Module 11: The US Regulatory Environment
30th October – 1 November 2023

Location: Fletcher Hotel, Rotterdam Airport, Rotterdam, Netherlands

Module Leader(s): Nancy Pire Smerkanich DRSc, Assistant Professor, Department of Regulatory & Quality Sciences, University of Southern California, Los Angeles, USA

Day 1: Monday 30th October

Time	Activity	
16.00	Registration	
16.15 – 16.30	Welcome & Introduction to the Module	
16.30 – 17.30	Lecture 1: History and Basis of Medical Product Regulation in the USA • US legislative process • Role and structure of the FDA • FDA jurisdiction and statutory powers Relevant legislation, policy and guidance documents	Scavenger Hunt
17.30 – 18.30	New Student Tutorial	Dr Zamzam Ahmed Course and programmes Director
19.30	Close for evening	

Day 2: Tuesday 31st October		
Time	**Activity**	**Workshop**
09:00– 10.30	**Lecture 2: Regulatory Pathways and Designations** Eligibility and Practical issues • FD&C 505 and PHS 351 • Fast Track & Breakthrough Designations • Accelerated Approval • Priority Review • Orphan Drug Designation	Use of drugs@fda
10.30 – 10.45	Refreshment Break	
10.45 – 12.00	**Lecture 3: Investigational Applications** IND Process for Drugs and Biologics • Types of INDs • Components of the IND: technical sections, financial disclosure, commitments undertaken, Forms FDA 1571 and 1572 • IND process: original submission, review, approval and 30-day notification period • Issues: clinical hold, how to manage inactive INDs, GCP compliance and enforcement • Maintenance of INDs: updates and annual reports IDE Process for Medical Devices Electronic Submissions	Form FDA 1571 Review
12.00 – 13.00	Lunch	
13.00 – 14.45	**Lecture 4: Safety Reporting** • FDA regulations and reporting procedures • Pre- and post- marketed products • Domestic and international activities • CIOMS and ICH	AE/SAE Workshop
14.45– 15.00	Refreshment Break	

Day 2: Tuesday 31st October		
Time	**Activity**	**Workshop**
15.00 – 16.30	**Lecture 5: Communicating with the FDA** • Role of regulatory project manager (RPM) • Initiating and maintaining contact (formal and informal). What is FDA's expectation • Types of meetings (A, B, C) with their respective timetables and package requirements, including "the program" for NMEs/NCEs. • Use of the Target Product Profile during development • Advisory committee meetings: structure, format, preparation, working examples of meetings and their outcomes	FDA Communication Activity: Meeting Request
16.30 – 18.30	Group Project: Case Study using TPP and US PI	
19.30	Close for evening	

Day 3: Wednesday 1st November

Time	Activity	Workshop
9:00 – 10:30	Lecture 7: The NDA and BLA • Definition of drugs, biologics and devices • NDA/BLA – Content and Format • Pediatric Plans • FDA review process and Advisory Committee meetings • NDA maintenance – Changes, Post approval obligations and annual reports • Electronic submissions	FDA Form 356h Review
10.30 – 10:45	Break	
10.45 – 12:00	Lecture 8: Labelling and Advertising Controls • Definitions • Content and Format • Controls and meaning of the legislation • Direct to consumer advertising • OPDP Interactions and Submissions	DTC Ad Review
12:00 – 13:00	Lunch	
13:00 – 14:00	Lecture 9: Generics and OTC Products: • Drug Competition and Patent Term Restoration Act • Abbreviated New Drug Applications (ANDAs): Content, Data requirements and FDA Review • GDUFA • Legal basis for OTC • Registration of new OTC formulations • Switching from prescription to OTC	Labeling Comparison
14.00 – 14.15	Break	
14.15 – 15.30	Lecture 10: Advanced Therapies and Emerging Technologies • Cell and Gene Therapies • Biosimilars Combination Products	Discussion of Trends
15.30 – 16:00	Course Evaluation and Close	