CRED Successfully navigating European GMO Regulations

Course Chairman: **Jayne Hunt**, Boyd Consultants

On-demand presentations

Date of release	Session	Presenter
23 March 2020	**Introduction to the Pharmaceutical GMO environment** • Understand the challenges for Clinical Trials using GMO Containing Investigational medicinal Products • Understand GMO legislation • Overview of Practical Aspects • Overview of new GMO Developments at European Commission Level	**Janneke Westra-de Vlieger** Janssen Vaccines & Prevention B.V.
27 March 2020	**GMOs in clinical trials: Understanding current legislations and changes with the upcoming EU clinical trials regulation** • Introduction of genetically modified organisms • High level overview of GMO legislations • Proposed operationalisation of those requirements to organise your preparation activities	**Pierre Omnes** Syneos Health
30 March 2020	**Common pitfalls of GMO submissions – from the industry perspective** • Challenges with GMO clinical trials • GMO regulatory framework in 5 key countries	**Myra Widjojoatmodjo** Janssen Vaccines & Prevention B.V.
3 April 2020	**GMO Environmental Risk Assessments for clinical trials** • Overview of Environmental Risk Assessment (ERA) • Understand steps to perform in the ERA • Practical considerations	**Sabine Ruehle** Boyd Consultants
6 April 2020	**Beyond Europe – feedback from Canada** • GMO regulatory requirements for GM products in Europe, Canada & the USA • Canadian regulatory framework • Practicalities of submission processes	**Jayne Hunt** Boyd Consultants
9 April 2020	**Case study documentation to be sent to delegates**	

Live session: 23 April

Time	Session
9:30	**Welcome from Chairman** • Overview of the day
9:45	**Q&A Session**
10:15	**Introduction to the Case Study**
10:30	**Case Study** • Understanding regulatory strategy for GMOs • Understanding the core documentation
11:45	**Closing session**

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