Module 1: Strategic Planning in Regulatory Affairs

Module Leader: **Ineke Jonker-Hoogerkamp**

Co-Module Leader: **Hans van Bruggen**

Location: Topra Office: 6th Floor, Harbour Exchange, South Quay, London, E14 9G & Online

Wednesday 5th June – Friday 7th June 2024

Date: Wednesday 5th June 2024 Chairperson Ineke Jonker-Hoogerkamp

Time (BST)	Activity	Speaker
09.15– 09.30	Welcome & Introduction Aims and objectives of the module	Ineke Jonker-Hoogerkamp Eagle Pharma Consult
09.30 – 10.15	Lecture 1: Strategic Planning in the Pharmaceutical Industry	Ineke Jonker-Hoogerkamp Eagle Pharma Consult
10.15 - 10.30	**Refreshment Break**	
10.30 – 11.30	Lecture 2: EU Regulatory Procedures – Strategic Choices	Connie van Oers Sanofi-Genzyme
11.30 - 12.30	Lecture 3: Japan – Strategic Considerations Considerations for the Japanese market, implications for non-Japanese companies, working with affiliates, CROs. Working with the PMDA	Mohamed Oubihi Yakumed
12.30 - 13.30	**Lunch**	
13.30 - 14.30	Lecture 4: Regulatory Strategy for the Emerging Markets – Far East, Africa, Middle East, Latin America	Elliot Simonian
14.30 - 15.00	**Refreshment break**	
15.00 - 16.00	Lecture 5: The USA – Strategic Considerations Considerations for the US market, implications for a non-US company, working with affiliates, CROs, Joint ventures. Working	TBC

Module 1: Strategic Planning in Regulatory Affairs

Date: Thursday 6th June 2024 Chairperson Ineke Jonker-Hoogerkamp

Time (BST)	Activity	Speaker
09.30 - 10.30	Lecture 6: Orphan Drugs – Strategic Considerations Regulatory Strategy in orphan drug development – keep your stakeholders aligned	Liesbeth Hof ProPharma Group
10.30 – 11.00	**Refreshment Break**	
11.00 - 12.00	Lecture 7: Upcoming changes in Pharmaceutical Legislation – EU Pharmaceutical Legislation Reform and Joint Clinical Assessment	Marloes van der Geer Celegence
12.00 – 13.00	**Lunch**	
14.00 – 16.30	Case Study – Global Project Development Strategy with Refreshment Break	Module Leaders

Module 1: Strategic Planning in Regulatory Affairs

Date: Friday 7th June 2024 Chairperson Ineke Jonker-Hoogerkamp

Time (BST)	Activity	Speaker
08.30 – 09.30	Lecture 8: Regulatory Intelligence – Implications for Product Development Consider how to use/where to get information and how companies (both big and small) can influence the development of guidance documents	Alessandro Lazdins GSK
09.30 – 10.30	Lecture 9: Interaction with Regulatory Agencies – the Industry Perspective Scientific Advice, Protocol assistance, Joint Scientific Advice, SMEs	Ineke Jonker-Hoogerkamp Eagle Pharma Consult
10:30 – 11.00	**Refreshment Break**	
11.00 – 12.00	Lecture 10: Pharmacoeconomics Pricing and reimbursement strategies within the EU, when/what to build into product	TBC York Health Economics Consortium Ltd
12.00 – 13.00	Lecture 11: Electronic Submissions (eCTD) – Strategic Implications Gateways, Electronic data standards, Impact for global roll-out, Implications for smaller companies	Hans van Bruggen Celegence
13.00 – 14.00	**Lunch**	
14.00 – 15.00	Lecture 12: Medicines for Children – Strategic Considerations	PDCO member - TBC
15.00 – 15.30	**Refreshment Break**	
15.30 – 16.30	Lecture 13: Regulatory Planning and Life Cycle Management	Arjen ten Nijenhuis Janssen Biologics