PDA
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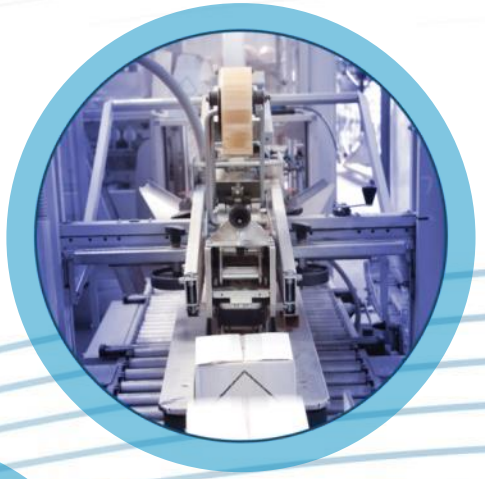
Best Practices and Points to Consider in Aseptic Processing

Berlin, 17. & 18. October 2018

by Guenther Gapp



Dr. Guenther Gapp - Instructor

- SME : Aseptic Processing & Microbiologist
- 20 years with Sandoz/ Novartis
  - Head QA/ QC Microbiology
  - > 20 FDA audits as SME
  - Global Sterility Assurance Expert & Troubleshooter
  - Created Risk Assessment Tool for Sterile Products
- 6 years independent Consultant
  - > 40 projects worldwide: USA/ India/ Europe/Corea/ Brasil and Argentina
- > 20 Years PDA
  - Publication Award 2011 (Sterile Product Compliance RA)
  - Speaker at PDA and other conferences since 2010
  - PDA EU Annex 1 Task Force Member
  - Co-Chair Taskforce ”Points to Consider for Isolators”
  - Member Science Advisory Board
- WEBSITE: www.gappquality.com

Risk Management in my leisure time

Mistakes have certainly a dramatic consequence

Parallels to Aseptic Processing

WE …

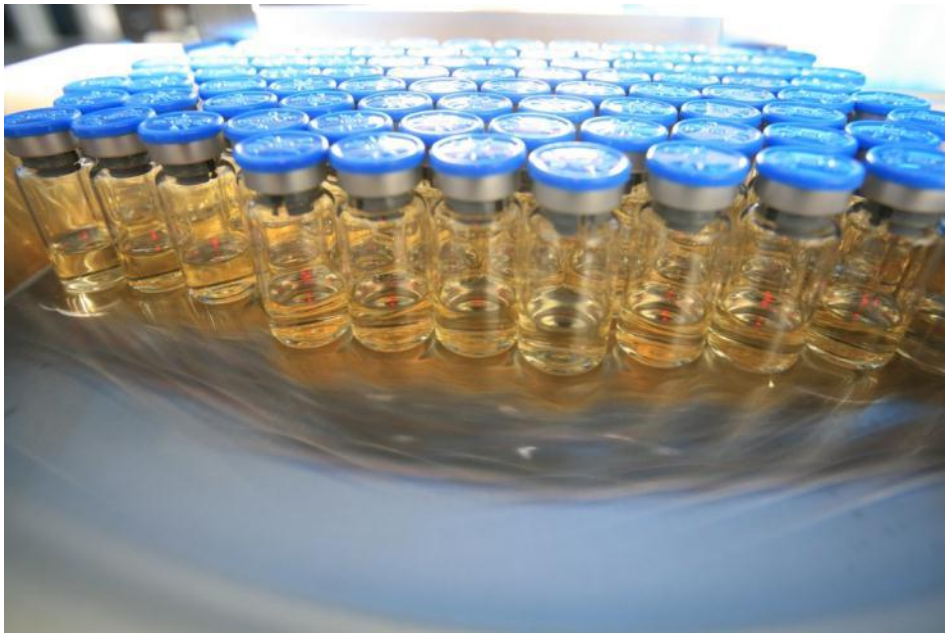
- must have good equipment and well maintained
- have to understand the procedures and rules
- have to follow these procedures
- must be (re)qualified and be (re)trained
- have often to practice it
- must have good controls in place and STOP if required
- must be self-confident
- must know how to do it
- must feel responsible
- have always to be aware that “human errors” may (also from others) – be prepared !

