

Monday, 22 November 2021

12:00	Reception and Welcome Coffee
12:30	INTRODUCTION <ul style="list-style-type: none"> • Collection and clustering of the questions contributed by the participants
13:00	THEORY 1 – INTRODUCTION TO FREEZE-DRYING PROCESSES <ul style="list-style-type: none"> • Why lyophilization? • History and Development • Examples in daily life and pharmaceutical industry • The freeze-drying process • Freeze-drying equipment • Pros and Cons for Lyophilization
13:45	THEORY 2– BASIC PRINCIPLES OF FREEZE-DRYING PROCESSES <ul style="list-style-type: none"> • Basic principles of freeze-drying processes <ul style="list-style-type: none"> ○ Physical understanding ○ Critical process parameters • Product attributes for designing lyophilization cycles <ul style="list-style-type: none"> ○ Differential scanning calorimetry ○ Freeze-drying microscopy • Development and composition of a (biological) formulation • Primary packaging components • Analytical characterization of lyophilizates including solid state characterization <ul style="list-style-type: none"> ○ Residual moisture (Karl Fischer, NIR) ○ Reconstitution time ○ Thermodynamic state (Xray powder diffraction) ○ Specific surface area (BET) ○ Cake appearance at different levels (visual inspection, 3D scanning, PDMS embedding, SEM, μCT)
15:00	Coffee Break
15:15	PRACTICE 1 - PREPARATION OF SOLUTIONS <ul style="list-style-type: none"> • Compounding of formulations <ul style="list-style-type: none"> ○ Calculation of composition ○ Compounding • Filling • Stoppering • Freezing experiment with distilled water under vacuum to develop a general understanding of the critical temperature
17:15	Transfer to the recommended Hotel
18:00	Transfer from the recommended hotel to Networking Dinner
18:30	Networking Dinner at Martin Christ facility
20:30	Transfer to the recommended Hotel

Tuesday, 23 November 2021

08:30	Transfer from the recommended hotel to Martin Christ facility
09:00	Recap and Summary of Day 1
09:10	<p>THEORY 3 - DEVELOPMENT OF A FREEZE-DRYING PROCESS</p> <ul style="list-style-type: none"> • Development of a lyophilization cycle <ul style="list-style-type: none"> – Which are the most important parameters? – How to choose them? – What happens if they are not chosen adequately? • Finalization of cycles • Discuss loading scheme
10:30	Coffee Break
10:45	<p>THEORY 4 - PROCESS CONTROL TOOLS</p> <ul style="list-style-type: none"> • Thermal resistance measurement (Lyo-RX) • Comparative pressure measurement (Pirani/capacitive pressure measurement) • Barometric temperature measurement (BTM/MTM) • Wireless temperature measurement (WTM) • Conductance sensor • Inline camera (LyoCam)
11:45	<p>PRACTICE 2: PROGRAMMING</p> <ul style="list-style-type: none"> • Programming the freeze-dryer with the programs developed in Theory 3
13:00	Lunch Break
13:45	<p>PRACTICE 3: FREEZING BEHAVIOR</p> <ul style="list-style-type: none"> • Loading of the shelves • Positioning of the thermo couples • Start of the lyophilization program
14:45	<p>PRACTICE 4:</p> <ul style="list-style-type: none"> • Introduction to the LyoCam technology • Play-back and discussion of prepared/available video sequences • Discussion on the correlation of the video sequences with the process parameters using the process graphs • Time lapse mode for identifying process advancement
15:00	Coffee Break
15:30	<p>THEORY 5 - OPERATING PRINCIPLES OF THE FREEZE-DRYER</p> <ul style="list-style-type: none"> • 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 • CIP/SIP • Interaction of the device modules in the freeze-drying process

16:15	THEORY 6 - LYO QUALIFICATION <ul style="list-style-type: none">• Explanation of the sequence DQ-RA-IQ-OQ-PQ• Measures for maintaining the qualified state
17:00	PRACTICE 5 - A GLANCE AT FREEZE DRYERS <ul style="list-style-type: none">• Discussion of the current status of the process• What is evident/what is not yet evident
17:45	Transfer from Martin Christ facility to the recommended hotel

Wednesday, 24 November 2021

8:30	Transfer from the recommended hotel to Martin Christ facility
9:00	<p>PRACTICE 6</p> <ul style="list-style-type: none"> • Discussion of the current status of the process in the freeze dryer • Recapitulation of Key Learnings from Day 2
9:30	<p>PRACTICE 7 - TOUR OF THE PRODUCTION ROOMS OF MARTIN CHRIST</p> <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
11:30	<p>PRACTICE 8 - INTRODUCTION TO THE GENERAL ORDER OF EVENTS IN OPERATION</p> <ul style="list-style-type: none"> • Brief explanation of all workstations • Explanation and instruction on the logistics
13:00	Lunch Break
13:45	<p>PRACTICE 9: WORKSTATION OPERATION SEQUENCE 1</p> <ul style="list-style-type: none"> • Calibration of pressure sensor/vacuum sensor • Calibration of temperature sensor • Shelf temperature mapping • Roughness measurement
14:15	CONTINUATION PRACTICE 9: WORKSTATION OPERATION SEQUENCE 2
15:00	Coffee Break
15:30	CONTINUATION PRACTICE 9: WORKSTATION OPERATION SEQUENCE 3
16:15	CONTINUATION PRACTICE 9: WORKSTATION OPERATION SEQUENCE 4
17:00	<p>PRACTICE 10</p> <ul style="list-style-type: none"> • Discussion of the current status of the process in the freeze dryer
17:30	Transfer from Martin Christ facility to the recommended hotel

Thursday, 25 November 2021

8:30	Transfer from the recommended hotel to Martin Christ facility
9:00	Recapitulation of Key Learnings from Day 3
9:15	<p>THEORY 7 - MAINTENANCE AND FAULT CORRECTION</p> <ul style="list-style-type: none"> • Introduction to the most frequently occurring faults -Diagnosis -Most probable causes -Correction • Introduction to a preventative maintenance concept • Presentation of examples of defective components with explanation of the causes
10:15	<p>THEORY 8 - CIP & SIP <i>[only theory! At that time, no corresponding equipment in production area of Christ for demonstration available]</i></p> <ul style="list-style-type: none"> • Inspection of CIP & SIP systems • Cleaning validation • Sterilization qualification • Turn-around concept
11:00	Coffee Break
11:15	<p>THEORY 9 – Guest Presentation</p> <p>COOLING TECHNOLOGY</p> <ul style="list-style-type: none"> • The future use of refrigeratns under the impact of current regulations
12:00	<p>Guest Presentation - REMOTE:</p> <ul style="list-style-type: none"> • Requirements for stoppers in the freeze-drying process (working title)
13:00	Lunch Break
14:00	<p>Mass Spectroscopy</p> <ul style="list-style-type: none"> • Method presentation (in theory and practice)
15:00	<p>THEORY 10 – CONTROLLED NUCLEATION</p> <ul style="list-style-type: none"> •Technology Overview
16:00	Coffee Break
16:15	<p>PRACTICE 11</p> <ul style="list-style-type: none"> • Discussion of the current status of the process in the freeze dryer • Visual control – examples
16:45	<p>THEORY 11 – AUTOMATION</p> <ul style="list-style-type: none"> • Loading and Unloading
17:15	Transfer to the recommended hotel
18:30	Farewell Dinner at Hotel Sauerbrey (recommended Hotel)

Friday, 26 November 2021

8:00	Transfer from the recommended hotel to Martin Christ facility
8:30	PRACTICE 12 <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
10:00	Q&A and conclusions
11:00	End of Course