

CAS Regulatory Affairs Pharma

Provisional Timetable Spring Semester 2027

23.07.2026_V0.1_wif1

CW	Date	Time	Modul	Location	Mode	Exam	Lecturer	Lessons	Remarks
18	30.04.2027	13.00–13.45 13.45–15.15 15.30–18.45	Start of the CAS / Organisation Introduction to RA Introduction to academic writing and to the semester work (Living Case)	BFH Biel (SIPBB)	On site		Ogie Ahanor Fabienne Weiss	1 2 4	Introduction to the topic
20	14.05.2027	13.00–14.30 14.30–17.45 18.00–18.45	Falsified medicines Introduction to EU Regulatory Framework Overview of the Regulatory Framework in the UK	BFH Biel (SIPBB)	Hybrid		Ruth Mosimann Dr. Michael Raez Shayni Tharma	2 4 1	Introduction to EU, UK and CH Regulatory Framework
21	21.05.2027	13.00–14.30 14.30–17.45	Structure and function of Swissmedic Swiss Regulatory Framework	BFH Biel (SIPBB)	Hybrid		Dr. Andreas Pfenninger Luzia Rüdlinger	2 3	Structure and function of Regulatory Bodies
22	28.05.2027	13.00–16.15 16.30–19.30	Structure and function of Regulatory Bodies in EU and USA Semester work (LC): Topic presentations	BFH Biel (SIPBB)	Hybrid	X	Ogie Ahanor Fabienne Weiss / Experts	4 4	Structure and function of Regulatory Bodies
23	04.06.2027	13.00–17.00	Global drug regulatory affairs (1)	BFH Biel (SIPBB)	Hybrid		Ogie Ahanor	5	Global drug regulatory affairs
24	11.06.2027	13.00–17.00	Global drug regulatory affairs (2)	BFH Biel (SIPBB)	Hybrid		Ogie Ahanor	5	Global drug regulatory affairs
25	18.06.2027	13.00–15.15 15.30–18.00	Scientific technical writing Scientific Dossier to accompany a MAA	BFH Biel (SIPBB)	Hybrid		Ogie Ahanor	3 3	Scientific Dossier to accompany a MAA
26	25.06.2027	13.00–15.15 15.30–18.00	Interacting with regulators Examples of how to prepare a scientific advice meeting	BFH Biel (SIPBB)	Hybrid		Ogie Ahanor	3 3	Interacting with regulators and how to prepare a scientific advice meeting
27	02.07.2027	13.00–15.15 15.30–18.45	Patient involvement in the lifecycle of therapeutic products Semester work (LC): Review	BFH Biel (SIPBB)	On site	X	Prof. Dr. Cristiana Sessa Chantal Britt Fabienne Weiss Experts	3 4	Interacting with regulators and how to prepare a scientific advice meeting
28	09.07.2027	13.00–14.30 14.30–17.00 17.15–18.00	Mid-semester exam Pricing and reimbursement + Role of HTA Recruiting tips & tricks	BFH Biel (SIPBB)	On site	X	Fabienne Weiss Dr. Muriel Grämer / Dr. Stephanie Vollenweider Thulashiga Kanagalingam	2 3 1	End of the first half of the semester

	12.07.2027–06.08.2027		Summer holidays						
33	13.08.2027	13.00–14.30 14.30–16.15 16.15–17.00 17.15–18.45	CTA process in EU (online) Pharmacovigilance Pharmacovigilance - Real life examples Post-approval change management protocol	BFH Biel (SIPBB)	Hybrid		Dr. Christel Gremion Viatte Dr. Thomas Stammschulte Dr. Adrian Panaite Speaker from CSLB	2 2 1 2	Regulatory Lifecycle of a Medicinal Product for Human Use and Post-Registration Activities
34	20.08.2027	13.00–15.15 15.30–17.00 17.15–18.45	Healthcare product lifecycle + post-registration activities Research ethics Preclinical studies	BFH Biel (SIPBB)	Hybrid		Speaker from CSLB Dr. Salome Adam Dr. Lisa Fischer	3 2 2	Regulatory Lifecycle of a Medicinal Product for Human Use and Post-Registration Activities
35	27.08.2027	13.00–18:00	Packaging	BFH Biel (SIPBB)	Hybrid		Elke Wagner	6	Packaging
36	03.09.2027	13.00–15:15 15.15–18:00	GxP: GLP GxP: GMP	BFH Biel (SIPBB)	Hybrid		Salieu Jalloh	3 3	GxP
36	10.09.2027	13.00–15.15 15.30–18.00	GxP: GVP GxP: GDP	BFH Biel (SIPBB)	Hybrid		Salieu Jalloh	3 3	GxP
38	17.09.2027	13.30–15.15 15.30–19.20 19.20–20.00	Labelling Semester work (LC): Final presentations Networking Apéro	BFH Biel (SIPBB)	On site	X	Salieu Jalloh Fabienne Weiss / Experts	3 5	Labelling
39	24.09.2027	13.00–16.15 16.15–18.00	Real World Evidence Digital transformation in pharma industry	BFH Biel (SIPBB)	Hybrid		Dr. Salome Adam Ogie Ahanor Dr. Nicolas Löffler-Pérez	4 2	New trends and challenges + Product classes with special regulations
40	01.10.2027	13.00–14.30 14.30–16.15 16.15–17.00	Human plasma: A special starting material Advanced Therapies Vaccines	BFH Biel (SIPBB)	Hybrid		Speaker from CSLB Dr. Ana Figueiredo Dr. Raffaella Brandi	2 2 1	New trends and challenges + Product classes with special regulations
41	08.10.2027	13.00–19.30	Reserve date, latest date for Expert Discussions		Hybrid	X			End of the CAS

Kontakt

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