Best Practices and Points to Consider in Aseptic Processing

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PDA Parenteral Drug Association

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Dr. Guenther Gapp / Introduction

- 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
  - 100 projects worldwide: India/ Europe/Korea/ USA/ Japan/…
- > 25 Years PDA
  - PDA Journal Publication Award 2011 (Sterile Risk Assessment)
  - Speaker at PDA and other conferences since 2010
  - PDA EU Annex 1 Revision Task Force Member
  - Co- Chair TR ”Points to Consider for Isolators”
  - Member Science Advisory Board for 6 years
  - Chair TR 28 Survey/ Member TR 13 (2022)
  - TR 22 Revision Member
  - Europe: Aseptic Training Courses since 2017 (J. Agalloco Award 2022)-
  - Since 2023: PTC RABS Co-Chair
  - PTC 1 and 2 Aseptic revision team member

- WEBSITE: www.gappquality.com

Sebastian Scheler

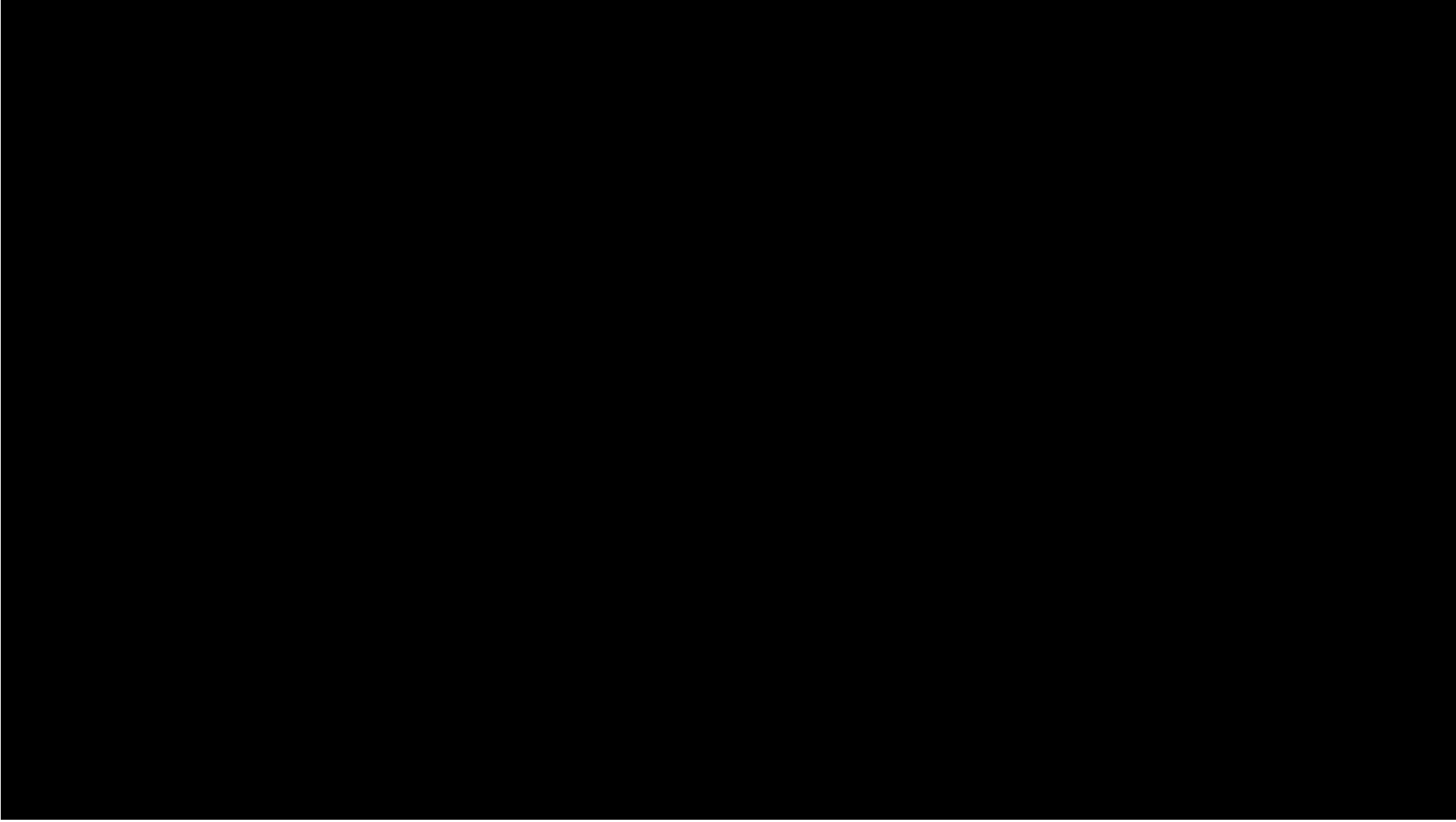
- Psychologist, professional trainer and expert for behavioral science and human error analysis
- Focus on human error awareness and training of aseptic techniques and cleanroom understanding
- Managing Director and Chief Methodologist at Innerspace, a global provider of high-end virtual reality simulators.

