

CAS Regulatory Affairs Pharma

Timetable Spring Semester 2026

25.11.2025_wif1 / provisional planning

CW	Date	Time	Modul	Location	Mode	Exam	Lecturer	Lessons	Remarks
17	24.04.2026	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		Fabienne Weiss	1 2 4	Introduction to the topic
18	01.05.2026	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
19	08.05.2026	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 4	Structure and function of Regulatory Bodies
21	22.05.2026	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 Exerts	4 4	Structure and function of Regulatory Bodies
22	29.05.2026	13.00–17.00	Global drug regulatory affairs (1)	BFH Biel (SIPBB)	Hybrid		Ogie Ahanor	5	Global drug regulatory affairs
23	05.06.2026	13.00–17.00	Global drug regulatory affairs (2)	BFH Biel (SIPBB)	Hybrid		Ogie Ahanor	5	Global drug regulatory affairs
24	12.06.2026	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
25	19.06.2026	13.00–15.15 15.30–18.00	Interacting with regulators Examples of how to prepare a scientific advise meeting	BFH Biel (SIPBB)	Hybrid		Ogie Ahanor	3 3	Interacting with regulators and how to prepare a scientific advice meeting
26	26.06.2026	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
26	03.07.2026	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. Natalya Izergina	2 3 1	End of the first half of the semester

	06.07.2026– 03.08.2026		Summer holidays						
32	07.08.2026	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		Francesca Borraccia Dr. Salome Adam Dr. Lisa Fischer	3 2 2	Regulatory Lifecycle of a Medicinal Product for Human Use and Post- Registration Activities
33	14.08.2026	13.00–14.30 14.30–16.15 16.15–17.00 17.15–18.45	CTA process in EU Pharmacovigilance Pharmacovigilance - Real life examples Post-approval change management protocol	BFH Biel (SIPBB)	Hybrid		Dr. Rita Alves-Baptista Dr. Thomas Stammschulte Dr. Adrian Panaite Dr. Sabine Rohner	2 2 1 2	Regulatory Lifecycle of a Medicinal Product for Human Use and Post- Registration Activities
34	21.08.2026	13.00–15.15 15.30–18.00	GxP: GLP GxP: GMP	BFH Biel (SIPBB)	Hybrid		Salieu Jalloh	3 3	GxP
35	28.08.2026	13.00–15:15 15.15–18:00	GxP: GVP GxP: GDP	BFH Biel (SIPBB)	Hybrid		Dr. Lisa Fischer Salieu Jalloh	1 3 3	GxP
36	04.09.2026	13.00–16.15 16.15–18.45	Labelling Packaging (1)	BFH Biel (SIPBB)	Hybrid		Corinne Meier Elke Wagner	4 3	Labelling and packaging
37	11.09.2026	13.00–15.15 15.30–18.45	Packaging (2) Semester work (LC): Final presentations	BFH Biel (SIPBB)	On site	X	Elke Wagner Fabienne Weiss Experts	3 4	Labelling and packaging
38	18.09.2026	13.00–16.15 16.15–18.00	Real World Evidence Digital transformation in pharma industry	BFH Biel (SIPBB)	Hybrid		Dr. Salome Adam Luis Miranda Dr. Nicolas Löffler-Pérez	4 2	New trends and challenges + Product classes with special regulations
39	25.09.2026	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		Dr. Gaelle Michaud Dr. Ana Figueiredo Dr. Raffaella Brandi	2 2 1	New trends and challenges + Product classes with special regulations
40	02.10.2026	13.00–19.30	Reserve date, latest date for Expert Discussions		Hybrid	X			End of the CAS
33									

Kontakt

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