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 departments

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

Faculty

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 more than 30 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, 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, and this method is used now worldwide. 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 Task Force, Science Advisory Board and Co-Chair in the Isolator Taskforce.

Wednesday, 17 October 2018 — 9:00 – 17:30

9:00	**Welcome and Collection of Participant Expectations**
09:30	**Introductional Test 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** – Technical Report 1 (TR 1) Validation of Moist Heat Sterilization Processes: Cycle Design, Development, Qualification – TR 3 Validation of Dry Heat Processes Used for Depyrogenation and Sterilization – TR 48 Moist Heat Sterilizer Systems: Design, Commissioning, Operation, Qualification and Maintenance – TR 61 Steam in Place • **Key elements for Cleaning & Disinfection in cleanrooms** – TR 70 Fundamentals of Cleaning and Disinfection Programs for Aseptic Manufacturing • **Gowning steps for entering grade A/B area**
12:30	**Lunch Break**
13:30	**Aspects of Clean Room Concepts and Good Aseptic Working Practices** • **Conventional filling lines** • **RABS systems 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 TR 34 Design and Validation of Isolator Systems for the Manufacturing and Testing of Health Care Products**
14:30	**Team Excercise 1: How to Maintain an Aseptic Environment**
15:30	**Coffee Break**
16:00	**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**
17:45	**End of Day 1**

Thursday, 18 October 2018 — 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 and API** – TR 22 Process Simulation for Aseptically Filled Products – TR 28 Process Simulation Testing for Sterile Bulk Pharmaceutical Chemicals • **(Re)Qualification of Operators** • **Categorization of Interventions**
10:00	**EU Annex 1 Revision** • **Selected Comments from the PDA Taskforce**
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** • **How to proceed in case of excursions**
11:30	**Team Exercise 2: Set-up a EM Program for Cleanrooms/Isolators**
12:30	**Lunch Break**
13:30	**Team Exercise 3: Share your own case studies and problems, and find resolutions as a team**
15:00	**Coffee Break**
15:30	**Team Exercise 4: Benchmarking between team members**
16:30	**End of Course**