

Application of a Risk-Based Approach to Freeze-Drying Processes

Overview

One masterpiece of current process validation approach is risk analysis. It allows defining and measuring the critical parameters of the process for which a specific level of scrutiny is necessary in order to end-up with a robust process under control. The objective of this course is to give an understanding of risk management through ICHQ9 applied to the Freeze-Drying process. The first part will review the guidelines, the Freeze-Drying process and the tools available to score the risks. The second part will be fully interactive. Participants will express their views in terms of detectability, occurrence and control of the various risks linked to the Freeze-Drying process. The session will be subdivided into different chapters: Product, Process, Critical Quality Attributes, Ancillary Function of the equipment and Aseptic Level. The different tools to perform risk analysis will be described and the main focus will be on an FMEA (Failure Mode and Effects Analysis) approach. The output of the workshop is a table consisting of the different parameters with their associated level of criticality that will be shared with the participant.

Who Should Attend:

This course is designed specifically for people having an interest in Freeze-Drying. The audience can come from the various horizons of people performing technical risk assessment, including, but not limited to: production, quality assurance, validation, engineering and development specialist.

Learning Objectives:

Upon completion of this course, you will be able to:

- Better understand the Freeze-Drying process explained through the different examples
- Master ICH Q9 approach in term of risk-based approach
- Recognize a critical parameters for a process
- Score the criticality of a parameters
- Work in team by reaching consensus around criticality levels



Yves Mayeresse, *GlaxoSmithKline Vaccines*

Yves Mayeresse is director in manufacturing technology inside MSAT by GlaxoSmithKline Vaccines. He has more than twenty years of experience in the pharmaceutical sector and has worked for different companies. Yves has managed activities such as parenteral production, set-up of new Freeze-Drying facilities, design of Freeze-Drying cycle and development of new stabilizers for freeze-dried products. Transfer of product towards different internal and external site. He has worked on the industrialization of new freeze-dried products and then in the technical life cycle management. Now, Yves is focusing on different technologies used for the primary and secondary operations. He is an engineer in biochemistry, has written articles about Freeze-Drying science and is a regular speaker for conferences on Freeze-Drying. Since 2016 he is the Leader of the PDA Interest Group Lyophilization and coordinates the group's activities in Europe.

Thursday, 29 November 2018**9:00 – 17:00**

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- 9:00** **Theoretical Part**
- ▶ *Brief review of ICH Q9*
 - ▶ *Description of Freeze-Drying Technology*
 - The equipment
 - The process
 - The product and the primary packaging items
 - The ancillary function (SIP, CIP)
 - Aseptic level (automatic loading, people presence)
 - ▶ *Tools Presentation*
 - Input / Output parameters
 - Dependent / Independent parameters
 - CQA: Critical Quality Attributes
 - FMEA approach
 - Examples
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- 10:30** **Coffee Break**
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- 11:00** **Practical Part**
- ▶ *Team rule and organization*
 - ▶ *Part I: Product*
 - Independent parameters linked to formulation
 - Independent parameters linked to freeze-dryer load
 - ▶ *Part II: Process*
 - Independent parameters linked to the freeze-dryer
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- 12:30** **Lunch Break**
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- 14:00** **Practical Part**
- ▶ *Part II (continued): Process*
 - Independent parameters that are measured and controlled during the cycle
 - Dependent parameters linked to the Freeze-Drying cycle
 - ▶ *Part III: Critical attributes linked to Freeze-Drying process*
 - ▶ *Part IV: Ancillary Function*
 - SIP
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- 15:30** **Coffee Break**
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- 15:45** **Practical Part**
- ▶ *Part IV (continued): Ancillary Function*
 - CIP
 - ▶ *Part V: Aseptic Level*
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- 16:30** **Conclusions**
- ▶ *Q&A*
 - ▶ *Feedback about the approach*
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- 17:00** **End of Training Course**
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