

## Module 6: Regulatory Strategy from Development to the Market Place



Date: 7 - 9 October 2024

**LOCATION:** Hilton Hotel, South Quay Square, Marsh Wall, London E14 9SH

**Module Leader:** Vina Mistry

**Date:** Monday 7<sup>th</sup> October 2024

Time	Activity	Speaker
<b>10.00 – 11.30</b>	Welcome & Introduction to the Module Lecture 1: Developing the Brand and Shaping its Market Place (Part 1)	<b>Vina Mistry MTOPRA</b> <i>Pharmistry Consulting Limited</i>
<b>11.30 – 12.00</b>	Refreshment Break	
<b>12.00 – 13.15</b>	Lecture 1: Maintaining and Extending Brand Awareness through Product Development. (Part 2)	<b>Vina Mistry MTOPRA</b> <i>Pharmistry Consulting Limited</i>
<b>13.15 – 14.15</b>	Lunch	
<b>14.15 – 15.30</b>	Lecture 2: Protecting the Brand: Intellectual Property and Data Exclusivity	<b>Christopher Leung,</b> <i>Fieldfisher</i>
<b>15.30 – 15.45</b>	Refreshment Break	
<b>15.45 – 17.00</b>	Lecture 3: Demonstrating Value and Market Access	<b>Daniel Jackson,</b> <i>UCB Pharma</i>

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**Date:** Tuesday, 8<sup>th</sup> October 2024

<b>Time</b>	<b>Activity</b>	<b>Speaker</b>
<b>09.00 – 10.15</b>	Lecture 4: Pharmacovigilance and Risk Management	<b>Amalia Alexe,</b> <i>Novartis Pharma</i>
<b>10.15 – 10.45</b>	Refreshment Break	
<b>11.15 – 12.30</b>	Lecture 5: An Agency Perspective: The success and failure of a medicinal product in the EU	<b>Gaëlle Andriantafika</b> <i>European Medicines Agency (EMA)</i>
<b>12.00 – 13.00</b>	Lunch	
<b>13.00 – 14.30</b>	Lecture 6: Advertising and Controls on Prescription Only Medicines (POMs)	<b>Carole Pugh</b> <i>CALEA Regulatory Ltd</i>
<b>14.30 – 15.00</b>	Refreshment Break	
<b>15.00 – 17.00</b>	Case Study: Advertising and Controls on Promotional Materials for POMs	<b>Carole Pugh</b> <i>CALEA Regulatory Ltd</i>

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**Date:** Wednesday, 9<sup>th</sup> October 2024

<b>Time</b>	<b>Activity</b>	<b>Speaker</b>
<b>09.00 – 10.15</b>	Lecture 7: Issue Management	<b>Janet Worrell FTOPRA,</b> <i>JensonR+ Group Limited</i>
<b>10.15 – 10.45</b>	Refreshment Break	
<b>10.45 – 12.00</b>	Lecture 8: Communicating with Patients and Prescribers	<b>Michelle Gleed,</b> <i>Camdia Ltd</i>
<b>12.00 – 13.00</b>	Lunch	
<b>13.00 – 14.30</b>	Lecture 9: OTC Switching	<b>Helen Erwood FTOPRA,</b> <i>ESPL Regulatory Consulting</i>
<b>14.30 – 15.00</b>	Refreshment Break	
<b>15.00 – 17.00</b>	Case Study: OTC Workshop & Close	<b>Helen Erwood FTOPRA,</b> <i>ESPL Regulatory Consulting</i>