



CRED: Document writing and management

15-16 February 2022

***All times are in GMT.**

Programme

Day 1: The Theory – 15 February 2022

Time	Presentation	Presenter
09:00	Registration and Coffee	
09:15	Welcome from TOPRA	Sinead Whelan Head of Membership and Data Insight
09:20	Welcome from Chairman <ul style="list-style-type: none"> • Overview of the day 	Dalna Harvey Pfizer
09:25	Introduction and AIM <ul style="list-style-type: none"> • Importance of good writing – Aim, Structure, Language • Style - Accuracy, Brevity, Clarity (ABC) • AIM: <ul style="list-style-type: none"> ◦ Purpose of document ◦ Who is my reader? What do they know already? ◦ What are they going to do with the information? • Types of Documents – Internal reports, CTD, CTA, IND, briefing packages, responses to questions, cover letters 	Joseph Irwin LRCS Ltd
10:00	Structure <ul style="list-style-type: none"> • How to organise/build a document • Tools such as Mind Mapping to gather all the data and information, and agree a “message” • When structure is already defined – ICH M4, Internal, Regulatory Authority (E.g. EMA briefing packages) • When to stick to structural templates, when to deviate 	Joseph Irwin LRCS Ltd
10:45	Tea/ coffee break	
11:15	MS Word - things all authors should know <ul style="list-style-type: none"> • Use templates and styles and toolbars if given, do not invent your own • Heading • Captions • Tables • Table of Contents • Cross referencing within a document • Hyperlinking 	Paul Browning ConvaTec

Time	Presentation	Presenter
11:45	Lunch	
12:45	Language <ul style="list-style-type: none"> • What makes a document hard to read? • Readability tools, as objective measures of readability and use of an example tool (Clarity Index) • Hints and tips on understanding your personal style and how to adjust for different circumstances. • Impact of style guides & templates • Paragraphs & signposting 	Hilary Gray ICON plc
14:00	Writing Overviews <ul style="list-style-type: none"> • Writing Overviews – summarising the detail in a clear way • How to distil complicated details in a clear manner <ul style="list-style-type: none"> ◦ Must dos / Don't do 	Paul Browning ConvaTec
14:30	Combination products – writing the device sections <ul style="list-style-type: none"> • Background to device component development • Key topics to cover in the device component sections of the dossier • Structure of the device component information in the CTD • The writing and review process – tips, watch-outs and hurdles 	Dalna Harvey Pfizer
15:30	Introduction to the Case Study	Hilary Gray ICON plc
15:45	Workshop	
	<i>Tea and coffee to be served during the workshop</i>	
17:00	Workshop presentations and discussions	
17:30	Close of Workshop - Day 1	

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Day 2: The Practice – 16 February 2022

Time	Presentation	Presenter
09:00	Registration and coffee	
09:15	Welcome from Chairman <ul style="list-style-type: none">• Overview of the day	Joseph Irwin LRCS Ltd
09:20	Regulatory Communications <ul style="list-style-type: none">• Regulatory Communications e.g. letters to agencies – best practice• Making the Agency letter an effective communication tool for assessors	Andrew Thornley UCB Pharma
09:50	Report writing (Technical examples) <ul style="list-style-type: none">• Writing technical reports• Good practice• Confidentiality	Kelly Smith Certara
10:30	Tea/ coffee break	
11:00	Dossier Management <ul style="list-style-type: none">• How it recorded, maintained and archived• a. Paper• b. Electronic<ul style="list-style-type: none">- compatibility of the document- the size of the document (MB, KB)- the software required to read the documents (standard or specific)• Hyperlinking• CTD granularity• Change Management• 'Global' dossiers• How to deal with old, historical, non-CTD, paper dossiers• Avoiding drift	Kathryn Brouder BioMarin (Europe Ltd)
12:00	Lunch	
13:00	Regulatory Operations and Publishing <ul style="list-style-type: none">• What happens to the documents between leaving our desks and arriving on the reviewer's desk• Why styles and technical requirements are important• What the Reviewer sees (has everyone seen an eCTD in practice?)• How to handle images, do we need them and are they readable?	Kathryn Brouder BioMarin (Europe Ltd)

Time	Presentation	Presenter
13:45	Case Study – summarising complicated documents in an Overview <i>Tea and coffee to be served during the workshop</i>	Hilary Gray /Dalna Harvey /Joseph Irwin
15:15	An Agency's perspective <ul style="list-style-type: none"> • Agency Expert - Opinion • Examples of good submissions • Must dos / Don't do 	Melanie Pires MHRA
16:00	Q&A and Wrap up of the day	
16:15	Close of Course - Day 2	

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