



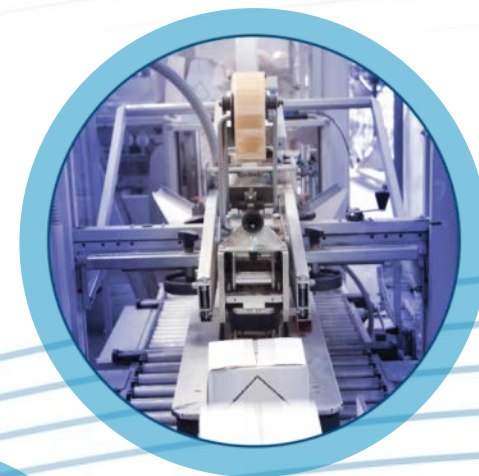
Connecting People, Science and Regulation®

Best Practices and Points to Consider in Aseptic Processing

18 and 19 October 2021

ONLINE

by Guenther Gapp

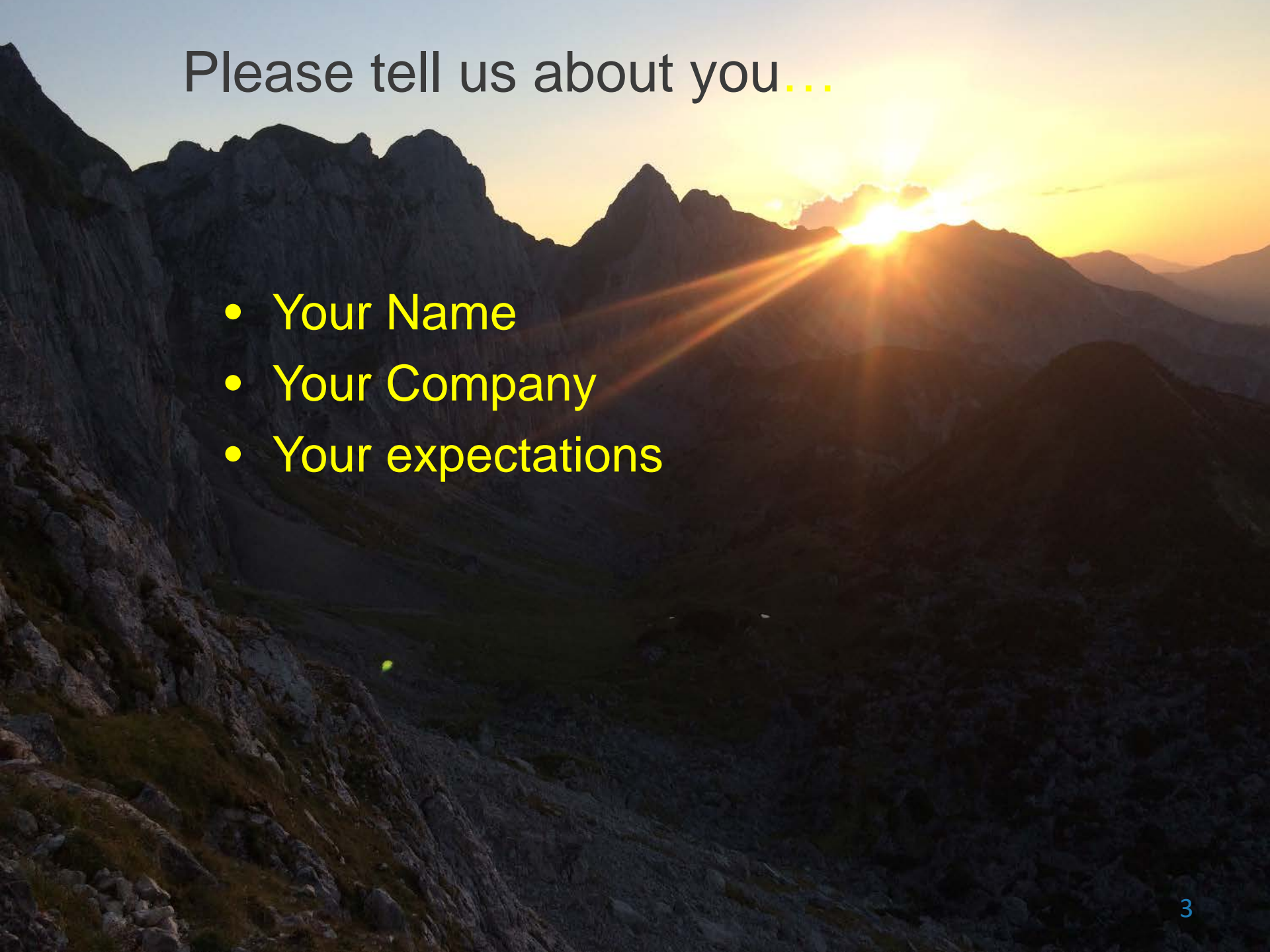




Dr. Guenther Gapp - Instructor

- 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
- 9 years independent Consultant
 - > 50 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
 - TR 28 Survey / TR 13 / TR 22 Revision TF Member
- WEBSITE: www.gappquality.com





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



Video



Video



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
- have always to be aware that “human errors” may (also from others) – be prepared !



Agenda :

Monday, 18 October 2021

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

Tuesday, 19 October 2021

Best Practices in Aseptic Processing Simulation

Effective Oversight at the Shop Floor, Good Training Methods

Important Aspects in Environmental Monitoring



Aseptic Processing: it's a lot about People !

Video



NOW LET`S START