Module 21: US Regulation of Medical Devices

Date:

LOCATION: TOPRA OFFICE, LONDON, UK / ONLINE

Module Leader(s): Richard Vincins

Day 1:

Time	Activity	Speaker
09.00 – 09.30	1. Module Introduction	
09.30 – 10.30	Lecture 1: Introduction to US FDA - History, Structure and Mission of FDA	
10.30 – 10.45	Morning break	
10.45 - 12.15	Lecture 2: Overview of US Regulatory Process and Pathway & FDA Communications / Q-subs	
12.15 – 13.15	Lunch	
13.15 – 14.30	Lecture 3: Classification, Drug Device Listing, Establishment Registration & FDA Database	
14.30 – 14.45	Afternoon break	
14.45 – 17.00	Case Study 1: Classification	

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Day 2:

Time	Activity	Speaker
09.00 – 09.30	Recap & Reconnect	
09.30 – 09.40	Short refreshment break	
09.40 – 11.00	Lecture 4: Submissions: Pre-Market Notification 510(k)	
11.00 – 11.15	Morning break	
11.15 – 12.00	Lecture 5: Submissions: *De Novo* Reclassification	
12.00 – 13.00	Lunch	
13.00 – 14.30	Lecture 6: Submissions: PMA Submission	
14.30 – 14.45	Afternoon break	
14.45 – 15.30	Lecture 7: Submissions: IDE, HDE, and Clinical Investigations	
15.30 – 15.45	Refreshment break	
15.45 – 17.00	Lecture 8: Combination Products	

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Day 3:

Time	Activity	Speaker
09.00 – 09.30	Recap & Reconnect	
09.30 – 10.45	Case Study 2: Submissions	
10.45 – 11.00	Morning break	
11.00 – 11:45	Case Study Feedback	
11:45 – 12.45	Lunch	
12.45 – 14.30	Lecture 9: Labelling and Advertising	
14.30 – 14.45	Afternoon break	
14.45 – 16.15	Lecture 10: Post-Market Requirements: Adverse Event Reporting, Recalls, and Inspections	
16.15 – 16.30	Close of Module	