

Agenda

Monday, 09 September 2024		
11:00	Reception and Welcome Coffee	
11:30	INTRODUCTION Collection and clustering of the questions & expectations contributed by the participants	Julian Lenger, <i>Bayer</i> Sascha Pfeiffer, <i>Pharmbiocon</i>
12:00	THEORY 1 – INTRODUCTION TO FREEZE-DRYING PROCESSES <ul style="list-style-type: none"> • 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, <i>Bayer</i>
12:45	Short Lunch Break in the room	
13:15	THEORY 2a – BASIC PRINCIPLES OF FREEZE-DRYING PROCESSES <ul style="list-style-type: none"> • Physical understanding • Critical process parameters • Development and composition of a (biological) formulation 	Julian Lenger, <i>Bayer</i>
14:45	Coffee Break	
15:00	THEORY 2b– DEVELOPMENT OF A LYOPHILIZATION CYCLE: PRACTICAL ADVICE <ul style="list-style-type: none"> • How to approach it? What are the most important parameters? • How to choose them for the different phases? • Development of cycles for practical work 	Julian Lenger, <i>Bayer</i>
15:45	THEORY 3 – ANALYTICAL CHARACTERIZATION OF LYOPHILIZATES <ul style="list-style-type: none"> • Product attributes for designing lyophilization cycles <ul style="list-style-type: none"> o Differential scanning calorimetry o Freeze-drying microscopy • Solid state characterization after lyophilization <ul style="list-style-type: none"> o Residual moisture (LOD, Karl Fischer, NIR, FMS) o Thermodynamic / Solid state (X-ray powder diffraction) o Specific surface area (BET) o Cake appearance at different levels (Vis. Inspec., SEM, μ-CT) o Reconstitution 	Julian Lenger, <i>Bayer</i>
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, 10 September 2024		
08:30	Transfer from the recommended hotel to Martin Christ facility	
09:00	Recap and Summary of Day 1	Julian Lenger, <i>Bayer</i>

09:15	<p>PRACTICE 1 – PREPARATION OF SOLUTIONS</p> <ul style="list-style-type: none"> • Compounding of formulations <ul style="list-style-type: none"> ○ Calculation of composition 	<p>Julian Lenger, <i>Bayer</i></p> <p>Sascha Pfeiffer, <i>Pharmbiocon</i></p>
09:45	<p>PRACTICE 1 – PREPARATION OF SOLUTIONS</p> <p style="text-align: center;">➔ Continuing in the lab</p> <ul style="list-style-type: none"> • Compounding • Filling • Stoppering <p>Freezing experiment with distilled water under a vacuum to develop a general understanding of the critical temperature</p>	<p>Julian Lenger, <i>Bayer</i></p> <p>Sascha Pfeiffer, <i>Pharmbiocon</i></p>
	<p>PRACTICE 2: PROGRAMMING</p> <p>Programming the freeze-dryer with the programs developed in Theory 3</p>	<p>Julian Lenger, <i>Bayer</i></p> <p>Sascha Pfeiffer, <i>Pharmbiocon</i></p>
	<p>PRACTICE 3: FREEZING BEHAVIOR</p> <ul style="list-style-type: none"> • Loading of the shelves • Positioning of the thermocouples <p>Start of the lyophilization program</p>	<p>Julian Lenger, <i>Bayer</i></p> <p>Sascha Pfeiffer, <i>Pharmbiocon</i></p>
13:00	Lunch Break	
13:45	<p>THEORY 4 – PROCESS ENGINEERING TOOLS</p> <ul style="list-style-type: none"> • PT Sensors • Pressure and Vacuum Sensors • Vacuum Sensors • Conductivity Sensors • Mass Spectrometer Theory • Camera systems • Alternatives Sensors 	<p>Sascha Pfeiffer, <i>Pharmbiocon</i></p>
15:00	Coffee Break	
15:15	<p>THEORY 5 – LYOPHILISATOR</p> <ul style="list-style-type: none"> • Construction of freeze dryers • Systems of freeze dryers • Different types of freeze dryers • Existing lines of freeze dryers • Parameters of freeze dryers 	<p>Sascha Pfeiffer, <i>Pharmbiocon</i></p>
16:00	<p>THEORY 6 – LYO QUALIFICATION</p> <ul style="list-style-type: none"> • Explanation of the sequence DQ-RA-IQ-OQ-PQ • Measures for maintaining the qualified state 	<p>Sascha Pfeiffer, <i>Pharmbiocon</i></p>
16:45	<p>PRACTICE 4 – A GLANCE AT FREEZE-DRYERS</p> <ul style="list-style-type: none"> • Discussion of the status of the process • What is evident/what is not yet evident 	<p>Julian Lenger, <i>Bayer</i></p>

