Module 5: Regulatory Control of Clinical Operations
8th - 10th June 2022
Location: TOPRA Office, 6th Floor, Harbour Exchange, London, E14 9GE and Online

Module Leader(s): **Angela Stokes and Eva Kopecna**

Date: Wednesday 8th June 2022

Time	Activity	Speaker
13.00 – 13.15	**Welcome & Introduction To Module 5**	Chairperson Angela Stokes Sharp Regulatory Consulting
13.15 – 14.15	**Lecture 1: GCP - The platform for clinical research.** Objective History Quality & Compliance Audits and Inspections	Eva Kopecna Acino International
14.15 – 15.15	**Lecture 2: GCP Inspections – Agency Experience**	Rachel Mead MHRA
15.15 – 15.45	**Refreshment break**	
15.45 – 17.00	**Lecture 3: Progression of clinical trials in relation to the toxicology programme** Purpose of toxicology studies in support clinical development Requirements for different stages of clinical development Requirements for different types of medical products (e.g. chronic, acute, delivery system)	Simon Craige EdGe Toxicology Consulting

Date: Thursday 9th June 2022

Time	Activity	Speaker
09.00 – 09.15	**Introduction**	Chairperson: Angela Stokes
09.15 – 10.45	**Lecture 4: Regulatory requirements for clinical trials - EU** Current Legislation Requirements The Clinical Trial Regulation and its Impact CTA applications / Medical Devices Ethics Committee Submissions Reporting of clinical trials. Industry experience	Pierre Omnes Transperfect Life Sciences
10.45 – 11.15	**Refreshment Break**	
11.15 – 12.00	**Lecture 5: The successful IMPD** Contents of the IMPD Pitfalls Updates	Graham Bell PRA HS
12.00 – 13.00	**Lecture 6: GMP, authorisation and importation requirements, clinical trial supplies management** 2003/94/EC *GMP Directive* Manufacturing and importation requirements including the role of the QP Regulatory framework under which clinical supplies are managed Planning of a clinical supplies programme Issues relating to manufacture, packaging and distribution of clinical supplies	
13.00 – 14.00	**Lunch**	
14.00 – 14.45	**Lecture 7: Pharmacovigilance & adverse event reporting in clinical trials** Adverse Event reporting -General requirements and definitions Safety reporting in the EU Pharmacovigilance. Future Proposals	Beatrice Panico MHRA
14.45 – 15.00	**Introduction to Case Study 1**	Angela Stokes
15.00 – 15.15	**Refreshment Break**	
15.15 – 17.00	**Case Study 1: Initiation of a Clinical Trial**	
17.00 – 17.30	**Presentation of feedback from Case Study 1**	

Date: Friday 10th June 2022

Time	Activity	Speaker
08.45 – 08.50	**Introduction**	Chairperson Eva Kopecna
08.50 – 09.50	**Lecture 8: Legal aspects of clinical trials** Product Information and Informed Consent Data Protection. Enforcement and Sanctions Liability. Clinical Study Contracts	Adela Williams Arnold and Porter
09.50 – 10.30	**Refreshment Break**	
10.30 – 11.30	**Lecture 9: Regulatory requirements for clinical trials - Japan** Legislation requirements Clinical Trial Notifications Japanese Regulatory Authorities Consultations with the Authorities Clinical Trials in Japan & GCP	Mohamed Oubihi Yakumed
11.30 – 12.30	**Lecture 10: Regulatory requirements for clinical trials – US and Canada** Legislation requirements CTA and IND applications & maintenance Ethics Committee GCP & Enforcement	Sarah Roberts PRAHS
12.30 – 13.30	**Lunch**	
13.30 – 13.45	**Introduction to Case study 2: GCP and Clinical Development Programme**	Eva Kopecna Acino International
13.45 – 14.45	**Case Study 2: GCP and Clinical Development Programme**	
14.45 – 15.15	**Presentation of feedback from Case Study 2**	