Agenda

Monday, 12 June 2023		
11:00	Reception and Welcome Coffee	
11:30	INTRODUCTION Collection and clustering of the questions & expectations contributed by the participants	Julian Lenger, *Bayer* Sascha Pfeiffer, *Pharmbiocon*
12:00	THEORY 1 – INTRODUCTION TO FREEZE-DRYING PROCESSES • Why lyophilization? • History and Development • Examples in daily life and the pharmaceutical industry • The freeze-drying processes • Freeze-drying equipment • Pros and Cons of Lyophilization	Julian Lenger, *Bayer*
12:45	Short Lunch Break in the room	

13:15	THEORY 2a – BASIC PRINCIPLES OF FREEZE-DRYING PROCESSES
	• Basic principles of freeze-drying processes
	  ○ Physical understanding
	  ○ Critical process parameters
	• Development and composition of a (biological) formulation
	• Primary packaging components
		Julian Lenger, *Bayer*

14:45	Coffee Break	

15:00	THEORY 2b– BASIC PRINCIPLES OF FREEZE-DRYING PROCESSES
	• Product attributes for designing lyophilization cycles
	  ○ Differential scanning calorimetry
	  ○ Freeze-drying microscopy
	• Analytical characterization of lyophilization including solid-state characterization
	  ○ Residual moisture (Karl Fischer, NIR)
	  ○ Reconstitution time
	  ○ Thermodynamic state (Xray powder diffraction)
	  ○ Specific surface area (BET)
	• Cake appearance at different levels
		Julian Lenger, *Bayer*

15:45	THEORY 3 – DEVELOPMENT OF A FREEZE-DRYING PROCESS
	• Development of a lyophilization cycle
	  ○ Which are the most important parameters?
	  ○ How to choose them?
	  ○ What happens if they are not chosen adequately?
	• Finalization of cycles
	• Discuss the loading scheme
		Julian Lenger, *Bayer*

17:00	End of Training Course Day 1	
17:15	Transfer to the recommended Hotel	
18:40	Transfer from the recommended hotel to Networking Event	
19:00	Networking Dinner sponsored by Martin Christ	
21:15	Transfer to the recommended Hotel	

Tuesday, 13 June 2023		
08:30	Transfer from the recommended hotel to Martin Christ facility	
09:00	Recap and Summary of Day 1	Julian Lenger, *Bayer*
09:15	PRACTICE 1 – PREPARATION OF SOLUTIONS • Compounding of formulations ○ Calculation of composition	Julian Lenger, *Bayer* Sascha Pfeiffer, *Pharmbiocon*
09:45	PRACTICE 1 – PREPARATION OF SOLUTIONS ➔ Continuing in the lab • Compounding • Filling • Stoppering Freezing experiment with distilled water under a vacuum to develop a general understanding of the critical temperature	Julian Lenger, *Bayer* Sascha Pfeiffer, *Pharmbiocon*
	PRACTICE 2: PROGRAMMING Programming the freeze-dryer with the programs developed in Theory 3	Julian Lenger, *Bayer* Sascha Pfeiffer, *Pharmbiocon*
	PRACTICE 3: FREEZING BEHAVIOR • Loading of the shelves • Positioning of the thermocouples Start of the lyophilization program	Julian Lenger, *Bayer* Sascha Pfeiffer, *Pharmbiocon*
13:00	Lunch Break	
13:45	THEORY 4 – PROCESS CONTROL TOOLS • Thermal resistance measurement (Lyo-RX) • Comparative pressure measurement (Pirani/capacitive pressure measurement) • Wireless temperature measurement • Conductance sensor • Method presentation (in theory and practice)	Sascha Pfeiffer & Simon Werner, *Pharmbiocon*
15:00	Coffee Break	
15:15	THEORY 5 – OPERATING PRINCIPLES OF THE FREEZE-DRYER • Overview of different operating and construction principles of freeze-dryers • Construction principle of the freeze-dryer and its device modules • Performance figures (port sizes, condenser sizes, evacuation times) • Chamber system • Cooling & vacuum systems • Filter systems	Sascha Pfeiffer, *Pharmbiocon*

