The Organisation for Professionals in Regulatory Affairs

MODULE 11 7FHH1108:
THE US REGULATORY ENVIRONMENT

Being held remotely using GoToMeeting

25-27 and 30-31 March 2020

Wednesday 25 March 2020

All Lectures will be delivered by Module Leader: Nancy Pire-Smerkanich, DRSc

TIME	TOPIC	ACTIVE LEARNING
16.00 – 16.30	Welcome & Introductions To Module 11	Come with a Question re: US Regulatory Environment
16.30 – 17.30 Lecture 1	History and Basis of Drug Regulation in the USA • US legislative process • Role and structure of the FDA • FDA jurisdiction and statutory powers • FDARA, PDUFA VI and all the UFAs Relevant legislation, policy and guidance documents	Pre-course reading: One Hundred Years of Drug Regulation Raymond Woosley 2013
17.30 – 18.30 Lecture 2	FDA Initiatives • FDA Modernization Plan • Data Integrity and QMS FDA Website Navigation	Homework #1: Regulatory Scavenger Hunt

Thursday 26March2020

16:00 – 17.15 Lecture 3	IND Process and How to Manage it • IND Requirements • Types of IND (sponsor, investigator, expanded access) • Components of the IND: technical sections, financial disclosure, commitments undertaken, Form FDA 1571 and 1572 and eCTD IND • IND Timelines, Issues and Actions • Maintenance of INDs: updates and annual reports	Workshop: Understanding the IND Forms and Lifecycle Management/eCTD Metadata
17:15 - 17:30	Break	
17:30 – 18:00 Lecture 4	Adverse Event Reporting • Definitions • FDA regulations and reporting procedures • Pre-marketed and post marketed products • CIOMS and ICH E2B/ICSR	Homework#2: SUSAR Activity

Friday 27 March 2020		
16.00 – 17.15 Lecture 5	US FDA Expedited Pathways and Designations for Serious Conditions: Fast Track and Breakthrough Therapy Designation, Accelerated Approval and Priority Review Orphan Drug Act - Provisions and Consequences	Homework #3A: Product Driven Scenario Workshop
17:15- 17:30	Break	
17:30 – 18.30 Lecture 6	Communicating with the FDA • Product assigned- Division and therapeutic group • Division structured and organization; Role of regulatory project manager • Initiating and maintaining contact (formal and informal) • Types of meetings (A, B, C) with their respective timetables and package requirements, • Advisory committee meetings: structure, format, preparation, working examples of meetings and their outcomes, insight into the public influence on approvals • Communicating with field officers	Homework #3B: Mock FDA Meeting : Regulatory Activities and Prep

Monday 30March2020

16:00 – 17:30
Lecture 7
	The NDA and BLA
	• Definition of drugs, biologics and devices
	• Types of NDAs: 505(b)(1) and (b)(2)
	• Pre-NDA/BLA meetings and pre-submission issues
	• NDA/BLA application structure and components.
	  ○ Module 1 –Forms, Certifications, User Fees, Labeling and drug listing /NDC codes
	  ○ Pediatric requirements and waivers
	  ○ US Datasets
	• FDA review process
	• Supplemental NDA (sNDA) and NDA maintenance
	  ○ Post approval obligations and annual reports
		Homework #4:
		Benefits Risk Assessment Review
		[REF: drugs@fda.gov]

17:30-17:45	BREAK	
17:45– 18.30 Lecture 8	US Labeling: Target Product Profile and PI	

Tuesday 31March2020

16:00-16:45 Lecture 9	Labelling and Advertising Controls • Definitions • Required formats • Controls and meaning of the legislation • Role and practises of the FDA • US Direct to Consumer advertising OPDP Interactions and Submissions	Review of DTC commercials
16:45-17:00	BREAK	
17:00 – 18:00 Lecture 10	Regulation of Emerging Technologies • Gene and Cell Therapies • Biomarkers • Drug Development Tools • Use of Wearables	Case Study by Group
18:00 - 19:00 Lecture 11	Other Types of Applications Combination Products • FDA Approach Biosimilars • Naming conventions • BSUFA Generic drugs • Drug Competition and Patent Term Restoration Act • Abbreviated New Drug Applications (ANDAs): Content, Data requirements and FDA Review Over the Counter Products (OTC) • Legal basis for OTC • Registration of new OTC formulations • Switching from prescription to OTC	FDA Orange and Purple Books
19:00	Course Concludes	Course Evaluations