

CRED: Document writing and management
17-18 February 2026

Day 1

Time	Presentation	Presenter
09:00	Registration and Coffee	
09:15	Welcome from TOPRA	
09:20	Welcome from Chairman	Dalna Harvey
	<ul style="list-style-type: none"> • Overview of the day 	
09:25	Introduction and AIM	Joseph Irwin XP Forte
	<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 	
09:45	Structure	Joseph Irwin XP Forte
	<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 	
10:30	Tea/coffee break	
11:00	MS Word - things all authors should know	Paul Browning ConvaTec
	<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 	
11:30	Language	Hilary Gray Syneos Health
	<ul style="list-style-type: none"> • Importance of language • Readability tools, as objective measures of readability and use of an example tool (Clarity Index) • How to make documents more readable • Hints and tips on understanding your personal style • Impact of style guides & templates • Paragraphs & signposting 	
12:30	Lunch	

Time	Presentation	Presenter
13:15	Dossier Management <ul style="list-style-type: none"> • How it recorded, maintained, and archived <ul style="list-style-type: none"> a. Paper b. 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)
14:15	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
14:45	Tea/coffee break	
15:00	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
15:45	Workshop	Hilary Gray
16:45	Workshop presentations and discussions	
17:15	Introduction to Day 2 Case Study	Hilary Gray
17:30	Close 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

Time	Presentation	Presenter
09:00	Registration and coffee	
09:10	Welcome from Chairman • Overview of the day	Hilary Gray
09:15	Combination products – writing the device sections • Background to device component development • Format of the device constituent information in the CTD • Key topics to cover in the device component sections of the dossier • The writing and review process – tips and watch-outs	Dalna Harvey
10:15	AI in Regulatory Document Management and Writing: What Has Changed, What Remains? • AI is changing regulatory workflows, what remains under human control • Case study highlighting real-world use in document creation	Keira Leger Syneos Health
10:55	Tea/coffee break	
11:05	• Regulatory Communications • Regulatory Communications e.g. letters to agencies – best practice • Making the Agency letter an effective communication tool for assessors	Obaid Khan
12:00	Lunch	
12:45	Future trends in submissions and publishing (AI) • Examples of how AI is influencing the pharma world today (Current status) • How will this impact interaction with agencies? • Panel discussion	Duncan Arbour Syneos Health
13:45	Case Study	Hilary Gray
14:45	Case Study discussion and presentations	
15:15	Tea/coffee break	
15:30	An Agency's perspective • Agency Expert - Opinion • Examples of good submissions Must dos/Don't do	Dr Abigail Moran MHRA
16:10	Q&A and Wrap up	
16:25	Close of course and Day 2	Hilary Gray