

Module 12: Data Management and Digitalisation in Regulatory Affairs



Module Leader: Peter Embley

Location: Topra Office: 6th Floor, Harbour Exchange, South Quay, London, E14 9G & Online

Wednesday 31st January – Friday 2nd February 2024

Date: Wednesday 31st January 2024

Time	Activity	Speaker
10.30	Registration	
11.00 – 11.15	Welcome & Introduction to Module 12	Peter Embley
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	Gill Penrose & Tabitha Sleaf Chaucer
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	Dennie van de Voort & Amy Williams Deloitte
14.15 - 14.30	Refreshment Break	



14.30 – 15:30	Lecture 3: Electronic Common Technical Document <ul style="list-style-type: none"> • Update on Worldwide Use • Current Technical Specifications • Electronic applications forms (eAF) • eCTD Demo • Future version of eCTD Electronic applications forms (eAF)	Remco Munnik Deloitte
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Date: Thursday 1st February 2024

Time	Activity	Speaker
9.15 – 10.15	Lecture 4: Introduction to Artificial Intelligence	Peter Fletcher-Dyer
10.15 – 10.45	Refreshment Break	
10.45 – 12.30	Lecture 5: EU Telematics Strategy <ul style="list-style-type: none"> • Update on 2025 Roadmap • Collaboration with EMA and National Has • EMA SPOR • Electronic applications forms (eAF) 	Amy Williams & Dorien de Vries Deloitte
12.30 – 13.30	Lunch	



13.30 – 15.00	Lecture 6: Technical Specifications and Compliance <ul style="list-style-type: none"> • eLabeling and ePI • xEVMPD and ISO IDMP 	Dorien de Vries & Dennie van de Voort Deloitte
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 	Nancy Pire-Smirkanich
17.00 -17.30	Workshop Activity	Peter Embley

Date: Friday 2nd February 2024

09.00 – 10.30	Lecture 8: Medical Device Related Presentation	Monir El Azzouzi Easy Medical Devices
10.30 – 10.45	Refreshment break	
10.45 – 12.15	Lecture 9: Medical Device & Digital Health	Monir El Azzouzi Easy Medical Devices



12.15 - 13.15

LUNCH

13.15 - 15.00

Lecture 10: The Look to the Future

Peter Fletcher-Dyer

- Machine Learning
- Artificial Intelligence
- Big Data
- RWD/E
- *AI & Data Governance*