Aseptic Manufacturing – Maintaining the Validated State

LIVE at:

14th-15th June 2022 at DGI Byen, Copenhagen

A collaboration between Key2Compliance and ValidEire ApS

Sponsored by Novatek International

Conference description:

This two-day intensive summit brings together the industry leaders in compliance, aseptic manufacturing and maintaining the validated state. The conference will go beyond presentations on best practice and consists of both presentations and workshops on different aspects of aseptic manufacturing. Attendees will therefore gain a deeper understanding of the new messages from the new Annex 1 draft, FDA focuses on inspecting sterile facilities, sterilisation, process validation, life cycle approach and more. The conference will showcase some of the tech that impacts aseptic manufacturing.

In addition to the many presentations and workshops, the conference will also provide many opportunities for networking. Read more about the individual presentations in the full agenda.

The conference will be a hybrid event, and this enables attendees to either view online or be physically present at the event. We believe this is optimal for our customers in the current climate and hope you will attend.

Conference objective:

The objective of this conference is to provide participants with practical knowledge and understanding of regulatory requirements and techniques that can be put to use in their own aseptic manufacturing process strategy. The presenters will focus on the newest information available and will cover a wide range of subjects relevant to aseptic manufacturing and maintaining the validated state.

The conference is primarily relevant for R&D staff, Production Leaders, Supporters, Commissioning, Qualification and Validation teams and Quality Assurance seeking the latest knowledge about risk- and cross

contamination control, as well as engineering companies wanting to learn more about the viewpoint of the pharmaceutical industry and exchanging experiences.

Agenda

08:45-09:20 Registration, breakfast and networking
09:30-16:15 Conference
16:30-18:00 Networking, mingling and snacks (compliments of sponsor)

Day 2
08:45-09:20 Breakfast and networking
09:30-15.45 Conference

Price:
1695 Euros

Incl. lunches and refreshments

Early bird up to 2nd May 2022: 1495 Euros
Note. Due to tax/VAT regulations within the EU (for courses/seminars/conferences), the conference fee is invoiced in the local currency and local VAT is added.
Accommodation is NOT included in the fee.

Conference outline

Day 1, Lars Eric-Ellow, K2C (Moderator)

08:45-09:20 **Registration and breakfast**

09:20-09:30 **Intro to Day1 by Moderator**

09:30-10:15 **EU Annex 1 - Manufacture of Sterile Medicinal Products**
Pierre Devaux, Theraxel

10:15-11:00 **Trending and Pattern Recognition as part of a Contamination Control Strategy**
Susan Cleary, Novatek International

11:00- 11:30 **Plenary Q&A**

11:30-12:30 Lunch

12:30-13:15 **Validation of Lyophilisation for Parenterals**
Kirstie Goggin, MTL Projects

13:15-14:00 **Equipment and Facility design of an Aseptic Facility**
Robert J. Hayes, SeerPharma (UK)

14:00-14:30 **Break/ Coffee & Tea**

14:30-15:15 **Cleanroom and Contamination Control Strategy**
Pierre Devaux, Theraxel

15:15-16:00 **Plenary Q&A**

16:00-16:15 Wrap-up

16:30-18:00 **Snack and refreshments- complimentary of**

Day 2, Lars Eric-Ellow, K2C (Moderator)

08:45-09:20 **Breakfast and networking**

09:20-09:30 **Intro to Day 2 by Moderator**

09:30-10:15 **Compliance Updates for Media Fill Validation**
John Y.Lee, Pharmaceutical Compliance Associates

10:15-11:00 **Aseptic training with VR**
Andreas Hablesreiter, Innerspace

11:00-11:30 **Plenary Q&A**

11:30-12:30 Lunch

12:30-13:15 **Annex 1 & Environmental monitoring**
Matt Kite, Lighthouse Worldwide Solutions

13:15-14:00 **Temperature Mapping- Validation and Temperature Measurement**
Enrique Riis, Ellab

14:00-14:30 **Networking break/ Coffee & Tea**

14:30-15:30 **Processing and transfer of primary packaging material for sterile production and transfer to the filling line**
Jana-Cathrien Müller, Atec Steritec GmbH

