considering those which are particular to the specific product of interest
- Quality requirements for investigational medicinal products
- Common Technical Document (CTD) modules 1, 2 and 3
- EU legal framework and national implementation of Good Manufacturing Practice (GMP), role and scope of GMP inspections
- European pharmacopeia structure and relevant monographs
- From assessment to product information

Module ‘Non-Clinical‘

- Principles and guidelines applying to the non-clinical development
- CTD modules 1,2 and 4
- Proof of principle: in vitro and in vivo studies addressing PD activity
- Pre-clinical studies to support first in human (FIH) study
- Establishing the clinical dose
- Non-clinical studies to support Marketing Authorisation Application (MAA)
- Importance of animal species selection
- Alternative approaches to animal model
- Basic principles of Good Laboratory Practice (GLP)
- Basic principlesof environmental risk assessment
- Studies in juvenile animals to support pediatric use
- Regulatory and scientific requirements for non-clinical development
- Integration of non-clinical results with quality and clinical data
- From assessment to product information

Module ‘Clinical‘

- Clinical trial legislation in the EU, Good Clinical Practice (GCP), Declaration of Helsinki and ethical principles, relevant guidelines
- Clinical Trial Application (CTA)
- EU clinical trials information system
- Pharmacovigilance in clinical trials
- Overview of the scientific guidelines
- CTD modules 1,2 and 5
- Structure and content of clinical study report
- Real world data and patient registries
- Paediatric medicines
- Orphan medicines
- Advanced Therapy Medicinal Products (ATPMs)
- Vaccines
- Biosimilar, generics and hybrid applications
- From assessment to product information

Module ‘Post-marketing Surveillance‘

- Pharmacovigilance legislation, GVP, relevant guidelines
- Collection and manaeement of suspected adverse reactions
- RISK Management Plan
- Post-authorisation Safety Studies (PASS), Post-authorisation Efficacy Studies (PAES) and other post-authorisation activities
- Risk Minimisation Measures
- Pharmacovigilance system
- Signal management
- Overview and Assessment of Periodic Safety Update Reports (PSUR)
- Referrals of safety reasons
- Renewals and annual reassessment
- Safety communication