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Swissmedic Regulatory Training, Fall 2026
AGENDA

Module 4 Surveillance and Vigilance

Day 2, Tuesday, 3 November 2026 Room H046

Time	*Topic*	*Speaker / Moderator*
09:15	**Start Day 2** **Departure Shuttle** from Hotel Ibis Styles =>Facility Hallerstrasse	Stefania Camerata *Assistant SHE*
09:30–09:45	Welcome and Introduction to Market surveillance	Christoph Küng *Head of Division Safety of Medicines*
09:45–10:15	Introduction Safety of Medicines / Pharmacovigilance	Christoph Küng *Head of Division Safety of Medicines*
10:15–10:30	**Coffee break**	
10:30–11:30	The Swiss Reporting System	Thomas Stammschulte *Deputy Head Division Safety of Medicines*
11:30–12:30	Swiss National Database: Medango	Irene Scholz *Senior Vigilance Assessor*
12:30–13:30	**Lunch @ Facility Hallerstrasse**	
13:30–15:00	Market control of Medicines (quality deficiencies handling) Control of Illegal Medicines on the Swiss market	Susanne Wegenast *Head of Division Market Monitoring of Medicines* Myrtha Näf *Scientific Officer Unit Control of Illegal Medicines*
15:00–15:30	**Coffee break**	
15:30–16:30	Market control continued Q&A / Discussion	Susanne Wegenast *Head of Division Market Monitoring of Medicines* Myrtha Näf *Scientific Officer Unit Control of Illegal Medicines*
16:30	**Social Event (on site)**	
18:00	**Departure Shuttle** from Facility Hallerstrasse= Hotel Ibis Styles	
	End of Day 2	

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Module 4 Surveillance and Vigilance

Day 3: Wednesday, 4 November 2026 Room H046

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	Risk Management • RMP Evaluation • PSUR Evaluation	Stephanie Storre *Head of Unit Risk Management* Nora Ruef *Senior Vigilance Assessor, Risk Management*
10:30–10:45	**Coffee break**	
10:45–11:30	Signal management	Giulia Paternoster *Vigilance Assessor, Risk Management*
11:30–12:30	Blood Surveillance incl. Q/A	Julia Engels *Vigilance Assessor*
12:30–13:30	**Lunch @ Facility Hallerstrasse**	
13:30–14:30	Pharmacovigilance Inspections	Adisa Cokoja *Senior inspector GCP/GVP Inspectorate, Division Clinical Trials*
14:30–15:00	Q/A on PV and Risk Management	All
15:00–15:15	**Coffee break**	
15:15–16:30	Signal detection and management in pharmacovigilance	Valeriu Toma *Vigilance Assessor / Deputy Head Unit Pharmacovigilance*
16:45	**Departure Shuttle** from Facility Hallerstrasse= Hotel Ibis Styles	
	End of Day 3	

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Module 4 Medical Devices - Surveillance and Vigilance

Day 4: Thursday, 5 November 2026 Room H044

Time	*Topic*	*Speaker / Moderator*
08:40	**Start Day 4** **Departure Shuttle** from Hotel Ibis Styles =>Facility Hallerstrasse	Stefania Camerata *Assistant SHE*
9:00–9:30	General Introduction to Market Surveillance of **Medical Devices**	Markus Wälti *Head of Division Medical Devices Vigilance*
9:30–10:00	International networking and collaboration	Markus Wälti *Head of Division Medical Devices Vigilance*
10:00–10:30	**Coffee break**	
10:30- 11:30	Clinical Trials of MDs	Yvonne Naegelin *Head MD Clinical Investigations*
11:30–12:15	MD Operations & Development	Sébastian Lerch *Head of Unit MD Operations & Development*
12:15–13:30	**Lunch @ Facility Hallerstrasse**	
13:30 – 14:30	MD Vigilance	Sandra Tanner *Scientific Officer MD Vigilance*
14:30 – 15:30	Market Surveillance of MDs	Elly Gysels *Inspector MD Surveillance*
15:30 – 16:30	Hospital Inspections	Yannick Bohren *Inspector MD Hospitals*
16:45	**Departure Shuttle** from Facility Hallerstrasse= Hotel Ibis Styles	
	End of Day 4	