

Module Leader Peter Embley

Date: Wednesday 1st December 2021

Time	Activity	Speaker
10.30	Registration	
11.00 – 11.15	Welcome & Introduction to Module 12	Peter Embley Bionical-Emas
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 Workshop/Activity	Peter Embley Bionical-Emas
12.15 - 13.15	Lunch	
13.15 – 14.15	Lecture 2: Document and Information Management <ul style="list-style-type: none">• Document Archiving• Registration Tracking• Trial Master Files	Rohit Malhotra Biogen
14.15 – 15.15	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	Remco Munnik Iperion
15.15 - 15.45	Refreshment Break	
15.45 - 16.15	Lecture 3 continued	Remco Munnik Iperion

Date: Thursday 2nd December 2021

Time	Activity	Speaker
9.00 – 10.15	Lecture 4: Regulatory Information, Intelligence and Knowledge Management <ul style="list-style-type: none">• RIM Systems and Capabilities• Regulatory Intelligence• Regulatory Knowledge and Management<ul style="list-style-type: none">○ Administration○ Systems	Rohit Malhotra Biogen
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)	Remco Munnik Iperion (confirmed)
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	Remco Munnik Iperion
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-Smerkanich University of Southern California
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Date: Friday 3rd December 2021

09.00 – 10.30	Lecture 8: Data and Document Best Practices and Process <ul style="list-style-type: none"> • Ensuring Compliance • Role of Regulatory Affairs Professional 	Michael Whitworth Chaucer
	Process and documentation workshop	
10.30 – 10.45	Refreshment break	
10.45 – 12.15	Lecture 9: The Look to the Future <ul style="list-style-type: none"> • Automatic processing and Data mining (PV and ICSR) • Machine Learning • Artificial Intelligence • Big Data 	Michael Whitworth Chaucer
	RWD/E	
12.15 – 13.15	LUNCH	
13.15 -15.15	Workshop	