Module 1 7FHH1098

Strategic Planning in Regulatory Affairs

Wings Hotel Rotterdam Airport, the Netherlands
8th – 10Th May 2019

Module Leaders:
Christine Degeling, MSc
Ineke Jonker-Hoogerkamp, PhD

Wednesday 8th May 2019	***Chair - Christine Degeling***

15.30 – 16.00	**Registration**		
16.00 – 16.15	**Introduction** Aims and objectives of the module.	Christine Degeling, MSD B.V., The Netherlands	
16.15 – 17.00	**Strategic Planning in the Pharmaceutical Industry** Opening presentation.	Christine Degeling, MSD B.V., The Netherlands	L1
17.00 – 18.00	**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.	Marga Oortgiesen, UCB, USA	L2
18.00 – 18.15	**Introduction to the MSc**	Laura Brown Course Director	
18.30 - 20.00	***Dinner***		

Thursday 9th May 2019	***Chair – Christine Degeling***

8.30 – 9.30	**EU Regulatory Procedures – Strategic Choices** Centralised v MRP v DCP, factors influencing the choice of a particular procedure, implications of New Medicines Legislation (conditional and accelerated approval) and EU enlargement	Connie van Oers, Xendo B.V., The Netherlands	L3

9.30 – 10.30	**Japan – Strategic considerations** Considerations for the Japanese market, implications for non-Japanese companies, working with affiliates, CROs. Working with the PMDA.	Mohamed Oubihi, Yakumed Ltd, UK	L4
10.30 – 11.00	***Coffee***		
11.00 – 12.00	**Regulatory Strategy for the Emerging Markets – Far East, Africa, Middle East, Latin America** Considerations for the emerging markets, working with the agencies.	Elliot Simonian PPD	L5
12.00 – 13.00	**Interaction with Regulatory Agencies – the Industry Perspective** Scientific Advice, Protocol assistance, Experience with joint Scientific Advice, SMEs	Ineke Jonker-Hoogerkamp, Eagle Pharma Consult, The Netherlands	L6
13.00 - 14.00	***Lunch***		
14.00 – 15.00	**Electronic Submissions (eCTD) – strategic implications** Gateways, electronic data standards, impact of electronic requirements fore global roll-out, implications for smaller companies and possibilities for an eCTD without the use of "special" software; PIM	Geoff Williams, MSD, UK	L7
15.00 – 17.30	**Case Study Global project development strategy with coffee**	Module Leaders	CS1
18.30	***Dinner***		

Friday 10th May 2019	***Chair – Christine Degeling***

8.30–9.30	**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	Carolyn Hynes, GSK, UK	L8
9:30-10:30	**Orphan drugs – Strategic considerations** Regulatory strategy in orphan drugs – keep your stakeholders aligned	TBC	L9
10.30 – 11.00	***Coffee + Check-out***		
11.00 – 12.00	**Pharmacoeconomics** Pricing and reimbursement strategies within the enlarged EU, when/what to build into product	Hayden Holmes, York Health Economics	L10

	development	Consortium Ltd, UK	
12.00–13.00	**Medicines for Children – Strategic Consideration** Regulatory issues and strategies	Maaike van Dartel, CBG-MEB, The Netherlands	L11
13.00 – 14.00	***Lunch***		
14.00 – 15.00	**The Relationship between Regulatory Affairs and Project Planning**	Elke Litzlbauer, Takeda, The Netherlands	L12
15.00 – 15.30	***Coffee***		
15.30 – 16.30	**Life Cycle Management** Regulatory issues and strategies	Sjaak Bot, J&J, The Netherlands	L13
16.30 – 16.45	**Panel and Plenary Discussion** Opportunity to debate and discuss current regulatory issues	Module Leaders, and ALL	
16.45 – 17.00	**Closing remarks**		