

Best Practices and Points to Consider in Aseptic Processing

Overview

Aim of this training course is to facilitate a deeper understanding and provide insights into the Aseptic Processing environment, and to go beyond what is commonly covered in books on that subject. A practical and highly interactive approach will enable participants to get actively involved, discussing guidelines and Warning Letters in addition to sharing perspectives and solutions to issues found in everyday job situations.

A kaleidoscope of hot topics such as Best Practices and Case Studies from different areas of Aseptic Processing, Sterile Production facilities, QA/ QC Microbiology Control, Shop Floor Mentoring and Oversight will be addressed. Training and Motivation of staff, use of Risk Assessments and Quality Culture are further relevant aspects.

Lively interactions will make this a valuable learning experience for all.

Who Should Attend

Personnel involved in Aseptic Processing from sterile production departments such as:

- Production Management and Shop Floor Supervisors
- QA and QC Microbiologists
- Qualified Persons
- Personnel from technical department

A basic understanding of Aseptic Processing is a prerequisite.

Learning Objectives

- Gain deeper knowledge and insights into specific topics like sterilization, training and motivation of shop-floor staff, correct aseptic working practices, media fill worst case criteria, effective environmental monitoring programs, good cleaning & disinfection practices, etc.
- Understand key requirements and challenges in parenteral production
- Understand the importance of a good quality culture within a company
- Apply the executed and presented case studies and team exercises in her / his daily job
- Get answers and interpretations about - potentially - unresolved questions and problems
- Gain confidence for audits



Guenther Gapp, *Independent Consultant, Gapp Quality GmbH*

Since 2013, the microbiologist Guenther Gapp has been working as an independent consultant for different clients around the globe, and has been engaged in approximately 50 projects e.g. in assignments for remediation of companies cited with a Warning letter. In the previous steps of his career, he served in the pharmaceutical industry during 20 years as Head of QA / QC Microbiology department and Sterility Assurance Expert and Troubleshooter in global projects and supplier audits. During this period, he gained in-depth experience in Aseptic processing key elements and Risk Assessments, Training and motivation of operators, media fill practices of finished dosage forms and bulk products, environmental monitoring, rapid testing methods and regulatory agency audits. Guenther has been a subject matter expert in more than 20 FDA audits. He also created a new sterile risk assessment tool to identify and reduce the microbial contamination and compliance risk of aseptically prepared, sterile products. The publication of this Risk Assessment tool won him the 2011 PDA Journal of Pharmaceutical Science and Technology Award. He has been a speaker at several PDA conferences in the past years. Since 2017 he has been member of PDA's EU Annex 1 Revision Commenting Task Force, Science Advisory Board and Co-Chair in the Isolator Taskforce.

Thursday, 5 September 2019 9:00 – 18:00

9:00 Welcome and Collection of Expectations of Participants

9:30 Introducing Quiz about Selected Hot Topics in Aseptic Processing

- Discussion of answers

10:30 Coffee Break

11:00 Important Aspects of Sterilization, Cleaning and Disinfection, Gowning Procedures

Steam & Dry Heat Sterilization

- Moist Heat sterilization (Fo- Concept)
- Dry Heat Depyrogenation
- What can go wrong and common Audit findings
- Following PDA TRs are briefly addressed:
- Technical Report 1 (TR 1) / TR 3 / TR 48 / TR 61

Key elements for

Cleaning & Disinfection in Cleanroom

- Procedures and Best Practices
- Common mistakes and audit finding
 - TR 70 Fundamentals of Cleaning and Disinfection Programs for Aseptic Manufacturing

Gowning steps for entering grade A/B area

- Teamwork
- Important points to consider

12:30 Lunch Break

13:30 Important Aspects of Sterilization, Cleaning and Disinfection, Gowning Procedures (cont.)

14:30 Team Exercise 1: How to Build Up a New Aseptic Filling Line

15:30 Coffee Break

16:00 Aspects of Clean Room Concepts and Good Aseptic Working Practices

- Conventional filling Lines
- RABS and isolators
- Understanding First Air and Barrier Concepts
 - TR 62 Recommended Practices for Manual Aseptic Processes
- Points to Consider for Aseptic Processing: Part 1 & Part 2
- Update on new PDA TR Points to Consider for Isolators

17:30 End of Day 1

Friday, 6 September 2019 9:00 – 16:30

9:00 Best Practices in Aseptic Processing Simulation

- Basic Concepts and Regulatory Framework about Process Simulations
- Best Practices in Media Fills for Finished Dosage Form
 - TR 22 Process Simulation for Aseptically Filled Products
- (Re)Qualification of Operators
- Categorization of Interventions

10:00 Effective Oversight at the Shop Floor, Good Training Methods

- Regulatory requirements and framework
- Sharing my best practices and effectiveness
- Examples from the shop floor worldwide

10:30 Coffee Break

11:00 Important Aspects in Environmental Monitoring

- TR 13 Fundamentals of an Environmental Monitoring Program
- Regulatory requirements and expectations
- Rationale for sample locations and frequency

11:30 Team Exercise 2: Set-up an EM Program for Cleanrooms / Isolators

12:30 Lunch Break

13:30 Team Exercise 3: Share your own case studies and problems, and find resolution approaches as a team

15:00 Coffee Break

15:30 Team Exercise 4: Benchmarking Between Team Members

16:30 End of Course