



## **CRED Project Management for Regulatory Affairs Professionals**

9-10 June 2021

### **Day 1 Programme**

<b>Time</b>	<b>Who</b>	<b>Presentation</b>
<b>09.30</b>	<b>TOPRA</b>	<b>Welcome from TOPRA</b>
<b>09.40</b>	<b>Joe</b>	<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>10.10</b>	<b>Joe</b>	<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>11.10</b>		<b>Tea/ Coffee break</b>
<b>11.30</b>	<b>Sinéad</b>	<b>Project Management and how it fits with Regulatory Affairs</b> <ul style="list-style-type: none"> <li>• Definitions of Regulatory Affairs and Project Management</li> <li>• What are regulatory projects? <ul style="list-style-type: none"> <li>◦ Roles of RA pre and post Marketing Authorisation Approval</li> <li>◦ Other RA projects</li> </ul> </li> <li>• Regulatory Affairs (RA) professionals as Project Managers</li> </ul>
<b>12.15</b>	<b>Joe</b>	<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>12.45</b>		<b>Lunch</b>
<b>13.30</b>	<b>Joe</b>	<b>Stage 1: Defining (Cont.)</b>
<b>14.30</b>		<b>Tea/ Coffee break</b>
<b>14.50</b>	<b>Joe/Oli</b>	<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>16.20</b>		<b>Review of the day</b>
<b>16.40</b>		<b>Close</b>



## Day Two Programme

Time	Who	Presentation
09.10	Joe	<b>Introduction</b>
09.30	Joe	<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>
10.40		<b>Tea/ Coffee break</b>
1100	Joe	<b>Stage 3: Implementation Cont'd</b>
12.00	Deep	<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>
12:30	Deep	<b>Practical example of a Regulatory Affairs Project</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>
13:00		<b>Lunch</b>
13:45	Sinéad	<b>Case Study: A Regulatory Project</b> <i>Tea/ coffee to be taken during case study</i>
15:30	Sinéad	<b>Case Study Feedback</b>
16:45	Oli	<b>Next steps</b>
17:00	Oli	<b>Review and discussion</b>
17:15		<b>Close of Meeting</b>