15:30-16:15 **Plenary Q&A all Speakers**

16:15-16:25 **Wrap-up by Moderator**

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FULL AGENDA
Abstracts
Day 1

09:30-10:15

EU Annex 1- Manufacture of Sterile Medicinal Products

Pierre Devaux, Theraxel/Delegate

This conference will start by a short introduction about the historical Process of Revision for the Annex 1 from the creation of the Annex up to the last draft published on February 2020. After this introduction, the conference will talk about the content of this last draft : Summary, organization of its different chapters and especially will bring the knowledge of the main changes, new requirements, hot topics found inside this document : Contamination Control Strategy, qualification of Cleanrooms, Aseptic Process Simulation, Barrier Technologies, Sterilizing Filtration and PUPSIT (Pre-Use Post Sterilisation Integrity Testing), Quality Control, utilitites and so on. The contaminants involved by the Annex 1 are mainly particles, microorganisms and pyrogens. That's an important point and a different way in comparison with chemical residues whose the presence in contact with critical surfaces are named : Cross Contamination.

10:15-11:00

Trending and Pattern Recognition as part of a Contamination Control Strategy.

Susan Cleary, Director Product Development, Novatek International

The presentation will include a review of key regulations as they relate to the need to use the data collected for trending, process control, investigation and root cause analysis.
The digitization is still in process, pharma industry due to the regulatory scrutiny are sometimes late adopters but the need to digitize is ever more important based on the evolution of the regulations encouraging trending and using data.
Discussion will then cover the key contamination control processes including pharmaceutical water, as well as environmental and personnel monitoring, also touching on cleaning validation and cleaning process monitoring.

The lion share of the talk time will relate to the different trending tools, when they should be used, and what they mean.
Examples of trends will be included in the presentation.
The conclusion will discuss the need to digitize to control the processes, and to meet regulatory compliance for data integrity, trending, and ultimately to enhance product quality.

- Understanding evolving regulations which make digitization of processes a must.
- Knowledge of processes that are part of a complete contamination control strategy
- List the critical data for investigation and root cause analysis
- Ability to define a trend review frequency in an SOP
- Insight into which trend tools to apply to the data
- Learn what the trend is telling us about the process

12:30-13:15 **Validation of Lyophilisation for Parenterals**
Kirstie Goggin, MTL Projects

Lyophilisation is a technique used during formulation of parenteral products, where stability in aqueous solution is an issue. This presentation will give a general overview of lyophilisation technology, discuss typical lyophilisation CQAs and CPPs and outline the standard MTL Projects approach to lyophiliser process validation, highlighting the regulatory requirements for process validation.

13:15-14:00

Equipment and Facility design of an Aseptic Facility

Robert J. Hayes, SeerPharma (UK)

Generally, the greatest challenge to maintaining sterility in an aseptic facility are the people. Whilst a fully automated facility would be ideal, these are rare.As we must allow people access, staff must behave appropriately and not be a source of contamination.

The presentation will look at the design of buildings and equipment to minimise the risk of contamination, and how proper planning can create the working environment that encourages appropriate behaviour. As well as the physical design of the facility, attention will also be given to the soft issues of human behaviour and how simple simulationcan be employed to optimise room and machine layout.

14:30-15:15

Cleanroom and Contamination Control Strategy

Pierre Devaux, Theraxel / Delegate

This conference will allow you to understand well the requirements of the European Medicines Agency concerning this new document named : Contamination Control Strategy. The CCS is not a Risk Analysis to ensure that microbial, particulate and pyrogen contamination is prevented in the final product. This document is more than a Risk Analysis, it is the Summarize of all the strategies established inside your company to manage the level of contamination. Among the sections inside the chapter 2 of the new draft of the annex1, you can find the different topics concerned to establish CCS. But rather than focus exclusively on them, it is certainly really important to consider that your CCS approach concerned in fact, the entire document, the whole sections of the new draft. You have to build a document and at the end of this conference, the speaker will present to you a possible way to do it. The CCS is certainly the most important topic of this new draft and will be in the future the most preferred document of our European Health Authorities Inspectors.

