

Module 17: Regulatory Strategy in the Post Market Phase
4th – 6th December 2024



LOCATION: TOPRA OFFICE, 6TH FLOOR, 3 HARBOUR EXCHANGE, LONDON, E14 9GE AND ONLINE

Module Leader(s): Jane Arnold- Round

Date: 4th – 6th December 2024

Wednesday 4th December 2024

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	Elizabeth-Anne Larsen CMC Law
15.30 – 16.00	Refreshment break	
16.00 – 17.00	Lecture 3: Advertising and Promotional Issues	Stuart Helmer & Bonnie Clemence CMC Law

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Date: Thursday 5th December 2024

Time	Activity	Speaker
09.00 – 11.00	Lecture 4: The UK Regulatory System	Kevin Butcher NAMSA
11.00 – 11.30	Refreshment Break	
11.30 – 12.30	Lecture 5: Interactions with Regulatory Authorities	Geoff Fatzinger Spectrum Global Consulting
12.30 – 13.30	Lunch	
13.30 – 14.30	Lecture 6: Unannounced Audits	Kevin Butcher NAMSA
14.30 – 15.30	Lecture 7: Data Privacy & Protection Freedom of Information and Transparency	Jonathan Craven Irhythmtech
15.30 – 15.45	Refreshment Break	
15.45 – 17.45	Case Study	Jane Arnold-Round NAMSA



Date: Friday 6th December 2024

09.00 – 10.00	Lecture 8: Intellectual Property	Sinan Utku Covington & Burling LLP
10.00 – 10.15	Refreshment Break	
10.15 – 11.15	Lecture 9: Environmental Legislation	Geoff Fatzinger Spectrum Global Consulting
11.15 – 12.15	Lecture 10: Reimbursement and HTA	Geoff Fatzinger Spectrum Global Consulting
12.15 – 13.15	LUNCH	
13.15 – 14.15	Lecture 11: When do the Obligations of Manufacturers Apply to You?	Howard Dobbs Howard Dobbs Associates
14.15 – 14.45	Refreshment Break	
14.45 - 15.45	Lecture 12: Trade Associations	Phil Brown ABHI
