Drug-device Combination Products: Major Changes Ahead!

Thursday 9 May 2019, TOPRA, 6th Floor, 3 Harbour Exchange, London, E14 9GE

Course Chair: Janine Jamieson

Time	Presentation	Speaker
8:45	**Registration and Coffee**	
9:10	**Welcome from TOPRA**	**Samantha Alsbury** TOPRA

9:15	**Welcome from Chairman and Working Party**
	• Overview of the day
	  o Janine Jamieson
	  o Margareth Jorvid
	  o Tim Chesworth
		Janine Jamieson
		JCombinations AB and International Pharmaceutical Quality (*formerly MHRA*)

9:30	**General introduction to combination products** • Overview of drug-device combination products • Drugs with device component • Combination products in different regions	**Margareth Jorvid** Methra Uppsala AB (*formerly at pharmaceutical and device companies and MPA*)

9:50	**Primary regulations and recent changes**
	• Current FDA Regulations and supporting guidelines
	• Current EU Regulations and supporting guidelines
	• New EU Regulations
	  o EMA CHMP QWP/BWP Concept paper
	  o EMA Q&A
		Tim Chesworth
		AstraZeneca

10:15	**EMA QWP/BWP guidance on developing a guideline on Quality requirements of medicinal products containing a device component for delivery or use of the medicinal product** • Update on guidance progress • Interactions with notified bodies • Feedback from stakeholders	**Abigail Moran** MHRA
10:45	**Q&A**	
11:00	**Coffee break**	

11:30	**'Combined product' development** • Selecting, customising or developing an administration device – implications for the Pharma company • Major areas to consider, e.g. QMS, Design Control, Risk Management, Human Factors Engineering, Suppliers, Manufacturing and Control, Documentation • Direct implications of Article 117 • Typical regulator questions and feedbacks, hot topics	**Mark Chipperfield** CorvusDevice Ltd
12:00	**Industry preparations for meeting evolving regulatory expectations** • Impact of the new EU Medical Devices Regulation on Pharma Industry, Notified Bodies, guidelines • Single approach to product development that meets multiple global regulatory requirements • Industry initiatives to collaborate with regulatory agencies	**Josie Wright** AstraZeneca
12:30	**Panel Discussion**	**All**
13:00	**Lunch**	
14:00	**Case study** • With practical examples of integration of device development into pharma development and regulation.	**Margareth Jorvid & Mark Chipperfield**
15:15	**Case Study feedback**	**All**
15:45	**Tea and Coffee**	
16:15	**Industry Case example – Repatha Pushtronix** • Development of on-body pump injector with device company • Regulatory strategy US • Regulatory strategy EU – single integral product definition • Learning points	**April Kent** Amgen
16:45	**Q&A and Panel discussion**	
17:15	**Close**	

Delegates will be encouraged to ask questions throughout the day to ensure the meeting is as interactive as possible.