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?**	**Myra Widjojoatmodjo,** *Johnson & Johnson*
12:30	***Lunch***	
13:15	**Is my innovative product a GMO?**	**Leoni Mahal,** *Achilles Therapeutics*
14:00	**International Planning of clinical trials**	**Pierre-Frederic Omnes,** *Transperfect*
15:30	***Coffee***	
15:45	**Strategic considerations for GMO Submission Dossiers**	**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	**Principals of Environmental Risk Assessments for GMOs**	**Erik Schagen,** *ProPharma* **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**	**Kathryn Parsley,** *Complement Therapeutics*
13:30	**Beyond Clinical Trials: Licensing Stage of GMOs**	**Sabine Ruehle,** *Boyd Consultants*
14:15	***Coffee Break***	
14:30	**What's on the Horizon: Impact of the New EU Pharma Legislation on GMOs**	**Amanda Wheeler,** *The Wheeler Partnership Ltd*
15:00	**Panel Discussion/Q&A**	
15:45	**Close Out Session**	**Course Leads**

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