2023 PDA Good Aseptic Manufacturing Conference

Solutions for Implementation of New EU GMP Annex 1 in Current Operations

Leipzig/Germany

23-24 May 2023

Tuesday, 23 May 2023		**09:00-17:25**
9:00	Welcome and Introduction	Falk Klar, *PDA Europe*
9:05	Welcome from the Chairs	Kerstin Wilken, *IDT Biologika* Paul Devuyst, *GSK*
Opening Plenary: Regulatory and Industry Updates		**Moderator: Kerstin Wilken, *IDT Biologika***
Session Description: In this session you will learn about the authorities' expectations for implementation of the new Annex 1 e.g., regarding the application of QRM. Also, the impact for aseptic fill & finish, manufacturer and user will be presented and discussed.		
9:15	**Opening Keynote:** Points-to-consider Implementing EU GMP Annex 1	Tracy Moore*, TM Pharma Group* & Richard Denk, *SKAN*
9:45	A Rapid Microbiological Methods in the Light of Annex	Christina Meissner, *AGES*
10:15	**Coffee Break, Poster Session & Exhibition**	
10:45	Transfer of People and Materials	Tracy Moore*, TM Pharma Group*
11:15	Impact of the Filling Machine, Manufacturer and User	Rainer Glöckler, *Ten23 Health* *&* Ralf Wagner, *Optima pharma GmbH*
11:40	Interactive Questionnaire Session	
11:55	Q&A, Panel Discussion	

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12:40	**Lunch Break, Guided Poster Session & Exhibition**			
Session 1	**Track A** **Barrier Systems**	**Moderator: Richard Denk, *SKAN***	**Track B** **Contamination Control Strategies**	**Moderator: Tracy Moore, TM Pharma Group**
Session Description: Barrier Systems are mentioned 15 times in the EU GMP Annex 1 and any alternative use should be justified. Closed RABS or Isolators are the recommended technologies as well as fully gloveless robotic aseptic filling lines. The first Robotic Award-Winning Solution will be presented from Novartis together with Groninger. What other challenges are addressed with new technologies in accordance with the new Annex 1 will be presented in this session from PM Group.			**Session Description:** During this session, the first presentation will provide guidance on implementing an effective Contamination Control Strategy (CCS) across an existing CDMO facility including best practices for robust sterility assurance. We'll also discuss during the second presentation, control elements to protect critical product contact surfaces and filling environments. End-user case studies will demonstrate successful CCS analysis and how to maintain sterility assurance and critical environment continuity.	
14:00	Gloveless Robotic Filling Line - How to meet Regulatory and Industry Requirements	Julian Petersen, *Groninger* & Aleks Kapun, *Novartis*	Contamination Control Strategy - From the Requirements of Annex 1 to Implementation	Helen Sauter, *Vetter*
14:25	Challenges for New Technologies in Sterile Medicinal Products - Outlined in the Revised Annex 1 Regulation	*Alan Kelly, PM Group*	Sterility Assurance and Contamination Control Strategies	Aaron Mertens, *STERIS*
14:50	Q&A, Discussion		Q&A, Discussion	
15:20	**Coffee Break, Poster Session & Exhibition**			

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Session 2	**Track A** **Aseptic Processing**	**Moderator: Peter Makowensky, GCon Bio**	**Track B** **CCS - focus testing**	**Moderator: Andrea Salmaso, Stevanato**
Session Description: At the heart of patient safety, aseptic processing is a critical component of drug product manufacturing. What tools are available to properly assess risk in our processes and enable process improvement? Is all autoclave packaging created equal and what processes should we employ to confirm what is most suitable and compliant? What risks exist around integrity testing of sterile filters post sterilization and what are best considerations? These are just a handful of topics the presenters will discuss ensuring everyone will leave enlightened from their discussions.			**Session Description:** Training and qualification of personnel are fundamental controls, and it can also be of benefit during the design and development phases of an aseptic manufacturing process. This session will give some insights how training and qualification could be embedded throughout the entire process lifecycle, including the use of novel technologies. The contamination control strategy is the fundamental basis of the new EU GMP Annex 1. This session will introduce some case studies regarding innovative techniques implemented or under implementation for ensuring the quality of components and products.	
15:50	PDA ANSI Standard Approach to QRM in Aseptic Processing	Amanda McFarland, *ValSource*	Development of a Holistic Aseptic Training Program – a Lifecycle Approach	Patrick Nieuwenhuizen, *Pharmalex*
16:05	Packaging Materials for sterilization process according to new Annex 1	Sara Iacoponi, *AM Instruments*	Fast Release of Sterile Primary Packaging Containers using a Rapid Microbial Method: Case Study	Greta Franzoso, *Stevanato* & Lucia Ceresa, *Charles River*
16:30	Implementation of PUPSIT to Compliment Annex 1	Terri Love & Stuart Rolfe, *Merck*	Moving Forward on Direction to Continuous and Real-time Environmental Monitoring for Aseptic Filling	Petra Merker, *Bayer*
16:55	Q&A, Discussion		Q&A, Discussion	
17:25	**End of Conference Day 1 & Networking Event**			

