CRED: Document writing and management
18-19 March 2025
Day 1: 18 March 2025

Time	Presentation	Presenter
09:00	**Registration and Coffee**	
09:15	**Welcome from TOPRA**	
09:20	**Welcome from Chairman** • Overview of the day	**Dalna Harvey** Pfizer

09:25	**Introduction and AIM**
	• Importance of good writing – Aim, Structure, Language
	• Style - Accuracy, Brevity, Clarity (ABC)
	• AIM:
	  • 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
		XP Forte

09:45	**Structure** • 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** XP Forte
10:30	**Tea/coffee break**	
11:00	**MS Word - things all authors should know** • Use templates and styles and toolbars if given • Heading • Captions • Tables • Table of Contents • Cross referencing within a document • Hyperlinking	**Paul Browning** ConvaTec
11:30	**Language** • 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	**Hilary Gray** Syneos Health
12:30	**Lunch**	

Time	Presentation	Presenter
13:15	**Dossier Management** • How it recorded, maintained, and archived 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** • Writing Overviews – summarising the detail in a clear way • How to distil complicated details in a clear manner • Must dos / Don't do	**Paul Browning**
14:45	**Tea/coffee break**	
15:00	**Regulatory Operations and Publishing** • 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: 19 March 2025

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	**Report writing (Technical examples)** • Writing technical reports • Good practice • Confidentiality	**Kelly Smith** Certara
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** Johnson & Johnson
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**