

Module 17: Regulatory and Related Activities through the Device Lifecycle

4th – 6th November 2020



LOCATION: ONLINE

Module Leader(s):

Date: 4th – 6th November 2020

Wednesday 4th November 2020

Time	Activity	Speaker
13.30 -14.30	Welcome & Introduction to the Module Lecture 1: The Role of the RA Professional and Good Regulatory Practice	Jane Arnold-Round NAMSA
14.30 – 15.30	Lecture 2: Product Liability Law	Shuna Mason CMS-CMNO
15.30 – 16.00	Refreshment break	
16.00 – 17.00	Lecture 3: Own Brand Labelling	Howard Dobbs Howard Dobbs Associates
17.00 – 18.30	Lecture 4: UDI, Counterfeiting and Case Study	John Deavin Deavin Associates

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Date: Thursday 5th November 2020

Time	Activity	Speaker
09.00 – 10.00	Lecture 5: Environmental Legislation	Geoff Fatzinger Spectrum Global Consulting
10.00 -11.00	Lecture 6: Implementing the New EU Regulations and Brexit	Jane Arnold-Round NAMSA
11.00 – 11.30	Refreshment Break	
11.30 – 12.30	Lecture 7: Unannounced Audits & ISO 13485	Alex Laan Namsa
12.30 – 13.30	Lunch	
13.30 – 14.30	Lecture 8: Supply Chain Management and e-Business	Bassil Akra Qunique
14.30 – 15.30	Lecture 9: Interactions with Regulatory Authorities	Geoff Fatzinger Spectrum Global Consulting
15.30 – 15.45	Refreshment Break	
15.45 – 17.45	Case Study	

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Date: Friday 6th November 2020

09.00 – 10.00	Lecture 9: Reimbursement and HTA	Geoff Fatzinger Spectrum Global Consulting
10.00 – 10.15	Refreshment Break	
10.15 – 11.15	Lecture 10: Intellectual Property Law	Sinan Utku Covington & Burling LLP
11.15 – 12.15	Lecture 11: Advertising and Promotional Issues	Ciara Farrell ICON
12.15 – 13.15	LUNCH	
13.15 – 14.15	Lecture 12: Data Privacy & Protection Freedom of Information and transparency	Chad McManamy Illumia
14.15 – 14.45	Refreshment Break	
14.45 - 15.45	Lecture 13: Trade Associations	Phil Brown ABHI Confirmed