CRED Regulatory Product Information

11 March 2020, London

Course Chairman: Petrina Pearce, Diamond BioPharm Ltd

Time	Session	Presenter
09:00	**Registration and Coffee**	
09:30	**Welcome from TOPRA**	**Raluca Radu** TOPRA
09:35	**Welcome from Chairman** • Overview of the day	**Petrina Pearce** Diamond BioPharm Ltd
09:40	**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	**Melanie Eatough** Celgene
10:10	**SmPC: Regulator's perspective** • 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** Celgene
12:25	**Case Study - SmPCs**	**Thomas Liebers** PRAHealthSciences
12:55	**Panel Discussion**	
13:10	**Lunch**	
14:10	**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
15:10	**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	**Matt Hancock** Pfizer

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15:40	**Break**	
15:55	**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	**Matt Hancock** Pfizer
16:40	**Case Study – Labels and Leaflets**	**Thomas Liebers** PRAHealthSciences
17:10	**Chairman's Review of the Day & Final Discussion Session**	**Petrina Pearce** Diamond BioPharm Ltd
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.