		Sascha Pfeiffer, <i>Pharmbiocon</i>
17:30	End of Training Course Day 2	
17:45	Transfer from Martin Christ facility to the recommended hotel	
Wednesday, 11 September 2024		
08:30	Transfer from the recommended hotel to Martin Christ facility	
09:00	PRACTICE 5 - A GLANCE AT FREEZE-DRYERS <ul style="list-style-type: none"> • Discussion of the status of the process in the freeze-dryer • Recapitulation of Key Learnings from Day 2 	Julian Lenger, <i>Bayer</i> Sascha Pfeiffer, <i>Pharmbiocon</i>
09:30	PRACTICE 6 - TOUR OF THE PRODUCTION ROOMS OF MARTIN CHRIST <ul style="list-style-type: none"> • 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 	<i>Martin Christ</i>
11:30	Presentation on Natural Refrigerants	<i>Martin Christ</i>
12:15	PRACTICE 7 - INTRODUCTION TO THE GENERAL ORDER OF EVENTS IN OPERATION <ul style="list-style-type: none"> • Brief explanation of all workstations • Explanation and instruction on the logistics PRACTICE 8: WORKSTATION OPERATION SEQUENCE 1 <ul style="list-style-type: none"> • Calibration of pressure sensor/vacuum sensor • Calibration of temperature sensor • Shelf temperature mapping • Roughness measurement 	<i>Martin Christ</i>
13:00	Lunch Break	
13:45	CONTINUATION PRACTICE 8: WORKSTATION OPERATION SEQUENCE 2	<i>Martin Christ</i>
14:30	CONTINUATION PRACTICE 8: WORKSTATION OPERATION SEQUENCE 3	<i>Martin Christ</i>
15:15	Coffee Break	
15:30	CONTINUATION PRACTICE 8: WORKSTATION OPERATION SEQUENCE 4	<i>Martin Christ</i>
16:15	PRACTICE 9 - A GLANCE AT FREEZE-DRYERS <ul style="list-style-type: none"> • Discussion of the status of the process in the freeze-dryer 	Julian Lenger, <i>Bayer</i>
17:00	End of Training Course Day 3	
17:15	Transfer from Martin Christ facility to the recommended hotel	

Thursday, 12 September 2024

08:30	Transfer from the recommended hotel to Martin Christ facility	
09:00	Recapitulation of Key Learnings from Day 3	<i>Martin Christ</i>
09:15	<p>THEORY 7 - MAINTENANCE AND FAULT CORRECTION</p> <ul style="list-style-type: none"> • Introduction to the most frequently occurring faults <ul style="list-style-type: none"> ○ Diagnosis ○ Most probable causes ○ Correction • Introduction to a preventative maintenance concept <p>Presentation of examples of defective components with an explanation of the causes</p>	<i>Martin Christ</i>
10:15	<p>THEORY 8 - CLEANING & STERILISATION</p> <ul style="list-style-type: none"> • CIP / SIP systems • Acceptance of CIP / SIP systems • Cleaning validation • Sterilization qualification • Turnaround process • In Process testing during Lyophilization 	Sascha Pfeiffer, <i>Pharmbiocon</i>
11:00	Coffee Break	
11:15	Mass Spectrometry Practice	Sascha Pfeiffer, <i>Pharmbiocon</i>
12:30	<p>Modelling the Lyophilization Process: A Quality by Design Approach to Optimize Cycle Performance and Product Quality</p> <p><i>Guest Presentation (remote)</i></p>	Andrea Arsiccio, <i>Coriolis-Pharma</i>
13:00	Lunch Break	
13:45	<p>Headspace Moisture and Water Activity Applications for Lyophilized Product</p> <p><i>Guest Presentation (remote)</i></p>	Derek Duncan, <i>LIGHTHOUSE Instruments</i>
14:30	<p>THEORY 9 – THE IMPORTANCE OF THE FREEZING STEP</p> <ul style="list-style-type: none"> • Controlled nucleation technology overview and annealing) 	Julian Lenger, <i>Bayer</i>
15:30	Coffee Break	
15:45	<p>PRACTICE 10 - A GLANCE AT FREEZE-DRYERS</p> <ul style="list-style-type: none"> • Discussion of the status of the process in the freeze-dryer • Visual control – examples 	Julian Lenger, <i>Bayer</i> Sascha Pfeiffer, <i>Pharmbiocon</i>
16:30	<p>Conceptual Planning of Lyoloading in Projects</p> <p><i>Guest Presentation</i></p>	Konstantin Große, <i>Motus Engineering</i>
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, 13 September 2024

08:30	Transfer from the recommended hotel to Martin Christ facility	
09:00	<p>PRACTICE 11</p> <ul style="list-style-type: none"> • Unloading the freeze-dryer • Evaluation of the process chart • Determination of reconstitution time • Visual Inspection • Assessment of the different results 	<p>Julian Lenger, Bayer</p> <p>Sascha Pfeiffer, <i>Pharmbiocon</i></p>
10:00	Q&A and conclusions	
11:00	End of Training Course	