



CRED US Regulation of Medicines

10 May 2021

*Please note all times are in BST (CEST -1 hour)

*Time	Topic	Speaker
13.00	Welcome & Introductions to Course	
13.30	History and Basis of Drug Regulation in the USA <ul style="list-style-type: none"> US legislative process Role and structure of the FDA FDA jurisdiction and statutory powers FDARA, PDUFA VI and all the UFAs FDA Website Navigation	Mark Cierpial Impact Pharmaceutical Services, Inc.
14.15	Break	
14.30	IND Process and How to Manage it <ul style="list-style-type: none"> Types of IND (sponsor, investigator, expanded access) Components of the IND: technical sections, Form FDA 1571 and 1572 eCTD IND IND Timelines, Issues and Actions Maintenance of INDs: updates and annual reports	Nancy Pire-Smerkanich University of Southern California
15.30	US FDA Expedited Pathways and Designations for Serious Conditions: <ul style="list-style-type: none"> Fast Track and Breakthrough Therapy Designation, Accelerated Approval and Priority Review Orphan Drug Act - Provisions and Consequences 	Carlos Langezaal Bristol-Myers Squibb
17.00	Close for the day	

11 May 2021

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*Time	Topic	Speaker
13.00	Q&A	
13.30	Communicating with the FDA <ul style="list-style-type: none"> Initiating and maintaining contact (formal and informal) Types of meetings (A, B, C) with their respective timetables and package requirements, FDA Advisory Committee Meetings	Carlos Langezaal Bristol-Myers Squibb
14.45	Break	
15.00	The NDA and BLA <ul style="list-style-type: none"> Definition of drugs, biologics and devices Types of NDAs: 505(b)(1) and (b)(2) NDA/BLA application structure and components. <ul style="list-style-type: none"> Module 1 –Forms, Certifications, User Fees, Labelling and drug listing /NDC codes Paediatric requirements and waivers US Datasets FDA review process	Mark Cierpial Impact Pharmaceutical Services, Inc.
16.00	NDA/BLA Lifecycle <ul style="list-style-type: none"> Supplemental NDA (sNDA) and NDA maintenance Post approval obligations and annual reports	Nancy Pire-Smerkanich University of Southern California
16.45	Q&A	
17.00	Close	