



## 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	<b>Registration and Coffee</b>	
09:20	<b>Welcome from TOPRA</b>	<b>TOPRA</b>
09:25	<b>Welcome from Chairman</b> <ul style="list-style-type: none"> <li>• Overview of the day</li> </ul>	<b>Hilary Gray</b> Indivior UK Ltd
09:30	<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> Lakeside Regulatory Consulting Services Ltd
10:15	<b>Structure</b> <ul style="list-style-type: none"> <li>• How to organise/build a document</li> <li>• Tools such as Mind Mapping to gather all the data and information, and agree a “message”</li> <li>• When structure is already defined – ICH M4, Internal, Regulatory Authority (Eg EMA briefing packages)</li> <li>• When to stick to structural templates, when to deviate</li> </ul>	<b>Joseph Irwin</b> Lakeside Regulatory Consulting Services Ltd
11:00	<b>Tea/ coffee break</b>	
11:20	<b>Language</b> <ul style="list-style-type: none"> <li>• What makes a document hard to read? (long words, sentences, paragraphs)</li> <li>• Clear language important when English not first language of reader and/or document will be translated</li> <li>• Readability tools, e.g. Clarity Index, as objective measures of readability vs style preferences</li> </ul>	<b>Hilary Gray</b> Indivior UK Ltd



Time	Presentation	Speaker
	<ul style="list-style-type: none"> <li>• Active v passive tense</li> <li>• Sentences – avoiding flannel and waffle</li> <li>• Level of detail to help minimise future changes</li> <li>• Paragraphs &amp; signposting</li> <li>• Smith v Brown example (Turk, C.C.R. (1978) Do You Write Impressively? Bulletin of the British Ecological Society, ix(3) 5–10)</li> <li>• Medical Writing accurate and detailed R&amp;D reports</li> <li>• Summarising published literature</li> <li>• Presentation of text               <ul style="list-style-type: none"> <li>○ Understanding Regulatory requirements</li> <li>○ Importance of an Internal Style Guide and sticking to it (examples of style guides)</li> <li>○ Templates</li> <li>○ Tabulation vs written text</li> <li>○ Requirements for Figures, tables</li> </ul> </li> </ul>	
<b>12:30</b>	<b>Lunch</b>	
<b>13:15</b>	<b>Working with teams</b>	<b>Tacye Connolly</b>
	<ul style="list-style-type: none"> <li>• Defining objectives</li> <li>• Managing the teams and peers</li> <li>• Managing disagreement</li> </ul>	
<b>13.45</b>	<b>An Agency's perspective</b>	<b>Melanie Pires MHRA</b>
	<ul style="list-style-type: none"> <li>• Agency Expert - Opinion</li> <li>• Examples of good submissions</li> </ul> <p>Must dos / Don't do</p>	
<b>14:30</b>	<b>Case Study</b>	
<b>15:55</b>	<b>Case Study presentations &amp; discussion</b>	<b>Hilary Gray Indivior UK Ltd</b>
<b>16:55</b>	<b>Regulatory Communications</b>	<b>Tacye Connolly</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>17:20</b>	<b>Close of Workshop - Day 1</b>	



## CRED: Document writing and management

### Day 2: The Practice

Chair: Joseph Irwin

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



Time	Presentation	Speaker
	<ul style="list-style-type: none"><li>• How to handle images, do we need them and are they readable?</li></ul>	
13:00	<b>Lunch</b>	
13:45	<b>MS Word - things all authors should know</b> <ul style="list-style-type: none"><li>• Use templates and styles and toolbars if given, do not invent your own</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> 3M Global Healthcare Business Group
14:15	<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</li><li>• Must dos / Don't do</li></ul>	<b>Paul Browning</b> 3M Global Healthcare Business Group
14:45	<b>Workshop</b> – summarising complicated documents in an Overview	<b>All</b>
	<b>Tea and coffee to be served during the workshop</b>	
16:15	<b>Q&amp;A and Wrap up of the day</b>	<b>All</b>
16:45	<b>Close of Workshop - Day 2</b>	

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