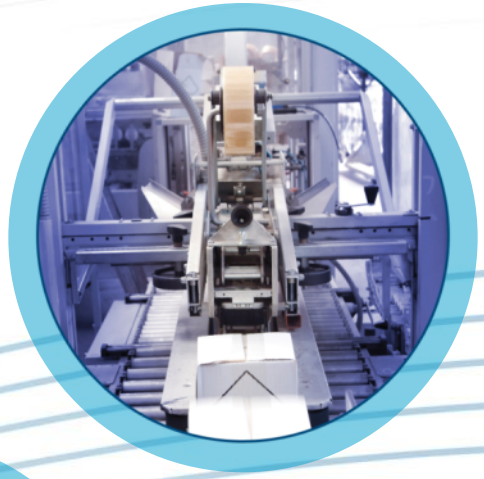
PDA Parenteral Drug Association

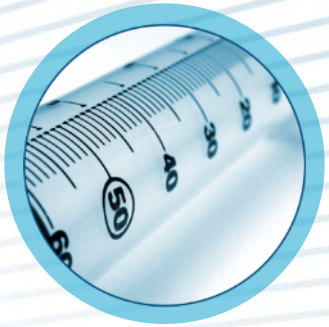
Connecting People, Science and Regulation®

Best Practices and Points to Consider in Aseptic Processing

Munich, 5. and 6. September 2019

by Guenther Gapp



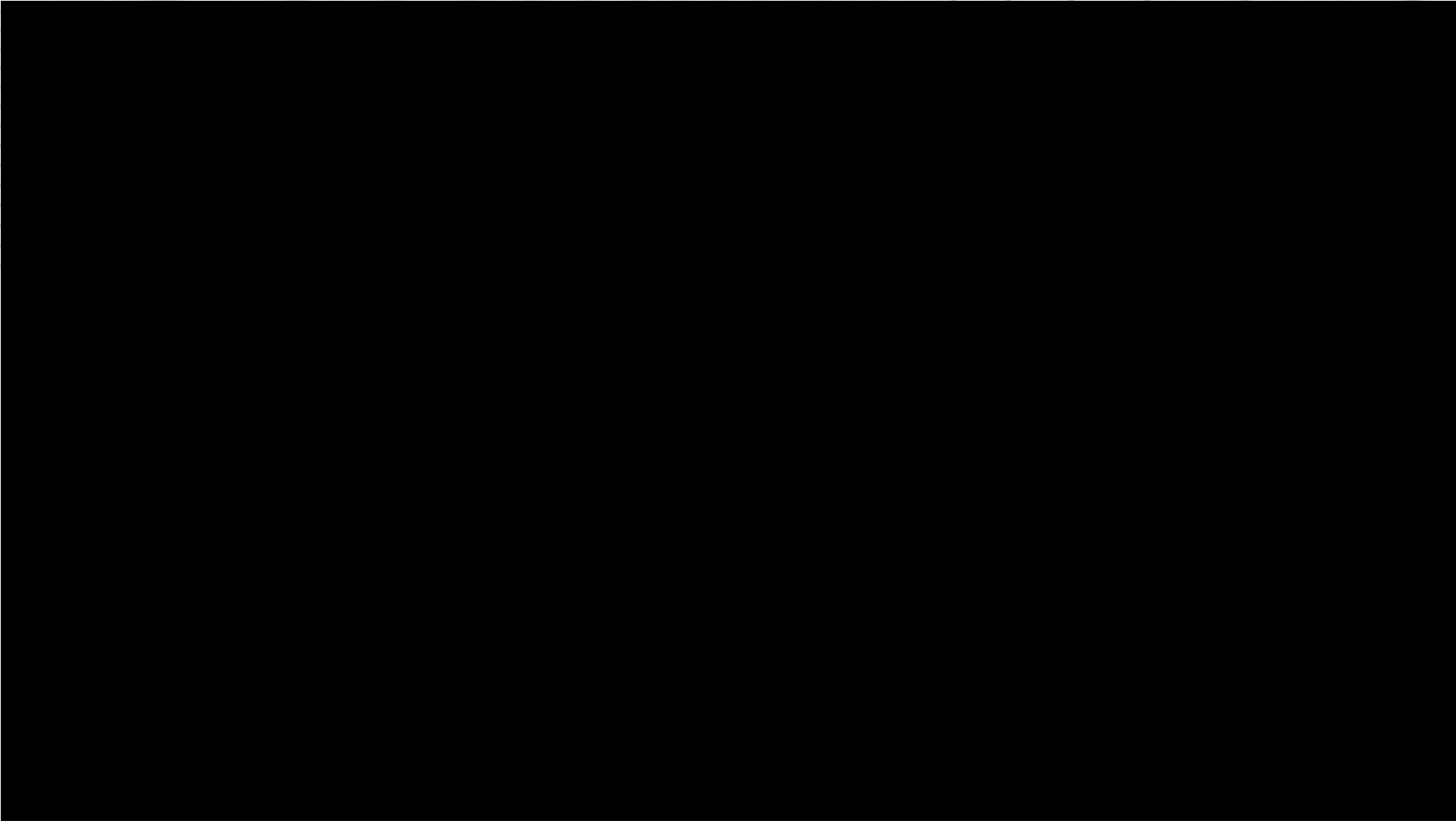


Dr. Guenther Gapp - Instructor

- 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 Assessments Tool for Sterile Products
- 7 years independent Consultant
  - 50 projects worldwide: USA/ India/ Europe/Korea/ Brasil/…
- > 20 Years PDA
  - Publication Award 2011 (Sterile Product Compliance RA)
  - Speaker at PDA and other conferences since 2010
  - PDA EU Annex 1 Revision Task Force Member
  - Chair Taskforce ”Points to Consider for Isolators”
  - Member Science Advisory Board
  - TR 13 / TR 22 Revision TF Member
- 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 !

Aseptic Processing: People !

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 has 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