

CAS Regulatory Affairs Pharma

Timetable spring semester 2026

provisional, 04.07.25

Introduction to the topic

Week	Date	Time	Module	Location	Mode	Exam	Lessons	Remarks
17	Friday, 24 April 2026	13.00-13.45	Start of CAS / Organisation	Biel	On site		1	
17	Friday, 24 April 2026	13.45-15.15	Introduction to RA	Biel	On site		2	
17	Friday, 25 April 2025	15.30-18.45	Introduction to academic writing and to the semester work (Living Case)	Biel	On site		4	

Global drug regulatory affairs

Week	Date	Time	Module	Location	Mode	Exam	Lessons	Remarks
18	Friday, 02 May 2025	13.00-17.00	Global drug regulatory affairs (1)	Biel	Hybrid		5	
18	Friday, 02 May 2025	17.15-18.45	Falsified medicines	Biel	Hybrid		2	
19	Friday, 08 May 2026	13.30-17.00	Global drug regulatory affairs (2)	Biel	Hybrid		5	

Structure and function of Regulatory Bodies / Introduction to EU, UK and CH Regulatory Framework

Week	Date	Time	Module	Location	Mode	Exam	Lessons	Remarks
20	Friday, 15 May 2026	13.00-16.15	Structure and function of Regulatory Bodies in EU and USA	Biel	Hybrid		4	
20	Friday, 15 May 2026	16.15-18.45	Semester work (LC): Topic presentations	Biel	Hybrid	x	3	
21	Friday, 22 May 2026	13.00-14.30	Structure and function of Swissmedic	Biel	Hybrid		2	
21	Friday, 22 May 2026	14:30-18.45	Swiss Regulatory Framework	Biel	Hybrid		5	
23	Friday, 05 June 2026	13.00-16:15	Introduction to EU Regulatory Framework	Biel	Hybrid		4	
23	Friday, 05 June 2026	16:15-17:00	Overview of the Regulatory Framework in the UK	Biel	Hybrid		1	The lecturer is connected online

Bioprinciples (not mandatory, advance reservation required)

Week	Date	Time	Module	Location	Mode	Exam	Lessons	Remarks
22	Wednesday, 27 May 2026	13.00-17.00	Basics of the life cycle and bioinformatics	Biel	Hybrid		5	
24	Wednesday, 10 June 2026	13:00-16:15	Pharmacogenetics	Biel	Hybrid		4	
25	Wednesday, 17 June 2026	13:00-16:15	Nanotechnology in Medicine	Biel	Hybrid		4	

Scientific Dossier to accompany a MAA

Week	Date	Time	Module	Location	Mode	Exam	Lessons	Remarks
24	Friday, 12 June 2026	13.00-15.15	Scientific technical writing	Biel	Hybrid		3	
24	Friday, 12 June 2026	15.30-18.00	Scientific Dossier to accompany a MAA	Biel	Hybrid		3	

Interacting with regulators and how to prepare a scientific advice meeting

Week	Date	Time	Module	Location	Mode	Exam	Lessons	Remarks
25	Friday, 19 June 2026	13.00-15.15	Interacting with regulators	Biel	Hybrid		3	
25	Friday, 19 June 2026	15.30-18.00	Examples of how to prepare a scientific advise meeting	Biel	Hybrid		3	
25	Friday, 19 June 2026	13.00-15.15	Patient involvement in the lifecycle of therapeutic products	Biel	Hybrid		3	
26	Friday, 26 June 2026	15.30-18.45	Semester work (LC): Review	Biel	Hybrid	x	4	

End of the first half of the semester

Week	Date	Time	Module	Location	Mode	Exam	Lessons	Remarks
27	Friday, 03 July 2026	13.00-14.30	Mid-semester exam	Biel	Remote	x	2	
27	Friday, 03 July 2026	14.30-17.00	Pricing and reimbursement + Role of HTA	Biel	Remote		3	
27	Friday, 03 July 2026	17.15-18.00	Recruiting tips & tricks	Biel	Remote		1	The lecturer is connected online

Regulatory Lifecycle of a Medicinal Product for Human Use and Post-Registration Activities

Week	Date	Time	Module	Location	Mode	Exam	Lessons	Remarks
32	Friday, 07 August 2026	13.00-15.15	Healthcare product lifecycle + post-registration activities	Biel	Remote		3	
32	Friday, 07 August 2026	15.30-17.00	Research ethics	Biel	Remote		2	
32	Friday, 07 August 2026	17.15-18.45	Preclinical studies	Biel	Remote		2	
33	Friday, 14 August 2026	13.00-14.30	CTA process in EU	Biel	Hybrid		2	
33	Friday, 14 August 2026	14.30-16.15	Pharmacovigilance	Biel	Hybrid		2	
33	Friday, 14 August 2026	16.15-17.00	Pharmacovigilance - Real life examples	Biel	Hybrid		1	
33	Friday, 14 August 2026	17.15-18.45	Post-approval change management protocol	Biel	Hybrid		2	

GxP

Week	Date	Time	Module	Location	Mode	Exam	Lessons	Remarks
34	Friday, 21 August 2026	13.00-15.15	GxP: GLP	Biel	Hybrid		3	
34	Friday, 21 August 2026	15.30-18.00	GxP: GMP	Biel	Hybrid		3	
35	Friday, 28 August 2026	13.00-13.45	GLP examples in CH	Biel	Hybrid		1	The lecturer is connected online
35	Friday, 28 August 2026	13.45-16.15	GxP: GVP	Biel	Hybrid		3	
35	Friday, 28 August 2026	16.15-18.45	GxP: GDP	Biel	Hybrid		3	

Labelling and packaging

Week	Date	Time	Module	Location	Mode	Exam	Lessons	Remarks
36	Friday, 04 September 2026	13.00-16.15	Labelling	Biel	Hybrid		4	
36	Friday, 04 September 2026	16.15-18.45	Packaging (1)	Biel	Hybrid		3	The lecturer is connected online
37	Friday, 11 September 2026	13.00-15.15	Packaging (2)	Biel	Hybrid		3	

37	Friday, 11 September 2026	15.30-18.45	Semester work (LC): Final presentations	Biel	Hybrid	x	4	
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New trends and challenges + Product classes with special regulations

Week	Date	Time	Module	Location	Mode	Exam	Lessons	Remarks
38	Friday, 18 September 2026	13.00-16.15	Real World Evidence	Biel	Hybrid		4	
38	Friday, 18 September 2026	16.15-18.00	Digital transformation in pharma industry	Biel	Hybrid		2	The lecturers are connected online
39	Friday, 25 September 2026	13.00-14.30	Human plasma: A special starting material	Biel	Hybrid		2	
39	Friday, 25 September 2026	14.30-16.15	Advanced Therapies	Biel	Hybrid		2	
39	Friday, 25 September 2026	16.15-17.00	Vaccines	Biel	Hybrid		1	

End of CAS

Week	Date	Time	Module	Location	Mode	Exam	Lessons	Remarks
40	Friday, 02 October 2026	13.00-18.45	Reserve date, latest date for Expert Discussion	Biel	Hybrid	x	7	

Contact

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