



CRED Project Management for Regulatory Affairs Professionals 08-09 May 2024

Day 1 Programme

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



Day Two Programme

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