






Time	ECA – Modern Sterile Operations 100% Control of Parenterals	ECA – Aseptic Technologies Current Aseptic Technologies	ECA – Data Integrity	Time
9:00 h	 Pharmaceutical Industry in digital change <i>Thomas Reiner, CEO, Berndt+Partner</i>			9:00 h
9:15 h				9:15 h
9:30 h				9:30 h
9:45 h				9:45 h
10:00 h				10:00 h
10:15 h	Break			10:15 h
10:30 h	Pharmacopeial- and GMP-requirements for visual inspection <i>Dr Daniel Müller, Local Authority of Baden-Württemberg</i>			10:30 h
10:45 h				10:45 h
11:00 h	Innovative therapeutic options – a challenge to aseptic technologies <i>Gerd Moelgaard, ECA Validation Interest Group</i>			11:00 h
11:15 h				11:15 h
11:30 h	Data Integrity in manufacturing and engineering environments - Another source of weaknesses or Compliance by Design? <i>Yves Samson, ECA DI & IT Compliance Interest Group</i>			11:30 h
11:45 h				11:45 h
12:00 h	Pharmacopeial- and GMP-requirements for Container-/Closure-Integrity testing <i>Dr Daniel Müller, Local Authority of Baden-Württemberg</i>			12:00 h
12:15 h				12:15 h
12:30 h	The evolution of current aseptic technologies <i>Dr Friedrich Haefele, Boehringer Ingelheim Pharma</i>			12:30 h
12:45 h				12:45 h
13:00 h	Requirements in Data Integrity <i>Dr Gerald Kindermann, F. Hoffmann La-Roche</i>			13:00 h
13:15 h				13:15 h
13:30 h	Lunch Break			13:30 h
13:45 h	Delivery of a Flexible Aseptic Filling Facility to a CMO <i>Dr Abdulaziz Awad, Saudi Biotechnology Manufacturing Company</i>			13:45 h
14:00 h				14:00 h
14:15 h	Requirements for Operating Computerized Systems and Data Management <i>Dr Philip Hörsch, Vetter Pharma Fertigung</i>			14:15 h
14:30 h				14:30 h
14:45 h	Bosch PreVAS Single-Use Dosing System – PreVAS means: - PreValidated / - PreAssembled / PreSterilized – Bosch Sterilizer validation / qualification made easy <i>Ellab</i> Fully automatic and integrated particle detection system for filters in hot air sterilization tunnels and LAF units <i>Bausch + Ströbel</i> Vial filling line VIRTUAL REALITY experience <i>Steriline</i>			14:45 h
15:00 h				15:00 h
15:15 h	Data Integrity from a QP's Perspective <i>Gabriela Schallmeiner, Austrian QP Association</i>			15:15 h
15:30 h				15:30 h
15:45 h	Break			15:45 h
16:00 h	Case Study Rommelag CMO – 100% inline CCI Testing and particle inspection of BFS ampoules <i>Dr Martin Haerer, Rommelag</i> <i>Dr Matthias Kahl, Wilco</i>			16:00 h
16:15 h				16:15 h
16:30 h	Case study Vetter Pharma-Fertigung: Next steps in the development of V-CRT®; Analytical monitoring of H ₂ O ₂ decontamination processes <i>Dr Ute Schleyer, Vetter Pharma-Fertigung</i>			16:30 h
16:45 h				16:45 h
17:00 h	Head Space Analysis for difficult to inspect containers <i>Wilco</i> Substitution of formaldehyde room decontamination by hydrogen peroxide and acceleration of decontamination process by application of innovative catalyst technology for effective decomposition of hydrogen peroxide <i>Stefan Bieler, IDT-Biologika</i>			17:00 h
17:15 h				17:15 h
17:30 h	Inspecting DI in Manufacturing – what does an inspector expect? <i>Dr Arno Terhechte, Regional Council Münster</i>			17:30 h
