

# LYOPHILIZATION 101

## Summary

This 2-day course focusses on giving a thorough introduction on pharmaceutical freeze-drying. During this course, the basic and fundamental aspects of the freeze-drying technique will be clearly explained from the bottom up. This includes getting to know the equipment and learning to understand the first-principles concerning both heat and mass transfer mechanisms during freeze-drying. In addition, as a secondary focus, an introduction will be given on the most important PAT tools and post-run analytics which are commonly used in the field. Finally, a hands-on experience and tour of the lab will be provided.

## MODULE 1: BASIC COURSE

### *Theoretical – day 1*

- 1) *Introduction to lyophilization*
  - a. Basic fundamentals
  - b. (Dis)advantages
  - c. Equipment overview
  - d. First-principles
- 2) *Introduction to the formulation*
  - a. What needs to be inside the formulation?
  - b. Characterization of the formulation
- 3) *Introduction to the freeze-drying cycle*
  - a. Basic fundamentals
  - b. Optimization
  - c. Modelling of the cycle
- 4) *Introduction to PAT implementation*
  - a. What is PAT?

### *Practical – day 1*

- 1) *Tour of the CESPE freeze-drying lab*
- 2) *Sample characterization*
  - a. Freeze-drying microscopy
  - b. DSC (Tg')
- 3) *Starting your first run*
  - a. Sample preparation
  - b. Cycle development and initiation

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## MODULE 1: BASIC COURSE

### *Theoretical – day 2*

- 1) *Continuation – PAT implementation*
  - a. Most important PAT tools
  - b. How to implement them?
  - c. What do you get out of it?
- 2) *Data analysis*
  - a. Pre-run analytics
  - b. Post-run analytics
- 3) *Introduction to biopharmaceutical analytics*
  - a. SEC
  - b. Reconstitution
  - c. Flow cytometry
  - d. ...
- 4) *Continuous vs. batch*
  - a. Basic principles
  - b. (Dis)advantages
  - c. Continuous freeze-drying technique

### *Practical – day 2*

- 1) *Finishing your first run*
  - a. Sample and data acquisition
  - b. Evaluation of the finished run
- 2) *Product characterization*
  - a. Water content determination via Karl-Fischer
  - b. Solid-state characterization of the freeze-dried product
- 3) *Sneak-peek of a continuous freeze-drying equipment*