Programme – 15 September 2020

Time	ECA – Data Integrity	ECA – Current Aseptic Technologies	ECA – Bioprocessing	ECA – Integrated Qualification with Suppliers
9:00 h	Key Note: Annex 1 Revision – the long and winding road *Dr Bernd Renger, Immediate Past Chair, European Qualified Person Association*			
9:15 h				
9:30 h				
9:45 h				
10:00 h	Break			
10:15 h				
10:30 h	Data Integrity from an Inspector's Point of View *Maria Kladi, National Organization for Medicines, Greece*	The evolution of Aseptic Technologies *Dr Friedrich Haefele, formerly Boehringer Ingelheim*	Technological overview: Single-use technologies for intensified and continuous bioprocesses (USP & DSP) *Prof Dr Regine Eibl , Zürcher University of Applied Science*	Future qualification and validation involves suppliers *Gert Moelgaard, ECA Validation Group*
10:45 h				
11:00 h				
11:15 h	Data Integrity by Design *Stefan Schöttle, Roche Diagnostics*	Challenges in manufacturing high value lyophilized oncologics - a case study *Fabio Gentilini, BSP Pharmaceuticals*	Live Demos: Intensified Downstream Processing through Continuous Manufacture *Pall Biotech*	GEP for Suppliers – A Prerequisite for Fast Track Qualification projects? *Ralf Gengenbach, gempex*
11:30 h				
11:45 h				
12:00 h	Lunch Break			
12:15 h	Virtuelle 3D-Einbausimulation und 3D-Kollisionsprüfung von Maschinen und Anlagen – MehrTec			
12:30 h	Aerosol Alcohol Applicator demonstration – Steris			
12:45 h	Live Demos: Leak testing during prodution of single use equipment – Lippok & Wolf			
13:00 h	Prozessindustrie 4.0 - CONEXO – GEMÜ			
13:15 h	Live Derouging mit BERA-DE NT und Deblacking mit BERA-GC HC – Beratherm			
13:30 h	DI as topic of GMP-inspections; an inspector's view *Dr Arno Terhechte, Bezirksregierung Münster*	From design to construction of a new integrated fill&finish facility – combination of proven and new technologies *Dr Gabriele Sabine Roidl, Lonza*	Continuous Biomanufacturing - a GMP inspector's view *Dr Daniel Müller, Local GMP Authority of Baden Württemberg*	Customer-Supplier Cooperation: A project example from Merck Healthcare KGaA *Holger Frey, Merck*
13:45 h				
14:00 h				
14:15 h	CASE STUDY - A risk based approach for systematic DI-assessments and -mitigation *Hannah Greiner, Epista Life Science*	Live Demos: B+S Multi Dosing System - 3 in 1! *Bausch + Ströbel*		An effort to build smarter: Transforming Novo Nordisk´s qualification and validation concept to focus on GEP and supplier collaboration *Peter Larsson, Novo Nordisk*
14:30 h		Single-Use Technology in Aseptic Processing – *Merck*		
14:45 h		Isolator Technology & RTP Transfer Systems – *Metall + Plastic | Castus*		
15:00 h	Break	N.N. *MK Versuchsanlagen*		
15:15 h	Live Demo 6 DPTE Transfer Trolley, the mobile transfer platform for smart use with all DPTE Beta solutions – Getinge			
15:30 h	Live Demos: High pressure washing in the pharma environment – IWT Tecniplast			
15:45 h	Requirements for Operating Computerized Systems and Data Management *Dr Philip Hörsch, Vetter Pharma Fertigung*	Case Study: Cycle Development & Validation of automated AHP decontamination processes for cleanrooms *Dr Markus Lesch, Vetter Pharma-Fertigung*	Case Study Biosana: Continuous Manufacturing of biosimilar antibodies: a small company's journey to phase 1 clinical studies *Maarten Pennings, Biosana*	Using ECA's Modern Qualification Guide as a pharmaceutical customer *Eva-Maria Baumgartner, Syntacoll*
16:00 h				
16:15 h				
16:30 h	Data Integrity Compliance Improvement: A Combined Approach to Mitigation *Matthias Runge, Bayer* *Dirk Denecke, Bayer*	EirGen Pharma– How state-of-the-art fill & finish equipment flexibility supports CMO business *Dermot O'Riordan, EirGen*	Case Study Bayer: Continuous Downstream Processing for manufacturing of protein therapeutics *Dr Felix Oehme, Bayer*	Panel Discussion
16:45 h				
17:00 h				
17:15 h	Discussion	Discussion	Discussion	
17:30 h				
18:00 h	Social Event for Congress Delegates, Speakers and Exhibitors			