17:45 h				17:45 h
18:00 h	Social Event for Congress Delegates, Speakers and Exhibitors			18:00 h

Time	ECA – Modern Sterile Operations Sterile Filtration	ECA – Aseptic Processing RABS & Isolators	ECA – Data Integrity	Time
9:00 h	 EU GMP Inspection in Sterile/Aseptic Production <i>Klaus Eichmüller, Wolnzach, c/o Regional Council Darmstadt, GMP Inspectorate, Germany</i>			9:00 h
9:15 h				9:15 h
9:30 h				9:30 h
9:45 h	Break			9:45 h
10:00 h	Break			10:00 h
10:15 h	Break			10:15 h
10:30 h	Sterile Filtration - GMP inspector's view <i>Dr Daniel Müller, Local Authority of Baden-Württemberg</i>	Closure Processing System for rubber stoppers: key aspects to consider to ensure process robustness in routine production <i>Sandrine Favre, Octapharma</i>	Data Integrity requirements to technical suppliers - Expectations to equipment suppliers and engineering service providers <i>Yves Samson, ECA DI & IT Compliance Interest Group</i>	10:30 h
10:45 h	Break			10:45 h
11:00 h	Adoption of a Single-Use Sterile Filtration Assembly <i>Merck Chemicals</i>	 Case study GSK Vaccines: Isolator decontamination by H₂O₂ nebulization process <i>Patrick Vanhecke, GSK Vaccines</i>	Audit trail functionality and review – expectations from an inspector <i>Ib Alstrup, DMA</i>	11:00 h
11:15 h	Sterilizing-grade Filtration in Biopharmaceutical Applications <i>Pall Life Sciences</i>			11:15 h
11:30 h	Break			11:30 h
11:45 h	Break			11:45 h
12:00 h	Break			12:00 h
12:15 h	Break			12:15 h
12:30 h	Break			12:30 h
12:45 h	Break			12:45 h
13:00 h	Break			13:00 h
13:15 h	Case study: Inline-Filtration using peristaltic pump: Implementation of a pressure control <i>Doris Rottenbusch, Vetter Pharma-Fertigung</i>	Key considerations for gene therapy manufacturing from early stage to fill-finish operations <i>Thomas Page, Fujifilm Diosynth Biotechnologies</i>	Expectations of an inspector on a training system with respect to data management <i>Klaus Eichmüller, Wolnzach, c/o Regional Council Darmstadt, GMP Inspectorate, Germany</i>	13:15 h
13:30 h	Break			13:30 h
13:45 h	Break			13:45 h
14:00 h	Sterile filtration – microbiological filter validation <i>Matthias Schaar, Novartis Pharma</i>	 DECOpulse® – The H₂O₂ bio-decontamination system with atomization-driven evaporation <i>Metall + Plastics</i> TBN <i>MK Versuchsanlagen und Laborbedarf</i>	 A Paperless Lab, a Good Idea for Data Integrity, Risk Minimization and Lean Management? <i>Dr Thomas Meindl, Labor LS</i>	14:00 h
14:15 h	Break			14:15 h
14:30 h	Break			14:30 h
14:45 h	Break			14:45 h
15:00 h	Break			15:00 h
15:15 h	TBN	TBN	Data Integrity Assessment Manufacturing: Preparation, Conducting and Remediation Activities <i>Stefan Schöttle, Roche Diagnostics</i>	15:15 h
15:30 h	Break			15:30 h
15:45 h	Break			15:45 h
16:00 h	TBN	The specific case of use of isolators and biosafety cabinets type III in Hospital Pharmacy <i>Prof Farshid Sadeghipour, Lausanne University Hospital</i>	TBN <i>Miro Zdilar, Teva</i>	16:00 h
16:15 h	Break			16:15 h
16:30 h	Break			16:30 h
16:45 h	Discussion	Discussion	Discussion	16:45 h
17:00 h	Break			17:00 h