Module 21: US Regulation of Medical Devices

Date: 3-5 June 2025

LOCATION: London, UK / Online

Module Leader(s): Richard Vincins

Day 1: Tuesday 3 June

Time	Activity	Speaker
	1. Module Introduction	
	Lecture 1: Introduction to US FDA - History, Structure and Mission of FDA	
	Morning break	
	Lecture 2: Overview of US Regulatory Process and Pathway & FDA Communications / Q-subs	
	Lunch	
	Lecture 3: Classification, Drug Device Listing, Establishment Registration & FDA Database	
	Afternoon break	
	Case Study 1: Classification	

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Day 2: Wednesday 4 June

Time	Activity	Speaker
	Recap & Reconnect	
	Short refreshment break	
	Lecture 4: Submissions: Pre-Market Notification 510(k)	
	Morning break	
	Lecture 5: Submissions: *De Novo* Reclassification	
	Lunch	
	Lecture 6: Submissions: PMA Submission	
	Afternoon break	
	Lecture 7: Submissions: IDE, HDE, and Clinical Investigations	
	Refreshment break	
	Lecture 8: Combination Products	

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Day 3: Thursday 5 June

Time	Activity	Speaker
	Recap & Reconnect	
	Case Study 2: Submissions	
	Morning break	
	Case Study Feedback	
	Lunch	
	Lecture 9: Labelling and Advertising	
	Afternoon break	
	Lecture 10: Post-Market Requirements: Adverse Event Reporting, Recalls, and Inspections	
	Close of Module	