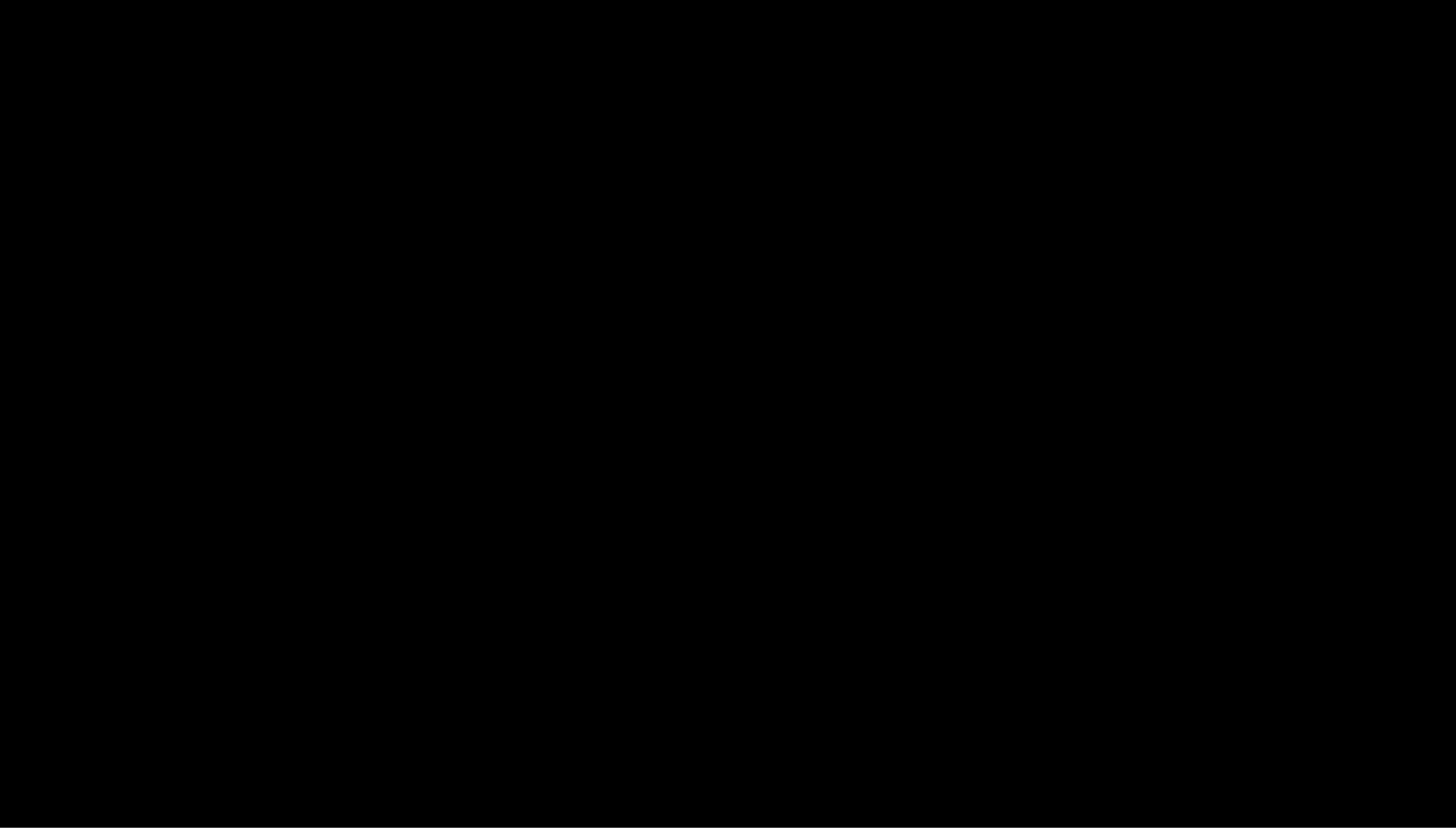
Please tell us about you…

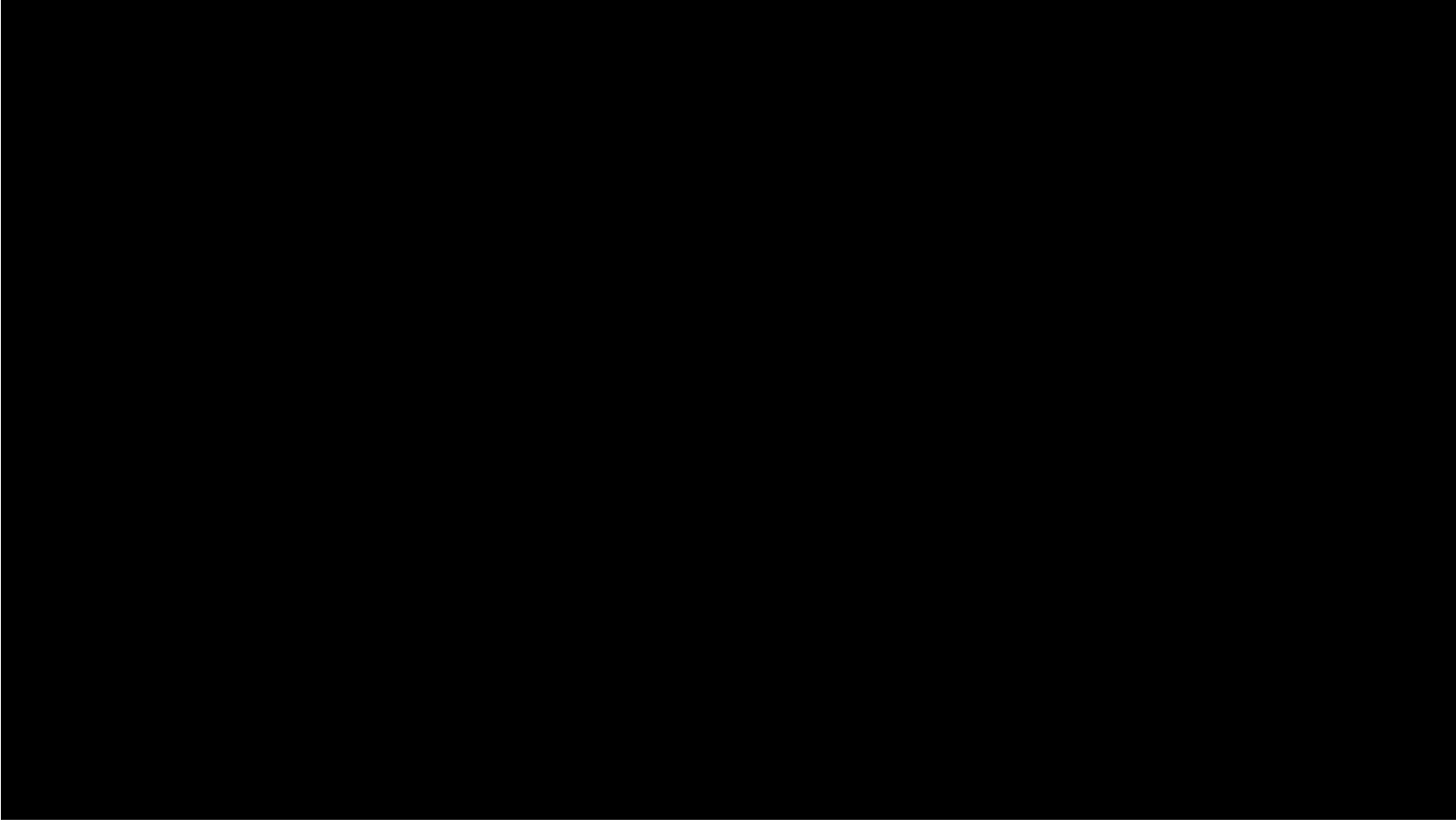
- Your Name
- Your Company
- Your expectations

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 !

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