CRED Development of Regulatory Product Information in Europe

27 September 2023

Course Chair: Petrina Pearce, Advanz Pharma

Time	Session	Presenter
08:45	**Registration and Coffee**	
09:00	**Welcome from TOPRA**	
09:05	**Welcome from Chairman** • Overview of the day	**Petrina Pearce** Advanz Pharma
09:10	**The Company Core Data Sheet** • Origins of the CCDS and its purpose • Preparation and implementation of the CCDS • Implications of regional differences for the CCDS and global labelling management	**Desta Black** GlaxoSmithKline
09:50	**SmPC: Regulator's perspective** • The role of the SmPC • Overview of SmPC legislation/guidelines and template • Current SmPC issues and developments	**Doreen Fagan** HPRA
10:50	**Break**	
11:05	**Strategy for the Development of the Optimal SmPC** • Definition of an optimal SmPC • Contributing factors to an optimal SmPC • Key Stakeholders in an optimal SmPC • Common Pitfalls in the development of an optimal SmPC • Influence of the optimal SmPC on the development programme • Competitor analysis	**Khristy Horsley and Lucy Paterson** ICON plc
12:05	**Case Study and feedback - SmPCs**	**Thomas Liebers** ICON plc **Gabriela Fok** Ipsen
12:45	**Panel Discussion**	
13:00	**Lunch**	
13:45	**Labels and Leaflets: Regulator's perspective** • Current legislation including recent changes • Label and leaflet requirements, including guidelines • Packaging with patient safety in mind • Good quality patient information & user testing • Future focus for patient information	**Julia Coombes** MHRA

Time	Session	Presenter
14:45	**Preparation of the Label and Leaflet: Industry perspective** Practical issues encountered when preparing proposed label and leaflet text for an MAA, including: • Specific requirements for Mutual Recognition, • Decentralised and Centralised procedures • Readability • Translations • Timings	**Robert Hetherington** ICON plc
15:15	**Break**	
15:30	**Implementation of Labels and Leaflets: Industry perspective** Practical issues encountered when implementing MA approved text into the marketplace, including: • Cross functional collaboration with stake holders • Safety issues • Commercial aspects • Production and logistical issues • Timelines	**Kay Loughrey** Jazz Pharmaceuticals
16:15	**Case Study – Labels and Leaflets**	**Thomas Liebers** ICON plc **Gabriela Fok** Ipsen
16:55	**Chairman's Review of the Day & Final Discussion Session**	**Petrina Pearce** Advanz Pharma
17:10	**Close of Workshop**	

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