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Day 2

09:30-10:15

Compliance Updates for Media Fill Validation

John Y. Lee, Pharmaceutical Compliance Associates

The basic requirements for media fill validation have been well established since the 1970s. This presentation reviews the additional and updated media fill compliance requirements and controls expected by the authorities (FDA and EU) to support the maintenance of a validated state for aseptic processing. These compliance requirements and controls include, for example, personnel participation, rejection of filled units, aborting a media fill run, media reconciliation, validation for each shift, post-incubation inspection and contamination rate. The review of these compliance issues also includes, where applicable, a comparison among the 2004 FDA aseptic processing guidance, current 2008 EU Annex 1, and 2020 draft EU Annex 1 related to media fill validation.

10:15-11:00

Aseptic training with VR

Andreas Hablesreiter, Senior Pharma Expert, Innerspace

Innerspace Deep Training is a revolutionary training system, in which aseptic production employees learn to master the key moments of their work. It offers a safe environment for repeatable, focused virtual experiences that create real, goal driven work experience. Innerspace uses high end Virtual Reality technology to implement research breakthroughs in Human Error Analysis and Transfer research in a powerful training system. In addition, the Training Management System supports documentation and integration of training data. All that allows Innerspace to support its customers with a cutting-edge digital solution to train employees in one of the most critical fields of human interaction in aseptic manufacturing.

Andreas Hablesreiter gives insights into the following aspects:

- Trainings- Transfer Problem and its effects on Human Errors
- DeepTraining Approach: Psychology and VR-Technology
- Innerspace DeepTraining: Evaluation, Reporting and Benefits
- Insights: Business Cases

12:30-13:15 **Annex 1 and Environmental Monitoring**
Matt Kite, Regional Manager, Lighthouse Worldwide Solutions.

Following the core theme 'maintaining the validated state', a journey from the 00's to the 20's. We take a deeper look at how Environmental Monitoring for manufacture of sterile product has evolved and adapted. Considering where we are heading with the new GMP Annex 1 2020 Draft and what this means for Cleanroom Classification and Monitoring:

- Latest Annex 1: What has changed?
    - Classification & Environmental Monitoring
    - Updates for Particle Counting
    - Updates for Microbial Monitoring
- A risk based approach to Environmental Monitoring
    - Using Quality Risk Management (QRM)
    - Establishing appropriate monitoring locations
    - Establishing appropriate alert limits
    - Managing deviations with corrective and preventive actions (CAPA)
- Embracing technological advances
    - Historic challenges with Environmental Monitoring
    - How Environmental Monitoring technology has developed to help mitigate risk

13:15-14:00 **Temperature Mapping - Validation and Temperature Measurement**
Enrique Riis, Ellab

Temperature mapping is the process of determining the temperature profile of a temperature- controlled environment or process. The goals of the mapping are discussed for controlled temperature units, as well as for processes. Furthermore, it is reviewed how to perform the measurements, which measuring equipment to use, when to use it, and which software tools are available to make the analyses needed to document the findings.

14:30-15:30 **Processing and transfer of primary packaging material (stoppers and cappers) for sterile production and transfer to the filling line**
Jana-Cathrien Müller, Atec Steritec GmbH

- Washing and Sterilization of primary packaging material
- Use of vessels, betaport container and bags for component transfer
- Presentation of the Atec transport systems with automatic transfer

Biographies

John Y. Lee,
Pharmaceutical Compliance Associates

John Y. Lee is Executive Director of Pharmaceutical Compliance Associates, an organization specializing in pharmaceutical compliance consulting, auditing, quality assurance, validation, and training. Prior to joining PCA, Mr. Lee held positions as Quality Assurance and Quality Control Director at Altana, Inc., Melville, New York; Quality Assurance Manager at Organon, Inc., West Orange, New Jersey; GMP Compliance Associate at Ortho Pharmaceuticals, Raritan, New Jersey; and Field Investigator at the FDA's Newark District Office. He has a B.A. degree in Biology from New York University and an MBA in Pharmaceutical Studies from Fairleigh Dickinson University.

