Module 6: Regulatory Strategy from Development to the Market Place

30th November - 2nd December 2022

Location: De Vere Latimer Estate, Chesham, HP5 1UG

Module Leader: Vina Mistry

Date: Wednesday 30th November

Time	Activity	Speaker
13:00	**Welcome & Introduction to the Module**	Vina Mistry Module Leader
	DEFINING THE PRODUCT AND ITS PLACE ON THE MARKET	
	Lecture 1: Developing the Brand and Shaping its Market Place.	
13:15 – 14:30	**Part 1:** The needs of the Market: what is the Market place, what does marketing want from regulatory. The input of the Regulatory representative in shaping a successful brand throughout the development stages.	**Vina Mistry** Pharmistry Consulting Ltd
14:30 – 15:00	***Refreshment Break***	
15:00 – 16:15	**Part 2:** Maintaining and extending brand awareness. The input of the Regulatory representative in maintaining and extending the brand throughout its lifecycle stages.	
	LEGAL FRAMEWORK: PROTECTING THE BRAND	
16:15 – 17:30	**Lecture 2: Protecting the Brand: Intellectual Property and Data Exclusivity** The importance of protecting the brand through its marketing life by use of patents, supplementary protection certificates, data exclusivity, brand names and trademarks.	**Christopher Leung** Fieldfisher Confirmed
	SUCCESSFULLY LAUNCHING THE PRODUCT ON THE MARKET	
17:30 – 18:45	**Lecture 3: Demonstrating Value and Market Access** Pricing and reimbursement policies Pharmacoeconomics Formularies, NICE Designing the clinical development programme with pharmacoeconomics in mind	**Daniel Jackson** UCB Biopharma Confirmed
19:00	**Dinner**	

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Date: Thursday 1st December 2022

Time	Activity	Speaker
	SUCCESSFULLY LAUNCHING THE PRODUCT ON THE MARKET	
09:00 – 10:15	**Lecture 4: Pharmacovigilance and Risk Management** Safety reporting requirements Maintaining the prescribing information Risk management	**David Lewis** Novartis Pharma GmbH Confirmed
10:15 – 10:45	***Refreshment Break***	
10:45 – 12:00	**Lecture 5: Falsified and Counterfeit Medicinal Products** The key issues, provisions and handling of falsified medicinal products. Overview of Falsified Medicines EU Directive. Key Challenges for the agency and any insight to the international collaboration efforts in tackling this issue. Real examples of types of issues seen and safety feature requirements on medicines	**Lynda Scammell** MHRA Confirmed
12:00 – 13:00	***Lunch***	
	COMMUNICATING WITH THE MARKET	
13:00 – 14.30	**Lecture 6: Advertising and Controls on Prescription Only Medicines (POMs)** Key provisions and controls for advertising and promotion of POMs in the UK and EU**.**	**Natalie Whittle** PMCPA confirmed
14:30 – 15:00	***Refreshment Break***	
15:00 - 17:00	**Case Study: Advertising and Controls on Promotional Materials for POMs** Feedback from individuals /groups	**Natalie Whittle** PMCPA Confirmed `
18:30	**Dinner**	

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Date: Friday 2nd December

Time	Activity	Speaker
	COMMUNICATING WITH THE MARKET (Cont'..d)	
09:00 – 10:15	**Lecture 7: Issue Management** Issues and crisis management, including communication strategies. Maintaining supply to the market and the role of the Regulatory Representative.	**Janet Worrell** JensonR+ Limited Confirmed
10:15 – 10:45	**Refreshment Break**	
10:45 – 12:00	**Lecture 8: Communicating with Patients and Prescribers** The importance of the information contained in the SmPC and its use in communications with patients and prescribers. Patient information, public assessment reports and educational materials. The role played by patient organisations and key opinion leaders	**Carole Pugh** Eudrac Confirmed
12:00 – 13:00	***Lunch***	
	EXTENDING THE LIFECYCLE OF THE PRODUCT	
13:00 - 14.30	**Lecture 9: OTC Switching** Strategic and practical considerations for changing legal status and critical success factors. Advertising of over-the-counter (OTC) products in the EU and US	**Helen Erwood** ESPL Regulatory Consulting confirmed
14:30 – 15:00	***Refreshment Break***	
15:00 – 17:00	**Case Study: OTC Workshop** Feedback from individuals /the group	**Helen Erwood**
17:00	**Close of Module**	**Vina Mistry**