

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

Time	Topics	Speakers/Moderators
08:45	Registration & Welcome Coffee “Festsaal”, next to the Hotel	
09:30	Welcome address	
	Introduction of the topic	Barbara Herzog Swissmedic
09:45	Introduction into PIC/S Annex 2b/EMA Annex 2 Biologicals	Kevin Bailey MHRA
10:30	Risk Management for Biological Drug Substance: Contamination Control Essentials <ul style="list-style-type: none"> Discuss how principles of Annex 1 can provide a robust framework for ensuring quality and supply continuity Use of technologies and manufacturing strategies that mitigate contamination risk Identify topics for discussion during a Q&A session that enables mutual understanding of technical challenges 	David Churchward Astra Zeneca, Head of Operations Quality, Compliance and External Affairs
11:30	Coffee break Hotel Banana City	
12:00	Application of Annex 2B in the industry: real case from industry New IMP plant: challenges, during planning and implementation with regards to Annex 2B	Marion Quartier Merck Biotech Development Center
13:00	Lunch Hotel Banana City	
14:30	Zone concept/monitoring and application of Annex 1 for biologics Cleanroom classifications – application of particulate & microbial contamination limits for the relevant grades, certification & qualification of cleanrooms/HVACs, application of appropriate environmental controls and monitoring and clothing requirements for the relevant cleanliness grades etc.	Catherine Neary HPRA, Health Products Regulatory Authority, Ireland
15:30	Coffee break Hotel Banana City	
16:00	Contamination Control in Biotech Manufacture Potential contaminations incl. microbiology and adventitious agents, CCS, pre and post viral clearance, Material and personal flow	Christina Meissner AGES Austrian Agency for Health and Food Safety
16:45	Annex 2B, Q&A	Franziska Isler & François Pinsard Swissmedic
17:30	End of day 1	
18:30	All participants are kindly invited for dinner 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	Workshops 1st run <i>Examples from real inspections and lessons learned</i> <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: Process Pool Holdtimes during Biological Manufacturing Processes 	Christina Meissner & Kevin Bailey Moderators Workshop 1 Catherine Neary Moderator Workshop 2 Paula Walser & Nicole Löffelholz , Swissmedic Moderators Workshop 3
10:15	Coffee break Hotel Banana City	
10.45	Workshops 2nd run <i>Examples from real inspections and lessons learned</i> <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: Process Pool Holdtimes during Biological Manufacturing Processes 	Christina Meissner & Kevin Bailey Moderators Workshop 1 Catherine Neary Moderator Workshop 2 Paula Walser & Nicole Löffelholz , Swissmedic Moderators Workshop 3
12:00	Lunch Hotel Banana City	
13:30	Workshops 3rd <i>Examples from real inspections and lessons learned</i> <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: Process Pool Holdtimes during Biological Manufacturing Processes 	Christina Meissner & Kevin Bailey Moderators Workshop 1 Catherine Neary Moderators Workshop 2 Paula Walser & Nicole Löffelholz , Swissmedic Moderators Workshop 3
14:45	Annex 1 and ATMPs – Developments in the EU	Christina Meissner
15:15	Coffee break Hotel Banana City	
15:45	Workshop summary 1-3: presentation and discussion	Workshop moderators and participants
16:45	Closing & End of Training	Swissmedic