



Berner  
Fachhochschule

## Datasheet CAS Regulatory Affairs in Life Sciences

Autumn 2024  
Definitive planning  
22.07.2024

Week	Date	From	To	Topic	Location	Modus	Lecturer	Exam	Note
43	Friday, 25 October 2024	13:00	13:45	CAS Start	Biel	on site	F. Weiss / M. Patwa		
				<b>Overview Regulations</b>					
43	Friday, 25 October 2024	13:45	16:15	Introduction to the MDR	Biel	hybrid	Dr. A. Tican		
43	Friday, 25 October 2024	16:15	18:45	Introduction to the GDPR	Biel	hybrid	M. Künzi		
44	Friday, 01 November 2024	13:00	18:00	Introduction to the IVDR	Biel	hybrid	S. Soniec / M. Eng		
44	Friday, 01 November 2024	18:00	18:45	Living Case: Introduction	Biel	hybrid	F. Weiss		
45	Friday, 08 November 2024	13:00	18:00	Swiss Regulations	Biel	hybrid	H. Klöss		
46	Friday, 15 November 2024	13:00	18:00	International Regulations	Biel	hybrid	S. Item		
47	Friday, 22 November 2024	13:00	18:00	Global RA strategy	Biel	hybrid	M. Maier		
48	Friday, 29 November 2024	13:00	18:00	Reserve date / Living Case: Submission of topic proposal					
49	Friday, 06 December 2024	13:00	16:15	Regulations of Nanotechnology in Medicine	Biel	on site	Dr. T. Matter		
49	Friday, 06 December 2024	16:15	18:45	Living Case: Topic presentations	Biel	on site	Experts / F. Weiss	X	
				<b>Quality and Risk Management</b>					
50	Friday, 13 December 2024	13:00	18:45	Risk management for medical products	Biel	hybrid	S. Gelebek		
51	Friday, 20 December 2024	13:00	16:15	QMS ISO 13485	Biel	hybrid	S. Gelebek		
51	Friday, 20 December 2024	16:15	18:45	Clinical evaluation	Biel	hybrid	Dr. med. K. Friedrich		
52	Friday, 27 December 2024			Ferien (Weihnachten/Neujahr)					
1	Friday, 03 January 2025			Ferien (Weihnachten/Neujahr)					
2	Friday, 10 January 2025	13:00	16:15	Clinical Risk Management	Biel	hybrid	N/A		
2	Friday, 10 January 2025	16:15	18:45	Documentation	Biel	hybrid	M. Angst		
3	Friday, 17 January 2025	13:00	15:15	Biomaterials and Biocompatibility	Biel	hybrid	Dr. R. Lerf		
3	Friday, 17 January 2025	15:30	18:45	Biological evaluation of medical devices ISO 10993	Biel	hybrid	N. Schwarz		
4	Friday, 24 January 2025	13:00	17:00	Medical device audits	Biel	on site	H. Klöss		
4	Friday, 24 January 2025	17:15	19:30	Living Case: Review	Biel	on site	Experts / F. Weiss	X	
5	Friday, 31 January 2025	13:00	15:15	Exam / CAS Feedback	Biel	on site	F. Weiss	X	Mid-semester exam, multiple choice
				<b>Product engineering</b>					
6	Friday, 07 February 2025	13:00	17:00	Software lifecycle of a medical device IEC 62304		remote	E. Studer		
6	Friday, 07 February 2025	17:15	18:45	Software as a Medical Device		remote	E. Studer		
7	Friday, 14 February 2025	09:00	13:45	From requirements to design transfer	Biel	hybrid	B. Steffen		
7	Friday, 14 February 2025	13:45	17:00	From design transfer to phase-out	Biel	hybrid	M. Angst		
8	Friday, 21 February 2025	13:00	18:00	Product Engineering - practical implementation	Biel	hybrid	M. Krieffewirth		
9	Friday, 28 February 2025	13:00	17:00	Product Engineering - practical implementation	Biel	hybrid	M. Krieffewirth		
10	Friday, 07 March 2025	13:00	17:00	Packaging and Labelling	Biel	hybrid	L. Stehling		
10	Friday, 07 March 2025	17:15	19:30	Design Control for Combination Products	Biel	hybrid	M. Krieffewirth		
				<b>Validation and Operation and Cybersecurity in Life Sciences</b>					
11	Friday, 14 March 2025	13:00	16:15	Computer System Validation		remote	E. Studer		
11	Friday, 14 March 2025	16:15	19:30	Digitalization and Cybersecurity in Life Sciences		remote	Dr. L. Naber / Dr. A. Tigan / M. Eng		
12	Friday, 21 March 2025	13:00	15:15	Regulations: Implementation in the market (vigilance)		remote	M. Maier		

12	Friday, 21 March 2025	15:30	19:30	Digitalization and Cybersecurity in Life Sciences		remote	Dr. L. Naber / Dr. A. Tigan / M. Eng		
				<b>End of the CAS</b>					
13	Friday, 28 March 2025	13:00	18:45	Living Case: Final presentations and Apéro	Biel	on site	Experts / F. Weiss	X	
14	Friday, 04 April 2025	13:00	18:45	Expert Discussion	Biel	Hybrid	Experts / F. Weiss	X	In the Expert Discussion, selected aspects of the semester project (Living Case) are discussed and justified by the students using arguments and the specialist knowledge acquired in the CAS.

**Optional courses**

<b>Statistics</b>									
2	Friday, 10 January 2025	09:00	12:00	Introduction to statistics and research design	Biel	hybrid	Chr. Lesimple		
3	Friday, 17 January 2025	09:00	12:00	Regulatory requirements	Biel	hybrid	Chr. Lesimple		
4	Friday, 24 January 2025	09:00	12:00	Practical consideration	Biel	hybrid	Chr. Lesimple		
<b>Regulatory requirements for medical devices in USA</b>									
3	Wednesday, 15 January 2025	13:00	16:15	Overview of US Market Access, Regulation, and Compliance for Medical Device	Biel	hybrid	V. Shcherba		
4	Wednesday, 22 January 2025	13:00	16:15	Fundamentals of FDA Premarket Submission	Biel	hybrid	V. Shcherba		
5	Wednesday, 29 January 2025	13:00	16:15	U.S. Quality Management System Requirements	Biel	Hybrid	V. Shcherba		
6	Wednesday, 05 February 2025	13:00	16:15	FDA Inspection and Market Protection	Biel	hybrid	V. Shcherba		