Module 21: US Regulation of Medical Devices:

Date: 1 – 3 February 2023

LOCATION: TOPRA OFFICE, LONDON, UK / ONLINE

Module Leader(s): Jonathan Hughes

Day 1: Wednesday 1st February 2023

Time	Activity	Speaker
09.00 – 09.30	1. Module Introduction	Jonathan Hughes
09.30 – 10.30	2. Introduction to US FDA - History, Structure and Mission of FDA	Jonathan Hughes
10.30 – 10.45	Refreshment Break	
10.45 - 12.15	3. Overview of US Regulatory Process and Pathway & FDA Communications / Q-subs	Jonathan Hughes
12.15 – 13.15	Lunch	
13.15 – 14.30	4. Classification, Drug Device Listing, Establishment Registration & FDA Database	Jonathan Hughes
14.30 – 14.45	Refreshment Break	
14.45 – 17.00	5. Case Study 1: Classification	Jonathan Hughes

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Day 2: Thursday 2nd February 2023

Time	Activity	Speaker
09.00 – 09.30	6. Recap & Reconnect	Jonathan Hughes
09.30 – 09.40	Short refreshment break	
09.40 – 11.00	7. Submissions: Pre-Market Notification 510(k)	Jonathan Hughes
11.00 – 11.15	Refreshment break	
11.15 – 12.00	8. Submissions: *De Novo* Reclassification	Richard Vincins
12.00 – 13.00	Lunch	
13.00 – 14.30	9. Submissions: PMA Submission	Richard Vincins
14.30 – 14.45	Refreshment break	
14.45 – 15.30	10. Submissions: IDE, HDE, and Clinical Investigations	Richard Vincins
15.30 – 15.45	Refreshment break	
15.45 – 17.00	11. Combination Products	Jonathan Hughes

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Day 3: Friday 4th February 2023

Time	Activity	Speaker
09.00 – 09.30	12. Recap & Reconnect	Jonathan Hughes
09.30 – 10.45	13. Case Study 2: Submissions	Jonathan Hughes
10.45 – 11.00	Refreshment Break	
11.00 – 11:45	14. Case Study Feedback	Jonathan Hughes
11:45 – 12.45	Lunch	
12.45 – 14.30	15. Labelling and Advertising	Richard Vincins
14.30 – 14.45	Refreshment Break	
14.45 – 16.15	16. Post-Market Requirements: Adverse Event Reporting, Recalls, and Inspections	Richard Vincins
16.15 – 16.30	Close of Module	Jonathan Hughes