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Programme – 16 September 2020

ECA –Data Integrity	ECA - Current Aseptic Compliance	ECA – Barrier Systems	Time
Key Note: Case Study AbbVie: The new Biologics Site in Singapore *Dr Rolf Ratke, Abbvie | Ronan Mc Garvey, AbbVie*			9:00 h
			9:15 h
			9:30 h
Break			9:45 h
			10:00 h
Data Integrity implementation at Curium *Dr Ruud van Stigt, Curium*	Status of Annex 1 revision? *Dr Beate Reutter, Landesamt für soziale Dienste Schleswig-Holstein, Kiel, Germany*	Grey Field Project for Production of Large Scale Bacterial antigen in an Aseptic Environment *Udara Yapa, MSD Animal Health Danube Biotech*	10:15 h
			10:30 h
			10:45 h
Practical applications of Data Integrity and Audit Trail Review *Sinéad Cowman, Lonza*	Environmental Monitoring in Modern Biopharmaceutical DP Facilities – A Proposal for a Harmonized Risk Based Approach for Selecting Monitoring Points and Defining Monitoring Plans *Patrice Wery, GSK Vaccines*	Aseptic processing and filling of a viral vector for gene and cell therapy *Leslie Southam, Oxford Biomedica*	11:00 h
			11:15 h
			11:30 h
Lunch Break			11:45 h
			12:00 h
Autoklavenvalidierung/-qualifizierung leicht gemacht – Ellab			12:15 h
Live Demos: Experience a new generation of transfer hatches live! – Ortner			12:30 h
Stimmt der Druck im Tank? – Bürkert Fluid Control Systems			12:45 h
Practical Examples found and case studies on how to challenge DI potential issues *Swa Vandeweyer, formerly Janssen Pharmaceutica*	Case Study: Media Fill Design for aseptic Blow Fill Seal Filling *Dr Martin Haerer, Rommelag CMO*	Barrier Systems and Annex 1: GMP inspectors's point of view *Dr Daniel Müller, Local GMP Authority of Baden Württemberg*	13:00 h
			13:15 h
			13:30 h
Data Integrity in the interaction between business departments and IT as service provider *Thomas Wibbeling, Miltenyi Biotec*	Single Use Bioreactor Platform(SUB) for Microbial Fermentation in a GMP manufacturing facility *Dr Sofia Venceslau, Genibet*	New-Designed Isolator for Aseptic Filling *Quentin Majeau, Hydro Fill*	13:45 h
			14:00 h
			14:15 h
Break			14:30 h
			14:45 h
Data integrity from engineering to operations based on Comos DDMS at Boehringer Ingelheim *Günther Kurta, Boehringer Ingelheim*	Challenges and Opportunities of Aseptic Manufacturing Process Transfers *Dr Martin Schwab, Vetter Pharma-Fertigung*	Vaccines for the World - Insights into Design and Execution of a BSL2 Fill-Finish Facility *Rutger Vandiest, Bavarian Nordic*	15:00 h
			15:15 h
			15:30 h
Data Integrity and Process Validation: a virtuous circle *Yves Samson, ECA Data Integrity & IT Compliance Interest Group*	Areas of focus for Auditors of Sterile Operations *Hesham Elrayes, B. Braun*	Writing User Requirement Specifications (URS) for Isolator projects *Dr Timo Krebsbach, HHAC Labor Dr Heusler*	15:45 h
			16:00 h
			16:15 h
Discussion	Discussion	Discussion	16:30 h
			16:45 h
			17:00 h

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