



CRED: Document writing and management 25-26 April 2023

Day 1: 25 April 2023

Time	Presentation	Presenter
09:00	Registration and Coffee	
09:15	Welcome from TOPRA	
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 to gather all the data and information, and agree a “message” (e.g., mind mapping) • When structure is already defined – ICH, Internal, Regulatory Authority • 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 • Heading • Captions • Tables • Table of Contents • Cross referencing within a document • Hyperlinking 	Paul Browning ConvaTec
11:45	Language (part 1) <ul style="list-style-type: none"> • Importance of language • Readability tools, as objective measures of readability and use of an example tool (Clarity Index) 	Hilary Gray Syneos Health
12:15	Lunch	



Time	Presentation	Presenter
13:00	Dossier Management <ul style="list-style-type: none">• How it recorded, maintained, and archived<ol style="list-style-type: none">a. Paperb. Electronic (compatibility, size, software)• Hyperlinking• CTD granularity• Change Management• 'Global' dossiers• How to deal with old, historical, non-CTD, paper dossiers• Avoiding drift	Kathryn Brouder BioMarin (Europe Ltd)
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
14:30	Tea/coffee break	
14:45	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
15:30	Workshop	Hilary Gray
16:30	Workshop presentations and discussions	
17:00	Introduction to the Day 2 Case Study	Hilary Gray
17:15	Close of Workshop and Day 1	Dalna Harvey

Delegates are encouraged to ask questions throughout the day to ensure the meeting is as interactive as possible.



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Day 2: 26 April 2023

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
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	Obaid Khan Johnson & Johnson
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	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
12:00	Lunch	
12:45	Language (part 2) and presentation <ul style="list-style-type: none">• How to make documents more readable• Hints and tips on understanding your personal style• Impact of style guides & templates• Paragraphs & signposting	Hilary Gray
13:30	Case Study	Hilary Gray
14:45	Case Study discussion and presentations	
15:15	Tea/coffee break	
15:30	An Agency's perspective <ul style="list-style-type: none">• Agency Expert - Opinion• Examples of good submissions• Must dos/Don't do	Dr Abigail Moran MHRA
16:15	Q&A and Wrap up	
16:30	Close of course and Day 2	Joseph Irwin