Module: Strategic Planning in Regulatory Affairs
Date: 12/01/2027 - 14/01/2027

Location: TOPRA Third Floor, City Reach 5 Greenwich View Place London E14 9NN, UK
London,E14 9NN
Module Leaders: Luke Hill
Day 1: 12/01/2027

Time	Activity	Speaker
09.15– 09.30	**Welcome & Introduction** **Aims and objectives of the module**	**TBC**
09.30 – 10.15	**Lecture 1**: Strategic Planning in the Pharmaceutical Industry	**TBC**
10.15 - 10.30	**Refreshment Break**	
10.30 – 11.30	**Lecture 2:** Electronic Submissions (eCTD) – Strategic Implications Gateways, Electronic data standards, Impact for global roll-out, Implications for smaller companies	**TBC**
11.30 - 12.30	**Lecture 3:** Regulatory Strategy for the Emerging Markets – Far East, Africa, Middle East, Latin America	**TBC**
12.30 - 13.30	**Lunch**	
13.30 - 14.30	**Lecture 4:** Interaction with Regulatory Agencies – the Industry Perspective Scientific Advice, Protocol assistance, Joint Scientific Advice, SMEs	**TBC**
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 with the FDA	**TBC**

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Day 2: 13/01/2027

Time	Activity	Speaker
09.30 - 10.30	**Lecture 6:** Orphan Drugs – Strategic Considerations Regulatory Strategy in orphan drug development – keep your stakeholders aligned	**TBC**
10.30 – 11.00	**Refreshment Break**	
11.00 – 12.00	**Lecture 7:** EU Regulatory Procedures – Strategic Choices	**TBC**
12.00 – 13.00	**Lunch**	
13.00 – 14.00	**Lecture 8:** Upcoming changes in Pharmaceutical Legislation – EU Pharmaceutical Legislation Reform	**TBC**
14.00 – 16.30	**Case Study** – Global Project Development Strategy with Refreshment Break	**Module Leaders**

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Day 3: 14/01/2027

Time	Activity	Speaker
08.30 – 09.30	**Lecture 9:** 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 10:** Japan – Strategic Considerations Considerations for the Japanese market, implications for non-Japanese companies, working with affiliates, CROs. Working with the PMDA	**Mohamed Oubihi** Yakumed **(remote)**
10:30 – 11.00	**Refreshment Break**	
11.00 – 12.00	**Lecture 11:** Pharmacoeconomics Pricing and reimbursement strategies within the EU, when/what to build into product	**Luc Curtis**
12.00 – 13.00	**Lunch**	
13.00 – 14.00	**Lecture 12:** Medicines for Children – Strategic Considerations	**TBC**
14.00 – 15.00	**Lecture 13:** Regulatory Planning and Life Cycle Management	**Arjen te Nijenhuis** Janssen Biologics
15.00 – 15.30	**Closing**	