CRED Successfully Navigating European GMO Requirements
24 – 25 June 2025, London and Online

DAY 1: Successfully Navigating European GMO Requirements

Time	Session	Speaker
10:30	**Registration**	
11:00	**Welcome and Overview**	**Course Leads**
11:15	**Introduction: What are the Challenges for GMO based medicines?** • What is a GMO? • Why are GMOs regulated? • What is the regulatory framework? • Setting the scene	**Myra Widjojoatmodjo,** *Johnson & Johnson*
12:30	***Lunch***	
13:15	**Is my innovative product a GMO?** • Delineation of product types • Borderline product classification • Novel technologies	**Leoni Mahal,** *Cell and Gene Therapy Catapult*
14:00	**International Planning of clinical trials** • Strategic and operational planning • EU, UK, US and other key markets • Procedures and timelines • Interplay with the CTR	**Pierre-Frederic Omnes,** *Transperfect*
15:30	***Coffee***	

15:45	**Strategic considerations for GMO Submission Dossiers**
	• Introduction to Requirements & Content
	• Dossier options in EU and when to use:
	  ○ 'classical' DR & CU dossiers
	  ○ Common Application Form (CAF)-based dossiers
	• Strategic considerations
		Sabine Ruehle, *Boyd Consultants*

16:05	**Case Study 1: GMO Strategy - Clinical Trial**	
17:45	**Wrap-up**	**Course Leads**

Programme subject to changes

DAY 2: Successfully Navigating European GMO Requirements

Time	Session	Speaker
9:15	**Summary of Day 1 to lead into Day 2**	**Course Leads**
9:30	**How to prepare the GMO risk assessments dossier** • Where to start • Comparison of dossier requirements • Source information • How to prepare Technical Information, (Enviromental) Risk Assessment, SNIF, CAF • Practical considerations and resources	**Sabine Ruehle,** *Boyd Consultants*
10:30	***Coffee Break***	
10:45	**Case study 2: Practical Dossier Preparation**	
12:00	***Lunch***	
12:45	**How to Get Your Team on Board for GMO Requirements** • Why, when, what and how to establish an end-to-end process. • Experienced gained from small biotech/ large pharma in the form of case studies.	**Kathryn Parsley,** *Complement Therapeutics*
13:30	**Beyond Clinical Trials: Licensing Stage of GMOs** • Requirements for licensing in EU and US • Dossier requirements & review process • How GMO aspects are included in approval • Post-approval requirements	**Sabine Ruehle,** *Boyd Consultants*
14:15	***Coffee Break***	

14:30	**What's on the Horizon: Impact of the New EU Pharma Legislation on GMOs**
	• Impact of upcoming reforms on GMOs
	  ○ Impact on GMO IMPs
	  ○ Impact on GMO MAAs
		Amanda Wheeler, *The Wheeler Partnership Ltd*

15:00	**Panel Discussion/Q&A**	
15:45	**Close Out Session**	**Course Leads**

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