CRED Project Management for Regulatory Affairs Professionals
5-6 March 2019

Presenters:
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- **Joe Cheal,** Imaginarium Learning & Development
- **Sinéad Usher,** Smart Regulatory Services Ltd

Day 1 Programme

Time	Presentation
09.15	**Registration and coffee**
09.30	**Welcome from TOPRA**
09.40	**Introduction** • Welcome & domestics • Introduction to the speakers • Course overview/objectives • Your aims/objectives? • Your introduction (including personal aims)

10.10	**What is Project Management**
	• What is a project?
	• Life cycle: The four-stage project
	    o Define (what/why), Plan (how), Implement, Final Review
	    o The Fantasy – Reality Gap
	• The Time Cost Quality Triangle… plus the missing piece!
	• Qualities of effective project managers

11.10	**Tea/ Coffee break**

11.30	**Project Management and how it fits with Regulatory Affairs**
	• Definitions of Regulatory Affairs and Project Management
	• What are regulatory projects?
	    o Roles of RA pre and post Marketing Authorisation Approval
	    o Other RA projects
	• Regulatory Affairs (RA) professionals as Project Managers

12.15	**Stage 1: Defining**
	• What is the defining stage?
	• The Pre- Project 'P's
	• Identifying stakeholders
	    o Governance (Internal and External)
	• Project kick-off meeting
	    o Scope
	• Risk
	    o Contingency planning

12.45	**Lunch**
13.30	**Stage 1: Defining (Cont.)**
14.30	**Tea/ Coffee break**
14.50	**Stage 2: Planning** • Work Breakdown Structure

Time	Presentation
	o Roles & responsibilities
	• Gantt/Timeline Charts
	o Creating and reading charts
	o Milestones
	• Communication & reporting Plans
16.20	**Review of the day**
16.40	**Close**

Day Two Programme

Time	Presentation
09.10	**Introduction**

09.30	**Stage 3: Implementation**
	• Project delivery: Staying on track and within budget (time-cost-quality)
	• Handling change and handovers
	• Key skills:
	    o Juggling projects and everyday work
	    o Delegation
	    o Chairing project review meetings & how to maintain control
	    o Dealing with 'difficult' people (with different priorities)
	    o Maintaining motivation

10.40	**Tea/ Coffee break**
11.00	**Stage 3: Implementation Cont'd**

12.00	**Stage 4: Final Review**
	• Why review the project (and why does it not always happen)?
	• Making the reviews useful
	• Key questions to ask, e.g.:
	    o What to do differently next time?
	    o What to do now – follow up?
	    o How to celebrate?
	• Recording & sharing information/ lessons learnt

12.30	**Lunch**
13.15	**Case Study: A Regulatory Project** *Tea/ coffee to be taken during case study*
15.00	**Case Study Feedback**
16.15	**Review and discussion**
16.45	**Close of Meeting**