CRED: Critically Evaluating Dossiers

19 September 2019, London, UK

Time	Presentation	Speaker
9:00	**Registration and Coffee**	
9:30	**Welcome from TOPRA**	**Samantha Cooper** TOPRA
9:40	**Welcome from Chairman** • Overview of the day	**Sargon Daniel** Medpace
9:45	**Introduction** • Common Technical Document - the regulatory dossier • Description of Module 1 to 5	**Dora Halmai** Mylan
10:15	**Typical EU Module 1 Documents** • SmPC, Label, PIL • Environmental Risk Assessments • Risk Management Plans	**Adriaan Fruijtier** CATS Consultants GmbH
10:30	**Chemistry Manufacturing & Control (CMC)** • Critical sections of Module 3	**Christopher Carr** ERA Consulting
11:30	**Break**	
11:45	**Clinical and Non-clinical Study Reports** • How to decode Modules 4 and 5	**Steve Pinder** Envestia
13:30	**Lunch**	
14:15	**A Regulatory assessor's perspective** • Viewing and reviewing the dossier holistically	**Birka Lehmann** Ex-Regulator, BfArM
15:15	**Workshop** *Tea/coffee during case study*	**Dora Halmai** Mylan
16:15	Summary of the day and Mentimeter	
16:30	**Close**	

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