

CRED: Document writing and management

Preliminary Programme

Day 1: The Theory

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 	
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
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
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
11:45	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
12:55	Lunch	
13:40	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

Time	Presentation	Presenter
14:10	Combination products – writing the device sections <ul style="list-style-type: none"> • Background to device constituent development • Key topics to cover in the device constituent sections of the dossier • Structure of the device constituent information in the CTD • The writing and review process – tips, watch-outs and hurdles 	Dalna Harvey
15:10	Case Study	
16:25	Case study presentations and discussions	
17:30	Close of Workshop - Day 1	

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Day 2: The Practice

Time	Presentation	Presenter
09:20	Welcome from Chairman <ul style="list-style-type: none"> Overview of the day 	
09:30	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 	Hilary Gray
09:55	Report writing (Technical examples) <ul style="list-style-type: none"> Writing technical reports Good practice Confidentiality 	
10:40	Tea/ coffee break	
11:00	Dossier Management <ul style="list-style-type: none"> How it recorded, maintained and archived <ul style="list-style-type: none"> 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 	Andy Thornley
12:00	Lunch	
12:45	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? 	Andy Thornley
13:30	Workshop – summarising complicated documents in an Overview <i>Tea and coffee to be served during the workshop</i>	
15:00	An Agency's perspective <ul style="list-style-type: none"> Agency Expert - Opinion Examples of good submissions Must dos / Don't do 	Ben Rackstraw
15:45	Q&A and Wrap up of the day	
16:00	Close of Workshop - Day 2	

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