	• CIP/SIP • Interaction of the device modules in the freeze-drying process	
16:00	THEORY 6 – LYO QUALIFICATION • Explanation of the sequence DQ-RA-IQ-OQ-PQ • Measures for maintaining the qualified state	Sascha Pfeiffer & Simon Werner, *Pharmbiocon*
16:45	PRACTICE 4 – A GLANCE AT FREEZE-DRYERS • Discussion of the status of the process • What is evident/what is not yet evident	Julian Lenger, *Bayer*
17:30	End of Training Course Day 2	
17:45	Transfer from Martin Christ facility to the recommended hotel	
Wednesday, 14 June 2023		
08:30	Transfer from the recommended hotel to Martin Christ facility	
09:00	PRACTICE 5 - A GLANCE AT FREEZE-DRYERS • Discussion of the status of the process in the freeze-dryer • Recapitulation of Key Learnings from Day 2	Julian Lenger, *Bayer*
09:30	PRACTICE 6 - TOUR OF THE PRODUCTION ROOMS OF MARTIN CHRIST • Introduction to the different size classes of freeze-dryers • Introduction to the functional modules of the freeze-dryer • Visualization of the basic analogy of the functional modules across the size classes • Explanation of the step-by-step production process for freeze-dryers	*Martin Christ*
11:30	PRACTICE 7 - INTRODUCTION TO THE GENERAL ORDER OF EVENTS IN OPERATION • Brief explanation of all workstations • Explanation and instruction on the logistics	*Martin Christ*
12:00	PRACTICE 8: WORKSTATION OPERATION SEQUENCE 1 • Calibration of pressure sensor/vacuum sensor • Calibration of temperature sensor • Shelf temperature mapping Roughness measurement	*Martin Christ*
13:00	Lunch Break	
13:45	CONTINUATION PRACTICE 8: WORKSTATION OPERATION SEQUENCE 2	*Martin Christ*
14:30	CONTINUATION PRACTICE 8: WORKSTATION OPERATION SEQUENCE 3	*Martin Christ*
15:15	Coffee Break	
15:30	CONTINUATION PRACTICE 8: WORKSTATION OPERATION SEQUENCE 4	*Martin Christ*
16:15	PRACTICE 9 - A GLANCE AT FREEZE-DRYERS • Discussion of the status of the process in the freeze-dryer	Julian Lenger, *Bayer*
17:00	End of Training Course Day 3	
17:15	Transfer from Martin Christ facility to the recommended hotel	

Thursday, 15 June 2023		
08:30	Transfer from the recommended hotel to Martin Christ facility	
09:00	Recapitulation of Key Learnings from Day 3	*Martin Christ*

09:15	THEORY 7 - MAINTENANCE AND FAULT CORRECTION
	• Introduction to the most frequently occurring faults
	  o Diagnosis
	  o Most probable causes
	  o Correction
	• Introduction to a preventative maintenance concept
	
	Presentation of examples of defective components with an explanation of the causes
		Martin Christ

10:15	THEORY 8 - CIP & SIP • Inspection of CIP & SIP systems • Cleaning validation • Sterilization qualification • Turn-around concept	Sascha Pfeiffer, *Pharmbiocon*
11:00	Coffee Break	
11:15	Mass Spectrometry Theory	Simon Werner, *Pharmbiocon*
12:15	Modeling of Lyophilization Processes *Guest Presentation*	Alex Juckers, *Martin Christ*
13:00	Lunch Break	
13:45	Headspace Moisture and Water Activity Applications for Lyophilized Product *Guest Presentation* *remote*	Derek Duncan, *LIGHTHOUSE Instruments*
14:30	THEORY 9 – CONTROLLED NUCLEATION Technology Overview	Julian Lenger, *Bayer*
15:30	Coffee Break	
15:45	PRACTICE 10 - A GLANCE AT FREEZE-DRYERS • Discussion of the status of the process in the freeze-dryer • Visual control – examples	Julian Lenger, *Bayer*
16:30	Conceptual Planning of Lyoloading in Projects *Guest Presentation*	Alexander Wagner, *Motus Engineering*
17:15	End of Training Course Day 4	
17:30	Transfer from Martin Christ facility to the recommended hotel	
18:40	Transfer to Farewell Dinner at Restaurant “Piccolo Mondo”	
19:00	Farewell Dinner	
21:15	Transfer to recommended Hotel	

Friday, 16 June 2023		
08:30	Transfer from the recommended hotel to Martin Christ facility	
09:00	PRACTICE 11 • Unloading the freeze-dryer • Evaluation of the process chart • Determination of reconstitution time • Visual Inspection • Assessment of the different results	Julian Lenger, Bayer Sascha Pfeiffer, *Pharmbiocon*
10:00	Q&A and conclusions	
11:00	End of Training Course	