CRED Regulation of Drug-device Combination Products

Tuesday 7th June 2022

Time	Presentation
8:45	**Registration and Coffee**
9:00	**Welcome from TOPRA**

9:15	**Welcome from Chairs on behalf of the Working Party**
	• Overview of the day
	  ○ Janine Jamieson, IPQ
	  ○ Margareth Jorvid, LSM

9:30	**Primary regulations and recent changes - Tim Chesworth, AstraZeneca** • Overview of drug-device combination products • Current FDA Regulations and supporting guidelines - • Current EU Regulations and supporting guidelines • Combination products in different regions • New EU Regulations ○ EMA CHMP QWP/BWP guideline • EU Pharma strategy
10:00	**Combined Product Development – Louise Place, GSK** • 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
10:30	**Tea Break**
10.45	**EMA QWP/BWP Guideline on Quality documentation for medicinal products when used with a medical device – Ann Jans, FAMHP** • Update on guidance implementation • Background and experience so far • Collaboration between and across regulatory agencies • Key learnings and takeaways
11.15	**Notified Body Opinion Expectations – Christiana Hofmann, TÜV SÜD** • Impact of the 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

11:45	**Q&A including Isabelle Delneuville, Pharmaceutical Assessor, FAHMP**
12:15	**Lunch**
13:15	**Case study and Feedback – Tim and Louise** • With practical examples of integration of device development into pharma development and regulation
15:00	**Updates from the US FDA Office of combination products John (Barr) Weiner** • News from the OCP • FDA recognition of ISO 13485 in relation to 21 CFR 4 • Holistic approach to risk management of combined products and AAMI TR 105: Risk Management Guidance for Combination Products • International collaboration
15:30	**Tea Break**
15:45	**European Pharma Strategies and Meeting Global Regulatory Expectations Discussion, Christina Moerk Hansen, Ralex Consulting** • Lessons learned from recent EU submissions • Comparison to and learnings from global submissions • Interactive discussion: experiences from speakers and delegates
16:30	**Industry Experience – examples, learnings and meeting the challenges for combination products initial application and lifecycle management, Isabelle Mingam, UCB** • Examples of UCB drugs used with medical devices • Learnings from notified body opinion and Marketing Authorization Application for a pre-filled pen • Life cycle management challenges across a range of configurations of drugs used with a device
17:00	**Q&A and Wrap Up**
17:30	**Close**

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