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Wednesday, 24 May 2023		**09:00-16:30**
Session 3	**Operators, Training & Qualification**	**Moderator: Gabriele Gori, Thermo Fischer**
Session Description: Despite the advancement of technology, personnel remain a key player in the efficient manufacturing of quality products. Proper training and qualification of new personnel, as well as keeping their knowledge and expertise updated in the shortest possible time is even more important in the modern fast-paced environment, where launching of new products and the prevention of mistakes to avoid delays and waste of resources are of outmost importance. In order to achieve this, it is critical to define WHAT to train, and HOW to train. The traditional approach, based on providing permanent staff or temporary employees with a mountain of written SOPs to be read and understood does not work. The next presentations will provide the "Frame-by-Frame Risk Profiling" a novel approach to identify the areas and activities requiring focus in the training sessions and concrete examples of the use of innovative training approaches based on Augmented Reality & Virtual Reality to effectively address these needs.		
9:00	Human Factor Control Strategy for Aseptic Manufacturing: Introducing a Frame-by-Frame Risk Profiling & Mitigation Approach	Sebastian Scheler, *Innerspace* & Ron Smith, *Johnson & Johnson*
9:25	Facilitating Short and Efficient Training Periods for New Personnel	Henning Künstler, *Körber Pharma Consulting*
09:50	Q&A, Discussion	
10:20	**Coffee Break, Poster Session & Exhibition**	
Session 4	**Disinfection/Decontamination**	**Moderator: David Keen, Ecolab**
Session Description: Cleaning, Disinfection and decontamination form a vital part of any sites Contamination Control Strategy, join us, and learn from experts, both users and suppliers of current best practise for implementation of these vital control points.		
10:50	Meeting the Challenges of Annex 1 with Innovation in Rapid H2O2 Validation	Kate Marshall, *Protak Scientific*

		& Claus Rosenvang, *NovoNordisk*
11:15	Collaborating to Innovate Effective Disinfectant Rotation Strategies for Contamination Control	Laura Brennan, *Ecolab* & Speaker invited
11:40	Q&A, Discussion	
12:10	**Lunch Break, Poster Session & Exhibition**	
Closing: Application of Aseptic Processing to Various Product Classes		**Moderator: Paul Devuyst, *GSK***
Session Description: Speakers will focus on the various aspects and share their experience on how innovative developments could be the perfect answer and/or how to integrate Annex1 prescriptions and the consequences on concepts up to real implementation of a filling area for high potent drug substances and curious to collect inspector's thoughts and feed-back related to material transfer from Grade C/D environment to Grade A restricted Barriers. This closing session will also give the time to collect and summarize the lesson learned of these two days event and give a taste of what will be seen during the Visit to IDT Biologika.		
13:10	Interactive Questionnaire Session	
13:20	Aseptic Processing for Advanced Therapies – From Manual to Fully Automated Fill & Finish	Thorsten Heafner, *PSM*
13:45	Implementation of a New Aseptic Filling Area at Sanofi Frankfurt – A Reflection on the Impact of Annex I Revision	Rebecca Geyer, *Sanofi*
14:10	**Coffee Break, Poster Session & Exhibition**	
14:40	**Passport Raffle**	

14:45	*Title to be announced*	Sandra Boyd, *U.S. FDA*
15:10	Intro to Site Visit at IDT Biologika – Title TBA	Ulrike Fiedler, *IDT Biologika*
15:35	Final Q&A and Panel Discussion	
16:15	Chairs Conference Summary	Kerstin Wilken, *IDT Biologika* Paul Devuyst, *GSK*
16:30	Closing Remarks & Farewell	Falk Klar, *PDA Europe*
16:35	**End of Conference**	