Drug-device Combination Products: Major Changes Ahead!

Time (CEST)	Presentation	Speakers
8:45	**Registration and Coffee**	
9:10	**Welcome from TOPRA**	

9:15	**Welcome from Chairs on behalf of the Working Party**
	• Overview of the day
	  ○ Janine Jamieson
	  ○ Tim Chesworth	

9:30	**General introduction to combination products** • Overview of drug-device combination products • Drugs with device component • Different stakeholders involved	**Theresa Jeary** Scientific & Regulatory Affairs Ltd
9:50	**Stretching break**	

10:05	**Primary regulations and recent changes**
	• Current FDA Regulations and supporting guidelines -
	• Current EU Regulations and supporting guidelines
	• Combination products in different regions
	• New EU Regulations
	  ○ EMA CHMP QWP/BWP Draft guideline
	  ○ EMA Q&A
		Tim Chesworth
		AstraZeneca

10:30	**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 • Feedback • Collaboration between and across industry groups	
11:00	**Q&A**	
11:15	**Tea/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** Corvus Device
12:00	**Notified Body preparations for meeting evolving regulatory expectations** • Impact of the new EU Medical Devices Regulation on Pharma Industry, Notified Bodies, guidelines • TEAM-NB guidance on NBOp and GSPRs • Notified Body expectations on content and format of submission	**Susanne Fornero-Quaak,** BSI Group (Netherlands)
12:30	**Stretch and Panel Discussion**	
13:00	**Lunch**	
13:45	**Case study** With practical examples of integration of device development into pharma development and regulation.	
12:45	**Short break**	
15:00	**Case Study feedback**	
15:30	**Tea and Coffee break**	
15:45	**Industry Experience – preparing for an NBOp and MAA for a Pre-filled Pen** • Lessons learned from NBOp submission activities • Lessons learned from Pre-MAA submission activities • Observed redundancies between requested documentation	**Isabelle Mingam,** UCB
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.