

## CRED Project Management for Regulatory Affairs Professionals

03-04 May 2023

### Day 1 Programme

Time	Presentation	Presenter
09:30	<b>Welcome from TOPRA</b>	<b>TOPRA</b>
09:40	<b>Introduction</b> <ul style="list-style-type: none"> <li>• Welcome &amp; domestics</li> <li>• Introduction to the speakers</li> <li>• Course overview/objectives</li> <li>• Your aims/objectives?</li> <li>• Your introduction (including personal aims)</li> </ul>	<b>Joe Cheal</b> Imaginarium
10:10	<b>What is Project Management</b> <ul style="list-style-type: none"> <li>• What is a project?</li> <li>• Life cycle: The four-stage project <ul style="list-style-type: none"> <li>◦ Define (what/why), Plan (how), Implement, Final Review</li> <li>◦ The Fantasy – Reality Gap</li> </ul> </li> <li>• The Time Cost Quality Triangle... plus the missing piece!</li> <li>• Qualities of effective project managers</li> </ul>	<b>Joe Cheal</b> Imaginarium
11:10	<b>Tea/ Coffee break</b>	
11:30	<b>Project Management and how it fits with Regulatory Affairs</b> <ul style="list-style-type: none"> <li>• Definitions</li> <li>• Examples of regulatory projects</li> <li>• Regulatory Affairs (RA) professionals as Project Managers</li> </ul>	<b>Sinéad Usher</b> SMART Regulatory Services
12:15	<b>Stage 1: Defining</b> <ul style="list-style-type: none"> <li>• What is the defining stage?</li> <li>• The Pre- Project 'P's</li> <li>• Identifying stakeholders</li> <li>• Project kick-off meeting <ul style="list-style-type: none"> <li>◦ Scope</li> </ul> </li> <li>• Risk <ul style="list-style-type: none"> <li>◦ Contingency planning</li> </ul> </li> </ul>	<b>Joe Cheal</b> Imaginarium
12:45	<b>Lunch</b>	
13:30	<b>Stage 1: Defining (Cont.)</b>	<b>Joe Cheal</b> Imaginarium
14:30	<b>Tea/ Coffee break</b>	
14:50	<b>Stage 2: Planning</b> <ul style="list-style-type: none"> <li>• Work Breakdown Structure <ul style="list-style-type: none"> <li>◦ Roles &amp; responsibilities</li> </ul> </li> <li>• Gantt/Timeline Charts <ul style="list-style-type: none"> <li>◦ Working with charts</li> <li>◦ Milestones</li> </ul> </li> <li>• Communication &amp; reporting Plans</li> </ul>	<b>Joe Cheal</b> Imaginarium  <b>Oliver Rick</b> Reg One
16:20	<b>Review of the day</b>	
16:40	<b>Close</b>	

## Day Two Programme

Time	Presentation	Who
09:10	<b>Introduction</b>	<b>Joe Cheal</b> Imaginarium
09:30	<b>Stage 3: Implementation</b> <ul style="list-style-type: none"> <li>Project delivery: Staying on track and within budget (time-cost-quality)</li> <li>Handling change and handovers</li> <li>Key skills: <ul style="list-style-type: none"> <li>Juggling projects and everyday work</li> <li>Delegation</li> <li>Chairing project review meetings &amp; how to maintain control</li> <li>Dealing with 'difficult' people (with different priorities)</li> <li>Maintaining motivation</li> </ul> </li> </ul>	<b>Joe Cheal</b> Imaginarium
10:30	<b>Tea/ Coffee break</b>	
10:45	<b>Stage 3: Implementation Cont'd</b>	<b>Joe Cheal</b> Imaginarium
11:30	<b>Stage 4: Final Review</b> <ul style="list-style-type: none"> <li>Why review the project (and why does it not always happen)?</li> <li>Making the reviews useful</li> <li>Key questions to ask, e.g.: <ul style="list-style-type: none"> <li>What to do differently next time?</li> <li>What to do now – follow up?</li> <li>How to celebrate?</li> </ul> </li> <li>Recording &amp; sharing information/ lessons learnt</li> </ul>	<b>Joe Cheal</b> Imaginarium
11:45	<b>A Regulatory Project – knowledge transfer</b> <ul style="list-style-type: none"> <li>Project Plan</li> <li>Delivering the plan</li> <li>Identifying risks</li> <li>Optimising experiences</li> </ul>	<b>Gurdeep Bhangra</b> IQVIA Limited
12:15	<b>Lunch</b>	
13:00	<b>Case Study: A Regulatory Project</b> <i>Tea/ coffee to be taken during case study</i>	<b>Sinéad Usher</b> SMART Regulatory Services
15:15	<b>Case Study Feedback</b>	<b>Sinéad Usher</b> SMART Regulatory Services
16:30	<b>Next steps</b>	<b>Oliver Rick</b> Reg One
17:00	<b>Review and discussion</b>	<b>Oliver Rick</b> Reg One
17:15	<b>Close of Meeting</b>	