

## 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**

<b>Time</b>	<b>Topics</b>	<b>Speakers/Moderators</b>
09:00	<b>Registration</b>	
09:30	<b>Welcome address</b>	
	<b>Introduction of the topic</b>	<b>Barbara Herzog</b> Swissmedic
09:45	<b>Introduction into PIC/S Annex 2b/EMA Annex 2 Biologicals</b>	<b>Kevin Bailey</b> MHRA
10:30	<b>“Bio Break”</b>	
10:45	<b>Zone concept, CCS, SUS from the Industry perspective</b>	<b>David Churchward</b> Astra Zeneca
11:45	<b>“Bio Break”</b>	
12:00	<b>Application of Annex 2B in the industry: real case</b>	<b>Marion Quartier</b> Merck Biotech Development Center
12:45	<b>Lunch</b> (Hotel Banana City)	
14:00	<b>Contamination Control in Biotech Manufacture</b>	<b>Christina Meissner</b> AGES Austrian Agency for Health and Food Safety
14:45	tbd	
15:30	<b>Coffee break</b> (Hotel Banana City)	
16:00	<b>Zone concept/monitoring and application of Annex 1 for biologics</b> 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.	<b>Catherine Neary</b> HPRA, Health Products Regulatory Authority, Ireland
17:00	Risk Management and Annex 2B	<b>Swissmedic</b>
17:30	<b>End of day 1</b>	
	<b>All participants are kindly invited for dinner</b>	
18:30	<b>Meeting at Restaurant STRAUSS</b> Restaurant STRAUSS Stadthausstrasse 8, Winterthur	

## Day 2: Wednesday, 21 May 2025

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