Swissmedic Regulatory Training, Fall 2026
AGENDA

Module 3 Authorisations

Day 2: Tuesday, 3 November 2026 Room H044

Time	*Topic*	*Speaker / Moderator*
09:15	**Start Day 2** **Departure Shuttle** from Hotel Ibis Styles =>Facility Hallerstrasse	Stefania Camerata *Assistant SHE*
09:30–10:30	**Marketing Authorisation and Regulatory Management** • Introduction Marketing Authorisation • Processes incl. risk-based approaches and reliance • Swiss Medical Expert committee • Benchmarking	Rosa Stebler *Deputy Head of Division, Regulatory Operations and Development* Gierin Thomi *Responsible for Expert Affairs*
10:30–11:00	**Coffee break**	
11:00–12:00	**Marketing Authorisation and Regulatory Management** (continued) Q&A / Discussion	
12:00–13:00	**Lunch @ Facility Hallerstrasse**	
13:00–14:30	Introduction **Regulatory Assessment**	Sandra Zaugg *Head of Division Regulatory Assessment*
14:30–15:00	**Coffee break**	
15:00–16:00	**Introduction to Clinical Study Assessment**	Kirsten Leidreiter *Head Clinical Study Assessment*
16:30	**Social Event (on site)**	
18:00	**Departure Shuttle** from Facility Hallerstrasse= Hotel Ibis Styles	
	End of Day 2	

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Day 3: Wednesday, 4 November 2026 Room H047

Time	*Topic*	*Speaker / Moderator*
08:40	**Start Day 3** **Departure Shuttle** from Hotel Ibis Styles =>Facility Hallerstrasse	Stefania Camerata *Assistant SHE*
09:00–10:30	Introduction **Non-Clinical Assessment**	Elisabeth Klenke *Head of Division Non-Clinical Assessment*
10:30–10:45	**Coffee break**	
10:45–12:30	Introduction **Clinical Assessment** (Part 1) Generics	Arno Nolting *Senior Clinical Pharmacology Assessor* Andrea Villiger *Clinical Pharmacology Assessor*
12:30–13:30	**Lunch @ Facility Hallerstrasse**	
13:30–15:00	Introduction **Clinical Assessment** (Part 2) Case study: Step-by-step assessment report template	Jan Wagner *Senior Clinical Assessor* Alain Bizzini *Clinical Assessor*
15:00–15:15	**Coffee break**	
15:15–16:30	Introduction **Quality Assessment** MA Procedures for **Biosimilar Applications** in Switzerland	Lisa Eisenbeiss *Senior Quality Assessor* Pascal Crottet *Quality Assessor*
16:45	**Departure Shuttle** from Facility Hallerstrasse= Hotel Ibis Styles	
	End of Day 3	

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Day 4: Thursday, 5 November 2026 Room H045

Time	*Topic*	*Speaker / Moderator*
08:40	**Start Day 4** **Departure Shuttle** from Hotel Ibis Styles =>Facility Hallerstrasse	Stefania Camerata *Assistant SHE*
09:00–10:00	Introduction to **Advanced Therapeutic Medicinal Products** - General information ATMPs - Requirements on documentation for MA	Andreas Marti *Senior Nonclinical Assessor*
10:00–10:30	**Coffee break**	
10:30–12:00	Swissmedic collaborative **Marketing Authorisation and Scientific Advice Procedure** for Global Health products (MAGHP/SAGHP)	Lodovico Paganini *Deputy Head Stakeholder Engagement*
12:00–13:30	**Lunch @ Facility Freiburgstrasse**	
	Optional program in the afternoon: - Participation in session on MD (Modul 4) - Preparation of country presentation - Individual study time (room F036)	
16:45	**Departure Shuttle** from Facility Hallerstrasse= Hotel Ibis Styles	
	End of Day 4	