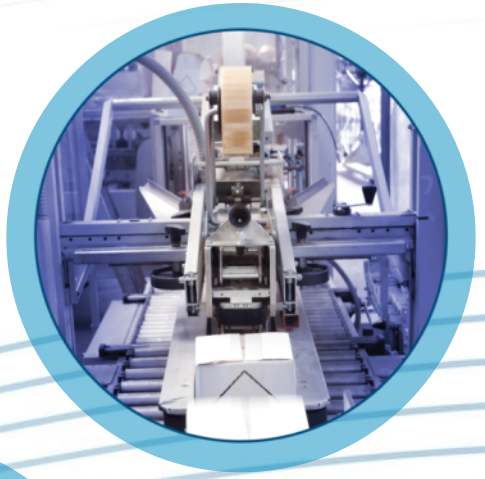
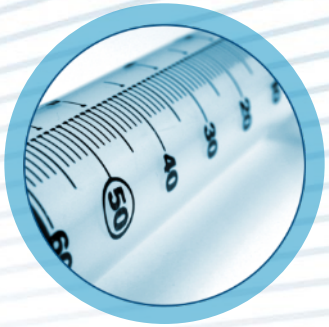
Connecting People, Science and Regulation®

Best Practices and Points to Consider in Aseptic Processing

Amsterdam, 22. and 23. September 2022

by Guenther Gapp & Sebastian Scheler





Dr. Guenther Gapp - Instructor

- SME : Aseptic Processing & Microbiologist
- 20 years with Sandoz/ Novartis in Austria
  - Head QA/ QC Microbiology
  - > 20 FDA audits as SME
  - Global Sterility Assurance Expert & Troubleshooter
  - Created Risk Assessments Tool for Sterile Products
- 10 years independent Consultant
  - + 70 projects worldwide: India/ Europe/Korea/ USA/…
- > 25 Years PDA
  - Publication Award 2011 (Sterile Product Risk Assessment)
  - Speaker at PDA and other conferences since 2010
  - PDA EU Annex 1 Revision Task Force Member
  - Chair TR ”Points to Consider for Isolators”
  - Member Science Advisory Board
  - Chair TR 28 Survey / TR 13 / TR 22 Revision Team Member
  - Aseptic Training Course since 2017 (J. Agalloco Award 2022)
- WEBSITE: www.gappquality.com

Sebastian Scheler

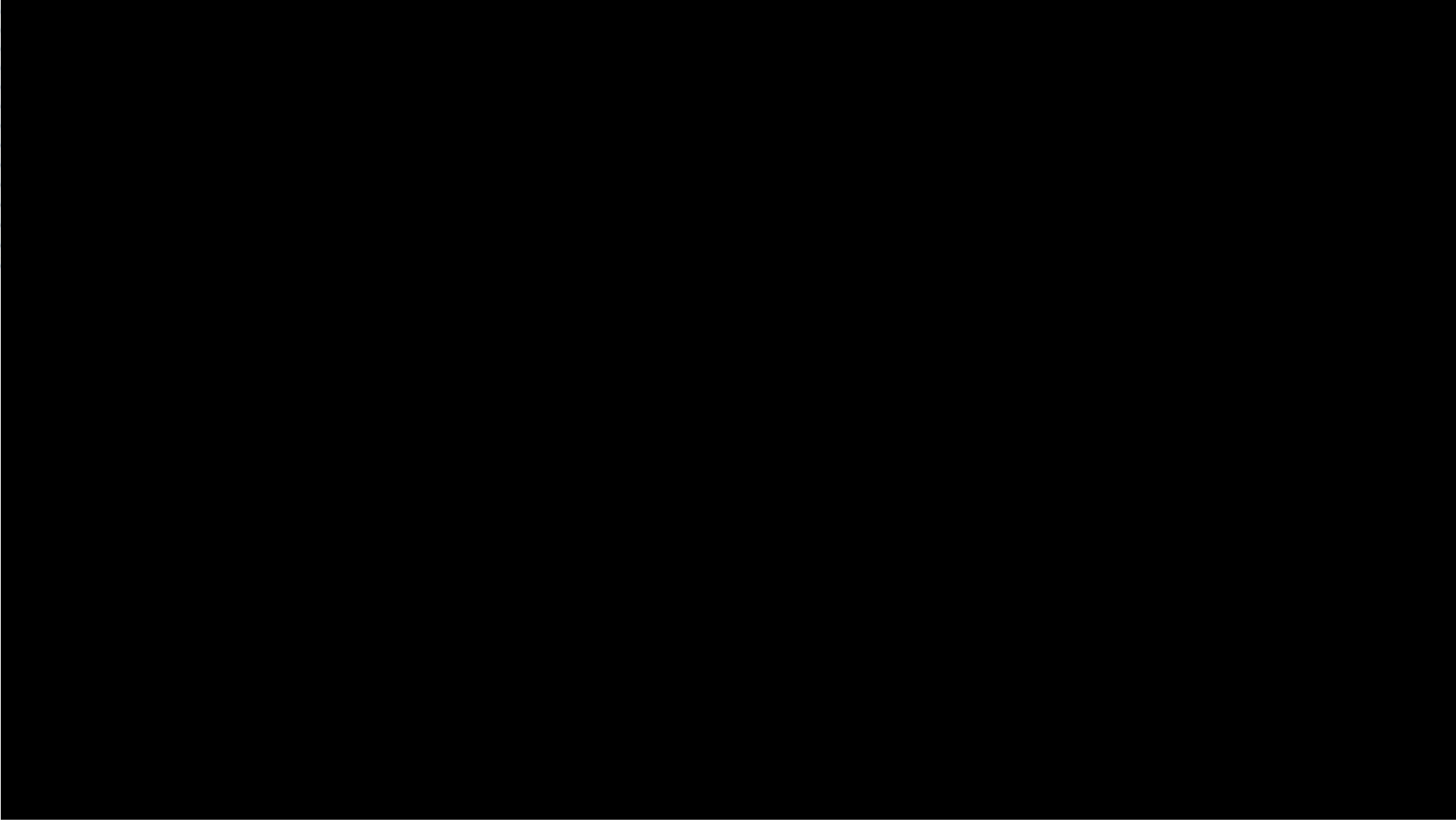
- Psychologist, professional trainer and expert for behavioral science and human error analysis
- Focus on human error awareness and training of aseptic techniques and cleanroom understanding
- Managing Director and Chief Methodologist at Innerspace, a global provider of high-end virtual reality simulators.

