



Berner  
Fachhochschule

## Datasheet CAS Regulatory Affairs in Life Sciences

Autumn 2024  
Provisorische Planung  
06.06.2024

Week	Date	From	To	Topic	Location	Modus	Lecturer	Exam	Note	Room
43	Friday, 25 October 2024	13:00	14:30	CAS Start	Biel		F. Weiss			
				Overview Regulations						
44	Sunday, 27 October 2024	14:30	18:00	Regulations of Nanotechnology in Medicine	Biel					
44	Friday, 01 November 2024	13:00	15:15	Introduction to MDR						
44	Friday, 01 November 2024	15:30	18:00	Swiss Regulations (national specificities)						
45	Friday, 08 November 2024	13:00	18:00	Introduction to IVDR	Biel					
46	Friday, 15 November 2024	13:00	18:00	International Regulations	Biel					
47	Friday, 22 November 2024	13:00	15:15	Introduction to GDPR	Biel					
47	Friday, 22 November 2024	15:30	18:00	Living Case: Einführung	Biel					
47	Friday, 22 November 2024	08:00	12:00	Reserve date	Biel					
				Quality and risk management						
48	Friday, 29 November 2024	13:00	18:45	Risk management for medical products	Biel					
49	Friday, 06 December 2024	13:00	16:15	QMS ISO 13485	Biel					
49	Friday, 06 December 2024	16:15	18:45	Documentation	Biel					
50	Friday, 13 December 2024	13:00	15:15	Biomaterials and Biocompatibility	Biel					
50	Friday, 13 December 2024	15:30	18:45	Biological evaluation of medical devices ISO 10993	Biel					
51	Friday, 20 December 2024	13:00	16:15	Clinical risk management	Biel					
51	Friday, 20 December 2024	16:15	18:45	Living Case: Presentation of topic proposals	Biel					
51	Friday, 20 December 2024	08:00	12:00	Reserve date						
3	Friday, 17 January 2025	13:00	18:45	Exams and CAS-Feedback and possibly a special event	Biel			X		
				Product engineering						
3		13:00	18:45	Software lifecycle of a medical device IEC 62304	Biel					
4	Friday, 24 January 2025	13:00	18:45	Product Engineering - practical implementation	Biel					
5	Friday, 31 January 2025	13:00	16:15	Product Engineering - practical implementation	Biel					
5	Friday, 31 January 2025	16:15	18:45	Desing Control for Combination Products	Biel					
6	Friday, 07 February 2025	13:00	17:00	Packaging and Labeling	Biel					
6	Friday, 07 February 2025	17:15	18:45	Living Case: Review	Biel					
6	Friday, 07 February 2025	08:00	12:00	Reserve date	Biel					
7	Friday, 14 February 2025	13:00	17:00	From the requirement to the desing transfer	Biel					
7	Friday, 14 February 2025	17:15	18:45	Software as a Medical Device	Biel					
8	Friday, 21 February 2025	13:00	17:00	From desing transfer to phase-out	Biel					
8	Friday, 21 February 2025	08:00	12:00	Reserve date	Biel					
				Validation and operation						
9	Friday, 28 February 2025	15:30	18:45	Computer System Validation						
6	Friday, 07 February 2025	13:00	15:15	Clinical evaluation	Biel					
6	Friday, 07 February 2025	15:30	18:00	Regulations: Implementation in the market (Vigilance)	Biel					
11	Friday, 14 March 2025	13:00	18:00	Global RA strategy	Biel					
11	Friday, 14 March 2025	08:00	12:00	Reserve date	Biel					
12	Friday, 21 March 2025	13:00	18:45	Living Case: Final Presentations	Biel			X		
14	Friday, 04 April 2025	13:00	18:45	Exams and CAS-Feedback	Biel			X		