



## CRED: Document writing and management 19-20 March 2024

### Day 1: 19 March 2024

Time	Presentation	Presenter
09:00	<b>Registration and Coffee</b>	
09:15	<b>Welcome from TOPRA</b>	
09:20	<b>Welcome from Chairman</b> <ul style="list-style-type: none"> <li>• Overview of the day</li> </ul>	<b>Dalna Harvey</b> Pfizer
09:25	<b>Introduction and AIM</b> <ul style="list-style-type: none"> <li>• Importance of good writing – Aim, Structure, Language</li> <li>• Style - Accuracy, Brevity, Clarity (ABC)</li> <li>• AIM: <ul style="list-style-type: none"> <li>• Purpose of document</li> <li>• Who is my reader? What do they know already?</li> <li>• What are they going to do with the information?</li> </ul> </li> <li>• Types of Documents – Internal reports, CTD, CTA, IND, briefing packages, responses to questions, cover letters</li> </ul>	<b>Joseph Irwin</b> XP Forte
09:45	<b>Structure</b> <ul style="list-style-type: none"> <li>• How to organise/build a document</li> <li>• Tools to gather all the data and information, and agree a “message” (e.g., mind mapping)</li> <li>• When structure is already defined – ICH, Internal, Regulatory Authority</li> <li>• When to stick to structural templates, when to deviate</li> </ul>	<b>Joseph Irwin</b> XP Forte
10:30	<b>Tea/coffee break</b>	
11:00	<b>MS Word - things all authors should know</b> <ul style="list-style-type: none"> <li>• Use templates and styles and toolbars if given</li> <li>• Heading</li> <li>• Captions</li> <li>• Tables</li> <li>• Table of Contents</li> <li>• Cross referencing within a document</li> <li>• Hyperlinking</li> </ul>	<b>Paul Browning</b> ConvaTec
11:30	<b>Language</b> <ul style="list-style-type: none"> <li>• Importance of language</li> <li>• Readability tools, as objective measures of readability and use of an example tool (Clarity Index)</li> <li>• How to make documents more readable</li> <li>• Hints and tips on understanding your personal style</li> <li>• Impact of style guides &amp; templates</li> <li>• Paragraphs &amp; signposting</li> </ul>	<b>Hilary Gray</b> Syneos Health
12:15	<b>Lunch</b>	



<b>Time</b>	<b>Presentation</b>	<b>Presenter</b>
<b>13:00</b>	<b>Dossier Management</b> <ul style="list-style-type: none"><li>• How it recorded, maintained, and archived<ol style="list-style-type: none"><li>a. Paper</li><li>b. Electronic (compatibility, size, software)</li></ol></li><li>• Hyperlinking</li><li>• CTD granularity</li><li>• Change Management</li><li>• 'Global' dossiers</li><li>• How to deal with old, historical, non-CTD, paper dossiers</li><li>• Avoiding drift</li></ul>	<b>Kathryn Brouder</b> BioMarin (Europe Ltd)
<b>14:00</b>	<b>Writing Overviews</b> <ul style="list-style-type: none"><li>• Writing Overviews – summarising the detail in a clear way</li><li>• How to distil complicated details in a clear manner<ul style="list-style-type: none"><li>• Must dos / Don't do</li></ul></li></ul>	<b>Joseph Irwin</b>
<b>14:30</b>	<b>Tea/coffee break</b>	
<b>14:45</b>	<b>Regulatory Operations and Publishing</b> <ul style="list-style-type: none"><li>• What happens to the documents between leaving our desks and arriving on the reviewer's desk.</li><li>• Why styles and technical requirements are important.</li><li>• What the Reviewer sees (has everyone seen an eCTD in practice?)</li><li>• How to handle images, do we need them and are they readable?</li></ul>	<b>Kathryn Brouder</b>
<b>15:30</b>	<b>Workshop</b>	<b>Hilary Gray</b>
<b>16:30</b>	<b>Workshop presentations and discussions</b>	
<b>17:00</b>	<b>Introduction to the Day 2 Case Study</b>	<b>Hilary Gray</b>
<b>17:15</b>	<b>Close of Workshop and Day 1</b>	<b>Dalna Harvey</b>

***Delegates are encouraged to ask questions throughout the day to ensure the meeting is as interactive as possible.***



## CRED: Document Writing and Management

Day 2: 20 March 2024

Time	Presentation	Presenter
09:00	Registration and coffee	
09:10	<b>Welcome from Chairman</b> <ul style="list-style-type: none"><li>• Overview of the day</li></ul>	<b>Joseph Irwin</b>
09:15	<b>An Agency's perspective</b> <ul style="list-style-type: none"><li>• Agency Expert - Opinion</li><li>• Examples of good submissions</li><li>• Must dos/Don't do</li></ul>	<b>Dr Abigail Moran</b> MHRA
09:50	<b>Report writing (Technical examples)</b> <ul style="list-style-type: none"><li>• Writing technical reports</li><li>• Good practice</li><li>• Confidentiality</li></ul>	<b>Kelly Smith</b> Certara
10:30	Tea/coffee break	
11:00	<b>Combination products – writing the device sections</b> <ul style="list-style-type: none"><li>• Background to device component development</li><li>• Format of the device constituent information in the CTD</li><li>• Key topics to cover in the device component sections of the dossier</li><li>• The writing and review process – tips and watch-outs</li></ul>	<b>Dalna Harvey</b>
12:00	Lunch	
12:45	<b>Future trends in submissions and publishing (AI)</b> <ul style="list-style-type: none"><li>• Examples of how AI is influencing the pharma world today (Current status)</li><li>• How will this impact interaction with agencies?</li><li>• Panel discussion</li></ul>	<b>Duncan Arbour</b> Syneos Health
13:45	Case Study	<b>Hilary Gray</b>
14:45	Case Study discussion and presentations	
15:15	Tea/coffee break	
15:30	<b>Regulatory Communications</b> <ul style="list-style-type: none"><li>• Regulatory Communications e.g. letters to agencies – best practice</li><li>• Making the Agency letter an effective communication tool for assessors</li></ul>	<b>Obaid Khan</b> Johnson & Johnson
16:15	Q&A and Wrap up	
16:30	Close of course and Day 2	<b>Joseph Irwin</b>