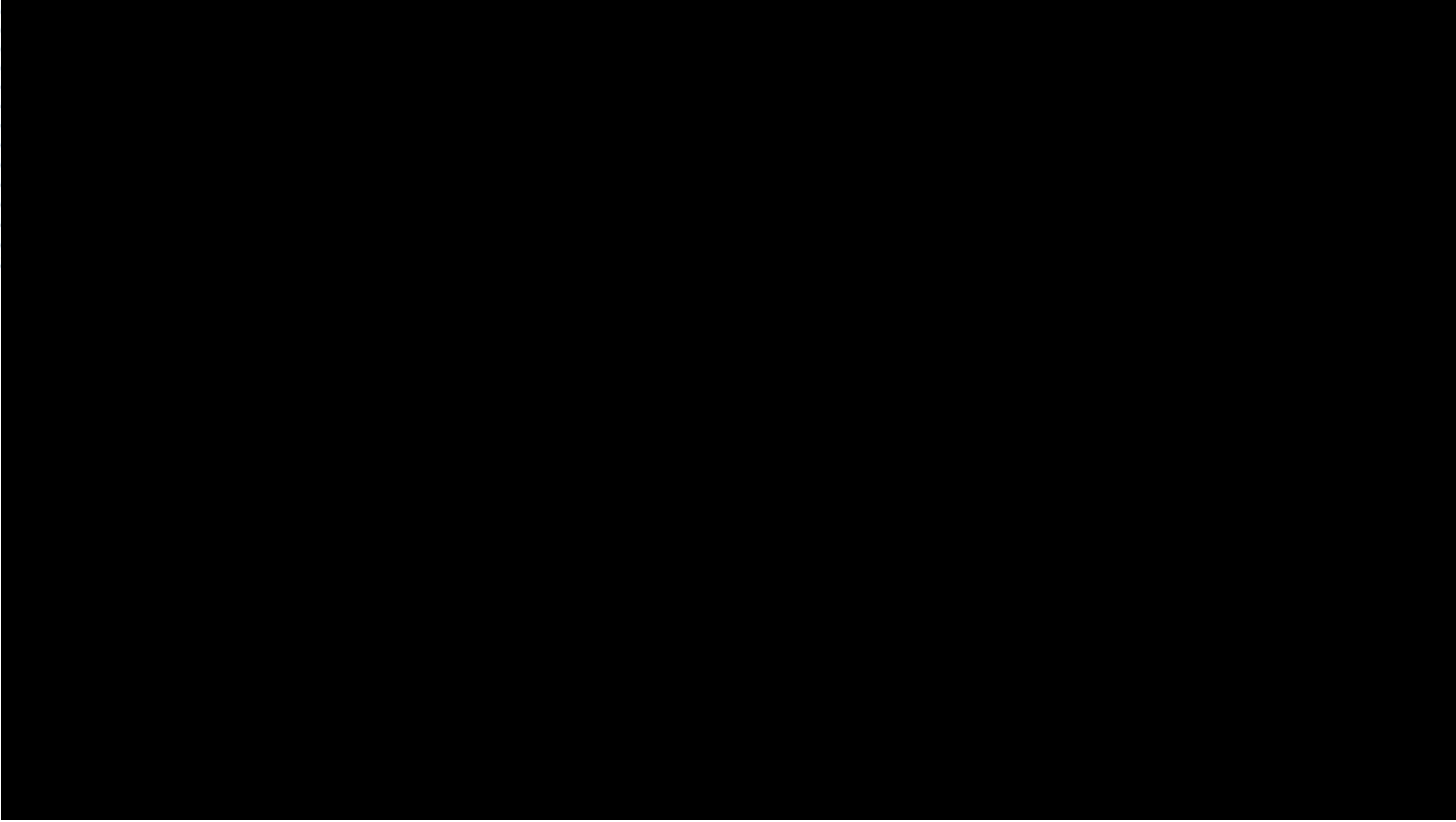
Please tell us about you…

- Your Name
- Your Company
- Your expectations

Risk Management in my leisure time

Mistakes have certainly a dramatic consequence, and there are a lot of parallels to Aseptic Processing !





Parallels to Aseptic Processing

- must have good equipment
- 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 for yourself and others
- have always to be aware that “human errors” might happen (also from others) – be prepared !

Agenda : Key Topics

Thursday, 22 September 2022

Welcome and Collection of Expectations of Participants

Important Aspects of Sterilization, Cleaning and Disinfection, Gowning Procedures

Aspects of Clean Room Concepts and Good Aseptic Working Practices

VR Technology and Training (both days)

Friday, 23 September 2022

Best Practices in Aseptic Processing Simulation

Effective Oversight at the Shop Floor, Good Training Methods

Important Aspects in Environmental Monitoring

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 technician glove (outer glove/ inner glove not damaged); Testing has been continued after exchange; Test failed; Invalidate Test – YES or NO
- **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). Is this correct, and discuss why – please decide, and comments

NOW LET`S START