



CRED Development of Regulatory Product Information in Europe

25 September 2024

Course Chair: Petrina Pearce, Advanz Pharma

Time	Session	Presenter
08:45	Registration and Coffee	
09:00	Welcome from TOPRA	
09:05	Welcome from Chairman <ul style="list-style-type: none"> Overview of the day 	Petrina Pearce Advanz Pharma
09:10	The Company Core Data Sheet <ul style="list-style-type: none"> 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 <ul style="list-style-type: none"> 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 <ul style="list-style-type: none"> 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 <ul style="list-style-type: none"> 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: <ul style="list-style-type: none"> • 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: <ul style="list-style-type: none"> • Cross functional collaboration with stake holders • Safety issues • Commercial aspects • Production and logistical issues • Timelines 	Kay Loughrey Jazz Pharmaceuticals
		Thomas Liebers ICON plc
16:15	Case Study – Labels and Leaflets	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.