



CRED Regulatory Product Information

11 June 2021, online

Course Chairman: **Petrina Pearce**, Advanz Pharma

Time	Session	Presenter
09:00	Registration and Coffee	
09:30	Welcome from TOPRA	
09:35	Welcome from Chairman <ul style="list-style-type: none"> Overview of the day 	Petrina Pearce Advanz Pharma
09:40	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 Regeneron Pharmaceuticals
10:10	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
11:10	Break	
11:25	Strategy for the Development of the Optimal SmPC	Melanie Eatough BMS
12:25	Case Study - SmPCs	Thomas Liebers PRAHealthSciences
12:55	Panel Discussion	
13:10	Lunch	
14:10	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
15:10	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 	Ronnie Mundair Pfizer Thomas Liebers PRAHealthSciences
15:40	Break	



Time	Session	Presenter
15:55	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 	Ronnie Mundair Pfizer Thomas Liebers PRAHealthSciences
16:40	Case Study – Labels and Leaflets	Thomas Liebers PRAHealthSciences
17:10	Chairman’s Review of the Day & Final Discussion Session	Petrina Pearce Advanz Pharma
17:25	Close of Workshop	

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