Definitions and Concepts

Sterile

Free from living organisms, especially microorganisms

Merriam-Webster definition

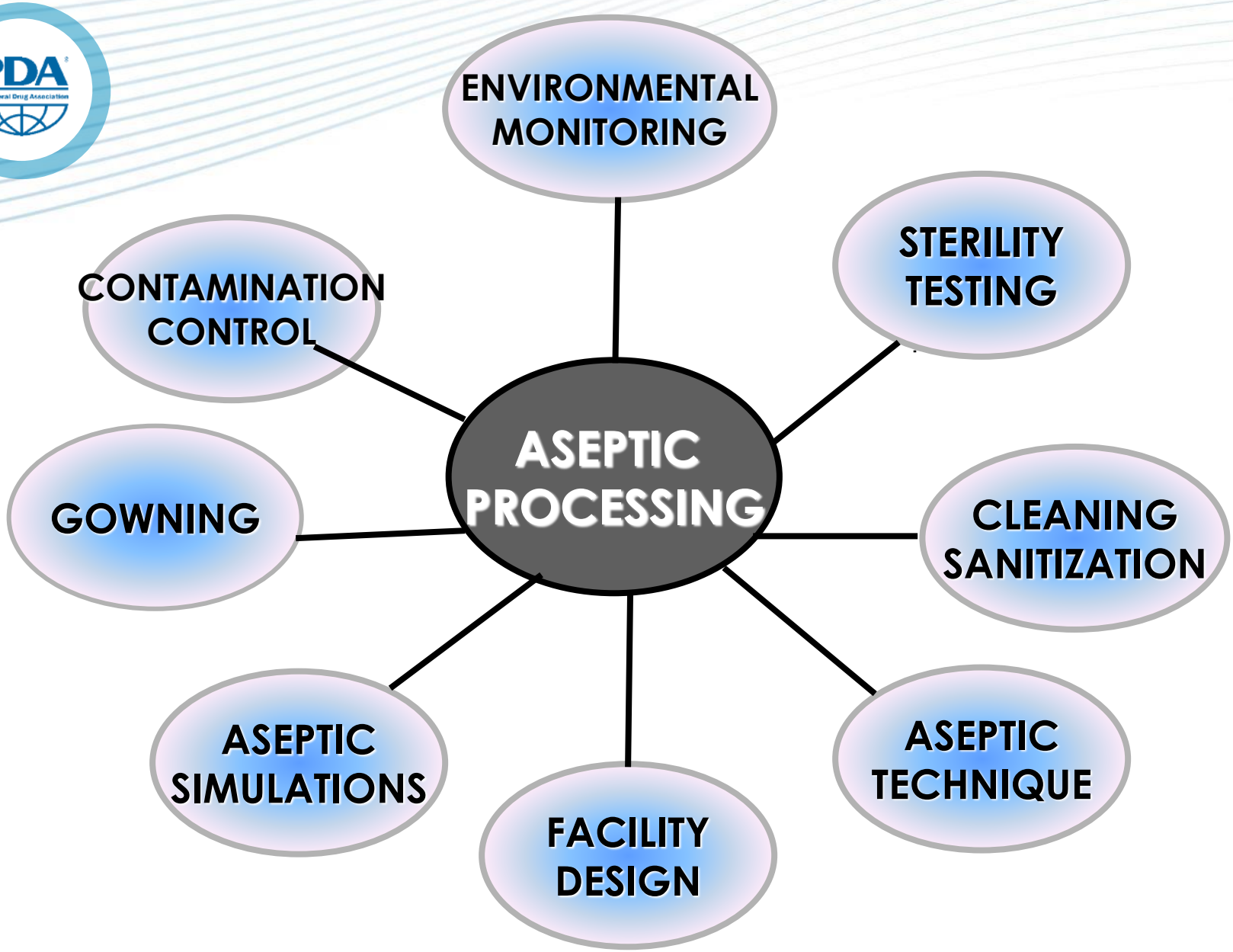


Definitions and Concepts

Aseptic Processing

WIKIPEDIA: Aseptic processing is the process by which a sterile (aseptic) product (typically food or pharmaceutical) is packaged in a sterile container in a way that maintains sterility.

The objective of aseptic processing methods is to assemble previously sterilized product, containers and closures within specially designed and controlled environments intended to minimize the potential of microbiological or particulate contamination.



Disclaimer

The following presentations reflect my personal Interpretations, Opinions and Best Practices, which may differ in some cases from current regulatory regulations !

The referenced PDA Technical Reports of the Training Agenda will not be addressed in detail, but I highly recommended to read them !

Please tell us about you…

- Your Name
- Your Company
- Your Position
- Your expectations for these 2 days

Introduction and Scope

Interactive !

For each presentation : let us recap “3 simple Take Away Messages”

INTRODUCTIONAL TEST AND COME TOGETHER SESSION

- **QUESTION 1**: A passing sterility test in the micro-lab assures, that an aseptically prepared batch is 100 % sterile – C or W , and comments
- **QUESTION 2**: A passing Media Fill run in the production assures, that all produced batches are sterile – C or W , and comments
- **QUESTION 3**: is it required as a Site QA Head to be present – at defined intervals - at the shop-floor in the manufacturing facility- C or W, and comments
- **QUESTION 4**: my company received a FDA Warning Letter – are we still allowed to sell product to USA – C or W, and comments

INTRODUCTIONAL TEST AND COME TOGETHER SESSION

- **QUESTION 5**: A breakdown occurred during routine aseptic filling, and a “risky” corrective intervention was required by a mechanic, which never has been simulated in a Media Fill. Afterwards batch filling has been continued: am I allowed to release the batch ? – C or W , and comments
- **QUESTION 6:** A microbiological EM excursion within grade A always requires a rejection of the batch– C or W , and comments
- **QUESTION 7**: An operator is allowed to participate in routine batch filling , after he/she gas been qualified for gowning - C or W, and comments
- **QUESTION 8**: A closed isolator provides a better protection against microbial/ particulates contamination than a RABS or open filling cabinet and if YES : WHY – C or W, and comments

INTRODUCTIONAL TEST AND COME TOGETHER SESSION

- **QUESTION 9**: The detection of bacterial spore-formers during EM is a common incidence within grade A/B cleanrooms – C or W , and comments
- **QUESTION 10**: Microlab: during Sterility Testing the technician identified a pinhole in the glove (outer glove of 2); Testing has been continued after exchange; Test failed; Invalidate Test – YES or NO , and comments
- **QUESTION 11**: a sterilizing filter failed the Post filter integrity testing(after filtration) – am I allowed to repeat integrity testing? How helpful is bioburden result of "0 cfu/ 100 ml", achieved 1 week later ?… YES or NO , and comments
- **QUESTION 12:** A Risk assessment should justify or analyze a process (proactive) or a deviation (retrospective) , and discuss why – please decide, and comments

3 Take Away Messages