CRED Regulation of Drug-device Combination Products

Wednesday March 6, 2024

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
	  ○ Ludivine Petit, Life2Science

9:30	**Primary regulations and recent changes – Ola Oyinloye, AstraZeneca** • Overview of drug-device combination products • Current FDA Regulations and supporting guidelines • Current EU Regulations and supporting guidelines • EMA CHMP QWP/BWP guideline • EU Pharma strategy • Combination products in different regions
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 • Typical regulator questions and feedbacks, hot topics
10:30	**Tea Break**
10.45	**Clinical Development – Amber McNair, IQVIA** • Challenges of conducting clinical trials/investigations with combination products • Complexities of submissions and approvals for combined studies in the EU, including some lessons learned • Update from the COMBINE initiative
11.15	**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

11:45	**Notified Body Opinion Expectations – Jon Sutch, BSI** • 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
12:15	**Lunch**
13:15	**Q&A**
15:00	**Case study and Feedback – Ola and Louise** With practical examples of integration of device development into pharma development and regulation
15:30	**Tea Break**
15:45	**Updates from the US FDA Office of combination products – James Bertram, FDA** • News and hot topics from the OCP • Holistic approach to risk management of combined products and impact on Essential Performance Requirements (EPRs) • Application of Human Factors Engineering Principles for Combination Products: FDA guideline September 2023 • International collaboration
16:15	**Industry Experience –Preparation and submission of a worldwide marketing authorization application for a combination product: From a drug perspective, Chris Le Page, UCB** • Development of an overall control strategy • Preparation of a marketing authorization application • Health authority questions and worldwide roll out
16:45	**Q&A and Interactive discussion: experiences from speakers and delegates**
17:30	**Close**

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