CRED: Document writing and management

24-26 February 2021

***All times are in GMT.**

Online

Day 1 – 24 February

Time	Presentation	Presenter
08:30	**Online registration**	
09:00	**Welcome from TOPRA**	
09:05	**Welcome from Chairman** Overview of the day	**Dalna Harvey** Regulatory Measures Ltd

09:10	**Introduction to IVD regulatory Affairs**
	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
		LCRS Ltd

09:50	**Break**	
10:00	**Structure** • 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** LCRS Ltd
10:45	**Break**	
11:00	**MS Word - things all authors should know** • 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** ConvaTec

11:30	**Language** • 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** PRA Health Sciences UK Ltd
12:30	**Break**	
12:45	**Introduction to the Case study**	**Hilary Gray** PRA Health Sciences UK Ltd
13:00	**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** ConvaTec
13:30	**Wrap up and Close of the day**	**Dalna Harvey** Regulatory Measures Ltd

Day 2 – 25 February

Time	Presentation	Presenter
08:30	**Online registration**	
09:00	**Welcome from Chairman** • Overview of the day	
09:05	**Combination products – writing the device sections** • 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 review process - – tips, watch-outs and hurdles	**Dalna Harvey** Regulatory Measures Ltd
10:05	**Break**	
10:15	**Case study**	
11:30	**Case study presentations and discussions**	**Hilary Gray /Dalna Harvey /Joseph Irwin**
12:15	**Break**	
12:30	**Regulatory Communications** • Regulatory Communications e.g. letters to agencies – best practice • Making the Agency letter an effective communication tool for assessors	**Missoune Bakhouche** In Market Access Ltd
13:00	**Report writing (Technical examples)** • Writing technical reports • Good practice • Confidentiality	**Marcello Menapace** M&Ms Consulting Ltd
13:45	**Introduction to the Workshop**	
14:00	**Wrap up and Close of the day**	

Day 3 – 26 February 2021

Time	Presentation	Presenter
08:30	**Online registration**	
09:00	**Welcome from Chairman** • Overview of the day	**Dalna Harvey** Regulatory Measures Ltd
09:05	**Dossier Management** • How it recorded, maintained and archived • a. Paper • b. Electronic - 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	**Kathryn Brouder** BioMarin (Europe Ltd)
10:05	**Break**	
10:15	**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** BioMarin (Europe Ltd)
11:00	**Break**	
11:15	**Workshop –** summarising complicated documents in an Overview	**Hilary Gray /Dalna Harvey /Joseph Irwin**
12:45	**An Agency's perspective** • Agency Expert - Opinion • Examples of good submissions • Must dos / Don't do	**Melanie Piers** MHRA
13:30	**Q&A and Wrap up of the day**	**Dalna Harvey** Regulatory Measures Ltd
13:45	**Close of Workshop**	

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