



CRED: Document writing and management

20 - 21 March 2019, TOPRA Office, London

Preliminary Programme

Chair: Hilary Gray

Day 1: The Theory

Time	Presentation	Speaker
09:00	Registration and Coffee	
09:20	Welcome from TOPRA	TOPRA
09:25	Welcome from Chairman <ul style="list-style-type: none"> Overview of the day 	Hilary Gray Indivior UK Ltd
09:30	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 Lakeside Regulatory Consulting Services Ltd
10:15	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 (Eg EMA briefing packages) When to stick to structural templates, when to deviate 	Joseph Irwin Lakeside Regulatory Consulting Services Ltd
11:00	Tea/ coffee break	
11:20	Language <ul style="list-style-type: none"> What makes a document hard to read? (long words, sentences, paragraphs) Clear language important when English not first language of reader and/or document will be translated Readability tools, e.g. Clarity Index, as objective measures of readability vs style preferences Active v passive tense 	Hilary Gray Indivior UK Ltd



Time	Presentation	Speaker
	<ul style="list-style-type: none"> • Sentences – avoiding flannel and waffle • Level of detail to help minimise future changes • Paragraphs & signposting • Smith v Brown example (Turk, C.C.R. (1978) Do You Write Impressively? Bulletin of the British Ecological Society, ix(3) 5–10) • Medical Writing accurate and detailed R&D reports • Summarising published literature • Presentation of text <ul style="list-style-type: none"> ○ Understanding Regulatory requirements ○ Importance of an Internal Style Guide and sticking to it (examples of style guides) ○ Templates ○ Tabulation vs written text ○ Requirements for Figures, tables 	
12:30	Lunch	
13:15	Working with teams	Tacye Connolly
	<ul style="list-style-type: none"> • Defining objectives • Managing the teams and peers • Managing disagreement 	
13.45	Regulatory Communications	Tacye Connolly
	<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 	
14:15	Case Study	
15:35	Case Study presentations & discussion	Hilary Gray
		Indivior UK Ltd
16:35	An Agency's perspective	Melanie Pires
	<ul style="list-style-type: none"> • Agency Expert - Opinion • Examples of good submissions • Must dos / Don't do 	MHRA
17:20	Close of Workshop - Day 1	



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Day 2: The Practice

Time	Presentation	Speaker
09:00	Registration and Coffee	
09:20	Welcome from Chairman <ul style="list-style-type: none">• Overview of the day	Joseph Irwin Lakeside Regulatory Consulting Services Ltd
09:30	Project Management <ul style="list-style-type: none">• Getting from data to submission• Process• RACI matrix• Don't forget reviewing and QC checking of data	Patricia Colin MDSSPRO
10:15	Technical reports <ul style="list-style-type: none">• Writing technical reports• Good practice• Confidentiality	Patricia Colin MDSSPRO
10:45	Tea/ coffee break	
11:15	Dossier Management <ul style="list-style-type: none">• How it recorded, maintained and archived<ul style="list-style-type: none">• a. Paper• b. Electronic<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	TBC
12:15	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?	TBC



Time	Presentation	Speaker
13:00	Lunch	
13:45	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	TBC
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• Must dos / Don't do	TBC
14:45	Workshop – summarising complicated documents in an Overview Tea and coffee to be served during the workshop	All
16:15	Q&A and Wrap up of the day	All
16:45	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.