

Agenda GMP Training 2025

Manufacture and controls of biologicals (application of PIC/S Annex 2b, EudraLex Annex 2)

20-21 May 2025, Hotel Banana City, Winterthur, Switzerland

Day 1: Tuesday, 20 May 2025

<i>Time</i>	<i>Topics</i>	<i>Speakers/Moderators</i>
09:00	Registration	
09:30	Welcome address	
	Introduction of the topic	Barbara Herzog Swissmedic
09:45	Introduction into PIC/S Annex 2b/EMA Annex 2 Biologicals	tbd
10:15	Zone concept/monitoring and application of Annex 1 for biologics	tbd
11:00	Coffee break (Hotel Banana City)	
11:30	How to inspect application of Annex 1 for Biologicals?	tbd
12:30	Lunch (Hotel Banana City)	
14:00	Contamination Control in Biotech Manufacture	Christina Meissner AGES Austrian Agency for Health and Food Safety
14:45	Part 1: Q&A of Annex 2B	Swissmedic
15:30	Coffee break (Hotel Belvedere, Locarno)	
16:00	Industry move to introduction of 'non-classified production areas' for Drug Substance (DS) Facilities Case study concerning Burkholderia cepacia complex (BCC) contamination events	Catherine Neary HPRA, Health Products Regulatory Authority, Ireland
17:00	Part 2: Q&A of Annex 2B	Swissmedic
17:30	End of day 1	
	All participants are kindly invited for dinner	
18:30	Meeting at Restaurant STRAUSS Restaurant STRAUSS Stadthausstrasse 8, Winterthur	

Day 2: Wednesday, 21 May 2025

<i>Time</i>	<i>Topics</i>	<i>Speakers/Moderators</i>
09:00	<p>Workshops 1st run</p> <p><i>Examples from real inspections and lessons learned</i></p> <ul style="list-style-type: none"> • Workshop 1: Practical Examples of Contamination Control in Biotech Manufacture • Workshop 2: Implementation of Annex 1 in biologicals • Workshop 3: Q&A Annex 2B 	<p>Christina Meissner Moderator Workshop 1</p> <p>Catherine Neary Moderator Workshop 2</p> <p>Swissmedic Moderator Workshop 3</p>
10:00	Coffee break (Hotel Banana City)	
10.30	<p>Workshops 2nd run</p> <p><i>Examples from real inspections and lessons learned</i></p> <ul style="list-style-type: none"> • Workshop 1: Practical Examples of Contamination Control in Biotech Manufacture • Workshop 2: Implementation of Annex 1 in biologicals • Workshop 3: Q&A Annex 2B 	<p>Christina Meissner Moderator Workshop 1</p> <p>Catherine Neary Moderator Workshop 2</p> <p>Swissmedic Moderator Workshop 3</p>
11:30	<i>tbd</i>	
12:00	Lunch (Hotel Banana City)	
13:30	<p>Workshops 3rd</p> <p><i>Examples from real inspections and lessons learned</i></p> <ul style="list-style-type: none"> • Workshop 1: Practical Examples of Contamination Control in Biotech Manufacture • Workshop 2: Implementation of Annex 1 in biologicals • Workshop 3: Q&A Annex 2B 	<p>Christina Meissner Moderator Workshop 1</p> <p>Catherine Neary Moderators Workshop 2</p> <p>Swissmedic Moderator Workshop 3</p>
14:30	Annex 1 and ATMPs – Developments in the EU	Christina Meissner
15:00	Coffee break (Hotel Belvedere, Locarno)	
15:30	Workshop summary 1-3: presentation and discussion	Workshop moderators and participants
16:30	Closing	Swissmedic
16:45	End of Training	