

Week	Date	From	To	Topic	Location	Modus	Lecturer	Exam	Note	Room
17	Friday, 25 April 2025	13:00	13:45	CAS Start		on site	F. Weiss			
				Introduction to the topic						
17	Friday, 25 April 2025	13:45	15:15	Introduction to Regulatory Affairs		on site	O. Ahanor			
17	Friday, 25 April 2025	15:30	18:00	Semester work (Living Case) + Introduction to academic writing		on site	F. Weiss			
				Global Drug Regulatory Affairs						
18	Friday, 02 May 2025	13:00	17:00	Global Drug Regulatory Affairs (1)		hybrid	O. Ahanor			
19	Friday, 09 May 2025	13:00	17:00	Global Drug Regulatory Affairs (2)		hybrid	O. Ahanor			
				Structure and function of Regulatory Bodies / Introduction to EU and CH Regulatory Framework						
20	Friday, 16 May 2025	13:00	16:15	Structure and function of Regulatory Bodies in EU and USA		on site	O. Ahanor			
20	Friday, 16 May 2025	16:15	18:45	Semester work (Living Case): Topic presentations		on site	F. Weiss and possible experts	X		
21	Friday, 23 May 2025	13:00	14:30	Swissmedic		hybrid	Dr. A. Pfenninger			
47	Friday, 23 May 2025	14:30	16:15	Swiss Regulatory Framework		hybrid	N/A			
21	Friday, 23 May 2025	16:15	18:45	Pharmaceutical legislation & regulation		hybrid	N. Müller			
23	Friday, 06 June 2025	13:00	16:15	Introduction to EU Regulatory Framework		hybrid	Dr. M. Ræz			
23	Friday, 06 June 2025	16:15	18:45	Falsified medicines		hybrid	R. Mosimann			
				Scientific Dossier to accompany a MAA						
24	Friday, 13 June 2025	13:00	15:15	Scientific technical writing		hybrid	O. Ahanor			
24	Friday, 13 June 2025	15:15	18:00	Scientific Dossier to accompany a MAA		hybrid	O. Ahanor			
				Interacting with regulators and how to prepare a scientific advice meeting						
25	Friday, 20 June 2025	13:00	15:15	Interacting with regulators		hybrid	O. Ahanor			
25	Friday, 20 June 2025	15:30	18:00	Examples of how to prepare a scientific advice meeting		hybrid	O. Ahanor			
26	Friday, 27 June 2025	13:00	16:15	Patient involvement in the lifecycle of therapeutic products		on site	Prof. Dr. med. C. Sessa			
26	Friday, 27 June 2025	16:15	18:00	Semester work (LC): Review		on site	F. Weiss and possible experts	X		
27	Friday, 04 July 2025	13:00	15:15	Mid-semester exam		on site	F. Weiss	X		
27	Friday, 04 July 2025	15:30	18:45	Pricing and reimbursement + Role of Health Technology Assessment (HTA)		on site	Dr. M. Grämer			
	Summer holidays									
				Regulatory Lifecycle of a Medicinal Product for Human use / Post-Registration Activities						
32	Friday, 08 August 2025	13:00	15:15	Healthcare product lifecycle + post-registration activities		hybrid	Speaker CSL Behring			
32	Friday, 08 August 2025	15:30	17:00	Preclinical studies		hybrid	Dr. L. Fischer			
32	Friday, 08 August 2025	17:00	18:45	Clinical Trial Application (CTA) process in EU		hybrid	Dr. J. Groeger			
33	Friday, 15 August 2025	13:00	14:30	Pharmacovigilance		hybrid	Dr. Th. Stammschulte			
33	Friday, 15 August 2025	14:30	17:00	Pharmacovigilance: Real life examples		hybrid	Dr. A. Panaite			
33	Friday, 15 August 2025	17:15	18:45	Post-approval change management protocol		hybrid	Dr. S. Rohner			
				GxP						
34	Friday, 22 August 2025	13:00	15:15	Good Laboratory Practice (GLP)		hybrid	S. Jalloh			
34	Friday, 22 August 2025	15:30	18:00	Good Manufacturing Practice (GMP)		hybrid	S. Jalloh			
35	Friday, 29 August 2025	13:00	15:15	Good Pharmacovigilance Practice (GVP)		hybrid	S. Jalloh			
35	Friday, 29 August 2025	15:30	18:00	Good Trade and Distribution Practice (GTDP)		hybrid	S. Jalloh			
35	Friday, 29 August 2025	18:00	18:45	GLP examples in Switzerland		hybrid	Dr. L. Fischer			
				Labelling and packaging						
36	Friday, 05 September 2025	13:00	16:15	Labelling		hybrid	C. Meier			
36	Friday, 05 September 2025	16:15	18:45	Packaging (1)		hybrid	C. Carley			
37	Friday, 12 September 2025	13:00	15:15	Packaging (2)		on site	C. Carley			
37	Friday, 12 September 2025	15:15	18:45	Semester work (LC): Final presentation		on site	F. Weiss and possible experts	X		
				New trends and challenges / Product classes with special regulations						
38	Friday, 19 September 2025	13:00	16:15	Real World Evidence (RWE) in Pharma Industry		hybrid	Dr. S. Adam			
38	Friday, 19 September 2025	16:15	18:00	Digital Transformation in Pharma Industry		hybrid	Speaker CSL Behring			
39	Friday, 26 September 2025	13:00	14:30	Human plasma: A special starting material		hybrid	Speaker CSL Behring			
39	Friday, 26 September 2025	14:30	16:15	Advanced Therapies		hybrid	Dr. A. Figueiredo			
39	Friday, 26 September 2025	16:15	17:00	Vaccines		Hybrid	Dr. R. Brandi			
39	Friday, 26 September 2025	17:15	18:00	Recruiting tips & tricks		Hybrid	Speaker CSL Behring			
				End of CAS						
40	Friday, 03 October 2025	13:00	18:45	No classes, latest date for Expert Discussions		hybrid	Experts / F. Weiss	X		