AGENDA

Lyophilization Cycle Development & Optimization: A Laboratory Based Approach

Each day will begin promptly at 8:00 am. The facility will be open at 7:30 am for your arrival.

Day 1 Schedule

Time	Description	Presenter
8:00 - 8:30 am	**Instructor's Opening Address** Course introduction and format • Instructor & participant introductions • Course goals	Jeff Schwegman, PhD
8:30 - 9:00 am	**Physical Properties of Materials** Crystalline vs. amorphous vs. mixed systems • Eutectic melting, glass transition & collapse temperatures • Partial collapse vs. melt-back • Examples of failed products	Jeff Schwegman, PhD
9:00 - 9:30 am	**Materials Characterization Techniques** Principals of thermal analysis • Thermal analysis techniques (DSC, OTA, TEA) • Freeze-dry microscopy equipment & techniques • Applications of thermal analysis and freeze-dry microscopy techniques for solutions and solids	Jeff Schwegman, PhD
9:30 - 9:45 am	**Break**	
9:45 - 10:30 am	**Freeze-Dry Microscopy**	Biopharma Group
10:30 am - 12:00 pm	**Freezing, Annealing, Primary, and Secondary Drying** Ice nucleation • Ice crystal growth • Effects of ice crystal particle size • Eutectic and/or glass formation • Annealing theory and techniques • Primary and secondary drying and protocols	Jeff Schwegman, PhD
12:00 - 1:00 pm	**Lunch**	
1:00 - 2:00 pm	**DSC for Thermal Analysis**	TA Instruments
2:00 - 5:00 pm	**Laboratory Sessions - Group Rotations (90 minutes each, take breaks as needed)** Station 1: Differential Scanning Calorimetry Station 2: Freeze Dry Microscopy Station 3: Introduction to LyoStar, MTM/SMART Station 4: Introduction to Shelf Freeze Dryers	Station 1: TA Instruments Station 2: Biopharma Group Station 3: SP Trainer Station 4: SP Trainer

Details for dinner arrangements on separate document.

Day 2 Schedule

Time	Description	Presenter
8:00 - 11:00 am	**Laboratory Sessions - Group Rotations (90 minutes each, take breaks as needed)** Station 1: Differential Scanning Calorimetry Station 2: Freeze Dry Microscopy Station 3: Introduction to LyoStar, MTM/SMART Station 4: Introduction to Shelf Freeze Dryers	Station 1: TA Instruments Station 2: Biopharma Group Station 3: SP Trainer Station 4: SP Trainer
10:30 am - 12:00 pm	**Laboratory Sessions - Thermal Treatment (Take breaks as needed)** Each group will be assigned a freeze dryer. Utilizing the thermal analysis and lecture information presented so far, students will develop a thermal treatment protocol, program the freeze dryer, then load product and start the freezing portion of the cycle. Groups will spend time explaining their choice of protocol later in the course.	SP Trainers
12:00 - 1:00 pm	**Lunch**	
1:00 - 2:00 pm	**Lyophilization Process Development & Cycle Design** Reviewing & utilizing the pre-formulation/formulation data • Reviewing & utilizing thermal analysis • Designing an optimized freezing protocol • Designing an optimized primary drying protocol • Designing an optimized secondary drying protocol • Characterizing the final dried formulation	Jeff Schwegman, PhD
2:00 - 3:00 pm	**Formulation of a Lyophilized Product** Formulation considerations • Buffers • Bulking Agents • Lyoprotectants/Cryoprotectants	Jeff Schwegman, PhD
2:00 - 5:00 pm	**Laboratory - Primary Drying (Take breaks as needed)** Students will develop a drying protocol for their product and program the drying steps into the freeze dryer. Real-time adjustments will then be made to the protocol based on process data. Each group should note the status of their cycle and make observations of the status of the freeze-drying cycle.	SP Trainers

Details for dinner arrangements on separate document.

Day 3 Schedule

Time	Description	Presenter
8:00 - 8:30 am	**Laboratory** Each group should note the status of their cycle and make observations of the status of the freeze-drying cycle. Adjustments should be made if necessary.	Jeff Schwegman, PhD
8:30 - 9:15 am	**Tunable Diode Laser Absorption Spectroscopy (TDLAS)**	Physical Sciences Inc.
9:15 - 9:30 am	**Break**	
9:30 - 10:30 am	**Critical Quality Attributes of Lyophilized Products**	Lyophilization Technology
10:30 - 11:15 am	**NIR for Lyophilized Sample Analysis**	Thermo Scientific
11:15 am - 12:00 pm	**Non-Destructive Headspace Analysis of Vials**	Lighthouse Instruments
12:00 - 1:00 pm	**Lunch**	
	Laboratory Sessions **(45 minute sessions, take breaks as needed)** **Students to remove samples from the dryer prior to going to stations.**	
1:00 - 1:45 pm	Full group - The Use of TDLAS to Measure Mass Flow	All: Physical Sciences Inc.
1:45 - 5:00 pm	Station 1: Karl Fischer Residual Moisture Analysis, Physical Appearance & Reconstitution Station 2: Non-Destructive Head Space Analysis of Vials Station 3: NIR Residual Moisture Analysis	Station 1: Lyophilization Technology Station 2: Lighthouse Instruments Station 3: Thermo Scientific

Details for dinner arrangements on separate document.

Day 4 Schedule

Time	Description	Presenter
8:00 - 8:30 am	**Container Closure Systems** Selection of containers and closures • Proper preparation of container closure systems (lab vs. production) • Specialized coatings and formulations	Jeff Schwegman, PhD
8:30 - 9:30 am	**Production Dryers, Auto-loading, and Scale-Up**	Charles Dern, PE
9:30 - 10:15 am	**Facility Tour**	Charles Dern, PE
10:15 - 10:30 am	**Break**	
10:30 - 11:15 am	**Scale-Up, Cycle Transfer & Maximum Throughput Capability** Critical parameters in scale-up and cycle transfer • Scale-up strategy• Mapping studies • Dryer configuration • Determining and preventing choked flow conditions	Jeff Schwegman, PhD
11:15 - 11:30 am	**Students Present Results & Discuss**	
11:30 am - 12:00 pm	**Case Studies**	Jeff Schwegman, PhD
12:00 - 1:00 pm	**Lunch**	
	End of Course -Thank You for Attending!	