

Session no.	Delivery method	Duration or Time - AM	Time - PM	Content	Description	Tutor
PRE-DAY 1						
1	LMS	20 min.		Course Introduction, Objectives and self assessment	Self-paced online slide deck for the delegates to review with voiceover.	PHG
2	LMS	20 min.		What do we want medicines to do?	Workbook/page within LMS Whiteboard exercise	PHG
3	LMS	40 min.		Introduction to Medicines Law	Self-paced online slide deck for the delegates to review with voiceover.	PHG
4	LMS	20 min.		Product Lifecycle and Controls	Workbook/page within LMS Whiteboard exercise	PHG
5	LMS	40 min.		EU Law – An Overview	Self-paced online slide deck for the delegates to review with voiceover.	RSC
6	LMS	30 min.		EUMarketing Authorisations	Self-paced online slide deck for the delegates to review with voiceover.	PHG
7	LMS	40 min.		Legislation in the EU affecting clinical trials	Self-paced online slide deck for the delegates to review with voiceover.	PHG
DAY 1						
8	Zoom Classroom	8.45 - 9.15	13.30 - 14.00	Welcome, Zoom classroom set-up and Tutor Introduction and overview of session	Plan for Day 1	PHG
9	Zoom Classroom	9.15 - 9.45	14.00 - 14.30	Review of Whiteboard from S02	Interactive review of responses to the exercise	PHG
10	Zoom Classroom	9.45 - 10.15	14.30 - 15.00	Review Law importance and medicines law	Interactive Q&A	PHG
		10.15 - 10.30	15.00 - 15.15	BREAK		
11	Zoom Classroom	10.30 - 10.50	15.15 - 15.35	Review of key points from S04	Interactive review of responses to the exercise	PHG
12	Zoom Classroom	10.50 - 11.20	15.35 - 16.05	Post Approval Changes & Variations (including ICH Q12)	Presentation	PHG
13	Zoom Classroom	11.20 - 11.50	16.05 - 16.35	Manufacturing and Wholesale Dealers Authorisations	Presentation	RSC
14	Zoom Classroom	11.50 - 12.20	16.35 - 17.05	GDP Guideline 'Find-it'	Breakout room exercise	RSC
15	Zoom Classroom	12.20 - 12.30	17.05 - 17.15	Final Questions and Close	Review of Day 1 and plan for Day 2	PHG
16	LMS	10 min.		Legal Duties of a QP	Self-paced online slide deck for the delegates to review with voiceover.	PHG
17	LMS	45 min.		Annex 16: Certification and Batch Release by the QP	Self-paced online slide deck for the delegates to review with voiceover.	PHG
18	LMS	40 min.		Regulatory Control of Starting Materials; APIs and Excipients	Self-paced online slide deck for the delegates to review with voiceover.	DW
19	LMS	40 min.		Recalls – EU and US Laws	Self-paced online slide deck for the delegates to review with voiceover.	DW

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20	LMS	40 min.		Structure of EudraLex Volume 4	Scavenger hunt' through Eudralex along with online information or workbook reading/ activities	RSC
21	LMS	30 min.		GMP Legislation exercise	Online self-study	PHG
DAY 2						
	Zoom Classroom	8.45 - 9.15	13.30 - 14.00	Welcome back and summary of topics completed so far	Review Key Learning Points from Day 1 and Plan for Day 2	RSC
22	Zoom Classroom	9.15 - 9.35	14.00 - 14.20	Answers for S21 GMP Legislation	Interactive review of responses to the exercise	PHG
23	Zoom Classroom	9.35 - 10.30	14.20 - 15.15	QP Release Scenarios	Breakout room exercise	PHG & RSC
		10.30 - 10.45	15.15 - 15.30	Break		
24	Zoom Classroom	10.45 - 11.15	15.30 - 16.00	Imported API Scenarios: QP Requirements and responsibilities	Breakout room exercise	PHG & RSC
25	Zoom Classroom	11.15 - 11.50	16.00 - 16.35	Complaint Scenario	Breakout room exercise	PHG
26	Zoom Classroom	11.50 - 12.20	16.35 - 17.05	Recall Responsibilities exercise	Breakout room exercise	RSC
27	Zoom Classroom	12.20 - 12.30	17.05 - 17.15	Final Questions and Close	Review of Day 2 and plan for Day 3	RSC
28	LMS	40 min.		Role of Pharmacopoeias	Self-paced online slide deck for the delegates to review with voiceover.	DW
29	LMS	90 min.		Data Integrity - Overview and Documentation	eLearning	RSC
30	LMS	120 min.		Data Integrity - Beyond the Basics	eLearning	RSC
DAY 3						
	Zoom Classroom	08.45 - 09.15		Welcome back and summary of topics completed so far	Review Key Learning Points from Day 1 and Plan for Day 2	PHG
31	Zoom Classroom	09.15 - 10.00		Data Integrity exercise		RSC
	Zoom Classroom	10.00 - 10.05		Final Questions and close of NSF sessions		PHG & RSC
		10.05 - 10.15		Break		
	Zoom Classroom	10.15 - 13.15		Norwegian Regulatory Update	Input from Norwegian regulatory authority	