

Location: TOPRA Office: 3rd Floor, City Reach 5, Greenwich View Place, London, E14 9NN

Module Leader: James Pink

Date: 13th of January 2025

Time	Activity	Speaker
10:30	Registration	
11:00 – 11:15	Welcome & Introduction to Module 12	James Pink JPA
11:15 – 12:15	Lecture 1: Data Management and Data Governance (DM/DG) <ul style="list-style-type: none"> • Background, History and Legal Basis <ul style="list-style-type: none"> ○ Electronic Data Capture (EDC) ○ Data Input/Output ○ Data Querying ○ Data Management Plans • Data Standards Regulatory Involvement in DM/DG Technical Specifications and Compliance <ul style="list-style-type: none"> • ISO IDMP and EMA SPOR • XEVMPD • ePI 	TBC
12:15 – 13:00	Lunch	
13:00 – 14:15	Lecture 2: Regulatory Information, Intelligence and Knowledge Management <ul style="list-style-type: none"> • RIM Systems and Capabilities • Regulatory Intelligence • Regulatory Knowledge and Management 	Victor Goncharuk Sanofi
14:15 – 14:30	Refreshment Break	
14:30 – 16:00	Lecture 3: GMDN, EUDAMED and Device Nomenclature Systems <ul style="list-style-type: none"> • GMDN (Global Medical Device Nomenclature) • EUDAMED (EU Medical Device Database) • EMDN (European Medical Device Nomenclature) Context and Relationship to GMDN • Integration and Regulatory Applications 	Graham Nash Gmdn Richard Houlihan EUDAMED
16:00	Close	

Date: 14th of January 2026

Time	Activity	Speaker
9:15 – 10:15	Lecture 4: Introduction to Artificial Intelligence <ul style="list-style-type: none"> • Introduction to Artificial Intelligence and Foundational Ideas • Artificial Intelligence Concepts • The Challenge of Artificial Intelligence Compliance • Q&A Session 	Abhishek Shivkuma Element Materials
10:15 – 10:45	Refreshment Break	
10:45 – 12:30	Lecture 5: EU Telematics Strategy <ul style="list-style-type: none"> • EMA SPOR • Electronic application forms (eAF) • Update on EMA 2025 Roadmap • Global IDMP implementation approaches and Health Authority collaborations 	Grzegorz Kojro Perrigo
12:30 – 13:30	Lunch	
13:30 – 15:00	Lecture 6: Electronic Common Technical Document <ul style="list-style-type: none"> • Update on Worldwide Use • Current Technical Specifications • Electronic application forms (eAF) • eCTD Demo • Future version of eCTD • Electronic application forms (eAF) 	Daniel Langa Asphalion
15:00 – 15:30	Refreshment Break	
15:30 – 17:00	Lecture 7: US Regulatory Requirements <ul style="list-style-type: none"> • US Data Standards and Resources • CDISC <ul style="list-style-type: none"> ◦ ADaM ◦ SEND • Reviewer's Guides • Data Traceability and Accountability • eLabeling – SPL • US FDA KASA System 	TBC
17:00 – 17:30	Workshop Activity	

Date: 15th of January 2026

Time	Activity	Speaker
9:00 – 10:30	Lecture 8: Medical Device-Related Presentation <ul style="list-style-type: none">• Medical Devices Regulation• Basics & Overview of the MDR	Michael M. Kania Meddevo
10:30 – 10:45	Refreshment Break	
10:45 – 12:15	Lecture 9: Medical Device & Digital Health <ul style="list-style-type: none">• Quality and Regulatory Application of Software Devices• Overview of SaMD and SiMD• Review of legislation changes	Sorcha Murphy GSK
12:15 – 13:15	Lunch	
13:15 – 15:00	Lecture 10: The Look to the Future <ul style="list-style-type: none">• Machine Learning• Artificial Intelligence• Big Data• RWD/E• AI & Data Governance	James Pink JPA
15:00 – 15:30	Close	
