Pharmaceutical Consultancy Services

Quality Management MODULE 3
in Sterile Manyfacturing

31 Oct to 02 Nov 2023

Three days of training on sterility assurance challenges in the pharmaceutical industry and hospital pharmacies.

TARGET AUDIENCE

Professionals in pharmaceutical and biotechnological industries, Professionals in institutions and Contract Research Organisations (CRO's), Hospital pharmacists and Postgraduate students.

LEARNING GOALS

- Apply the principles of specific sterility related subjects, such as monitoring, cleaning and disinfection, sterilization, and validation.
- Interpret the guidelines and common practices, and distinguish these facts from myths.
- Demonstrate a critical attitude towards sterility assurance in sterile manufacturing.

RESULTS

- A thorough understanding of the design and control factors related to the sterility assurance of sterile pharmaceutical products.
- Gained the principles of specific sterility related subjects, such as monitoring, cleaning and disinfection, sterilization, and validation.
- A critical attitude towards sterility assurance in sterile manufacturing.

CONTENTS

- Microbiology and implications for sterility
- Sterile manufacturing set-up
- Process and facility
- Sterilization (steam, dry heat, filtration and other)
- Cleaning and disinfection
- Cleanroom behavior
- Pharmaceutical water systems and utilities
- Control
- Environmental and water monitoring
- Sterility assurance in practice
- Validation and qualification (aseptic and analytical methods, operator qualification)
- Releasing the sterile product: The role of the QP in assuring the quality of sterile pharmaceuticals
- Real-life case studies

REGISTER NOW!

Go to the training overview on our website to register:

www.pcs-nl.com

GROUP DISCOUNTS APPLY, INQUIRE WHEN REGISTERING!

Quality Management MODULE 3

MODULE LEADER

Drs. J.H.A. (Jos) Mathôt - Mathôt Pharma Support

Jos is a pharmacist by education and has over 35 years of experience working with sterile pharmaceuticals and aseptic production. Jos was operations manager at Organon, a global manufacturing organization of sterile products and site leader of a pharmaceutical isotope manufacturing organization. He has been active in CEN and ISO working groups concerning sterilization and sterility with special attention for aseptic production.

GENERAL INFORMATION

Educational Form	Seminar
Date	31 Oct to 02 Nov 2023
Location	Area of Utrecht, the Netherlands

RELATED COURSES

Quality Management – the Role of the Qualified Person
This five-day training provides insight into an integrated approach on quality management as a good business practice.

Quality Management in Manufacturing of Biopharmaceuticals
Three days on manufacturing biopharmaceuticals & quality aspects

What makes a PCS training so special?

455

More than 455 participants so far!

34

This is the 34th edition of this training.

94%

94% of participants would recommend this training to others.

8,2

The average rating for this module is 8,2 out of 10.