Mr. Lee has lectured and published extensively on the topics of GMP compliance and auditing, quality assurance, validation, lyophilization, aseptic processing and filtration, clean rooms and pre-approval inspections. He is presently a course instructor for PharmaNet Inc. and served as symposium chairman, moderator and speaker for various professional organizations including the Parenteral Drug Association, the Centre for Professional Advancement, Medical Manufacturing TechSource, Pharm Tech Conference, American Society for Microbiology and Technomics.

Pierre Devaux,

Theraxel-Point Forty Five

Theraxel-Point Forty Five is a Company specialized in consulting, technical assistance, regulatory audits and training around the control of the chemical risk, Microbiological, particulate and pyrogenic for non-sterile, sterile and biotechnological pharmaceutical industries as well as related industries such as cosmetic industries. - Specialist in Part I, Annex 1 and Annex 15 of the European GMP, ICHQ9 and FDA guidelines on aseptic and validation processes and ISO22716- For 6 years, responsible for the quality control laboratories and the management of the environmental monitoring of the ZAC of the Excelvision Fareva French site;- For 5 years, Qualified Person/Quality Director of the ACM Pharma French laboratory, while carrying out consulting missions via the company UPS Consultants.- Head within the French Association A3P of the Common Interest Group on GMP Annex 15 and Cleaning Validation. Speaker for ISPE Nordic and Trainer for A3P Services as well as for Scandinavian Company Key2Compliance AB.

Kirstie Goggin,
MTL Projects

Kirstie Goggin Kirstie Goggin is a Validation Engineer working for MTL Projects Ltd. MTL Projects specialises in CQV of thermal systems, particularly autoclaves, tunnels, sterilisation and depyrogenation processes, as well as lyophilisers. Kirstie has extensive experience in R&D with regards to Analytical Methodologies. Kirstie's role at MTL Projects predominantly involves work with Cleaning Validation and Lyophiliser Technology. In this presentation she will share a typical MTL Projects Ltd approach to lyophiliser validation.

Robert J Hayes BSc, CEng, FIMechE, FIET Director, SeerPharma (UK)

Bob Hayes has worked in the Pharmaceutical Industry for nearly forty years. His experience includes Production and Engineering Management, New Product Development, Factory Design, Supply Chain Management, Validation and a variety of support functions. He has a special interest in the use of risk management and modern quality methodologies in the various aspects of regulatory compliance.
As well as his experience in the Pharmaceutical industry, Bob has also worked in a range of other industries, including: aerospace, precision engineering, FMCG, insurance and e-commerce. This breadth of experience presents the opportunity for Bob to introduce new ideas and best practices when working with his current clients.

Bob is Vice-Chair of the Pharmaceuticals Technical Activities Committee of the Institution of Mechanical Engineers Bob is a Chartered Engineer, a Fellow of the Institution of Mechanical Engineers and a Fellow of the Institution of Engineering and Technology.

Andreas Hablesreiter,
Senior Pharma Expert Innerspace – The Deep Training Company

Andreas Hablesreiter is Project Lead at Innerspace – The Deep Training Company.

Andreas Hablesreiter is educated as a Pharmaceutical Technician and possesses more than 35 years working experience in the pharmaceutical industry.

Having worked in various positions in sterile production department:

- -Leading aseptic filling department of an aseptic processing site in Austria.
- -Responsible for validation and qualification as well as training of personnel.
- -Lead and co-auditor in auditing Gxp suppliers

Project experience includes

-Leading a lot of projects of implementing new aseptic filling machinery.

-Project lead for implementation of VR-Simulator Training from Innerspace at Takeda Austria.

Matt Kit
Lighthouse Worldwide Solutions

Matt Kite, Regional Manager, Lighthouse Worldwide Solutions Multi-disciplinary engineer (BEng mechatronics). Experienced in lean manufacturing, product introduction, Particle Counting & Environmental Monitoring.

Matt Kite heads the European territory for Lighthouse Worldwide Solutions the US based leader in real time contamination monitoring systems and aerosol samplers. He started out his engineering career in production and lean manufacturing more than 20 years ago before first working with particle counters in 2006.
Supporting end users in UK hospitals, life science and validation companies, Matt developed a comprehensive and practical experience of particle counter technology and EU GMP Annex 1.

Susan B. Cleary, B.CS, M.B.A.
Director of Product Development,
Novatek International.

Susan B. Cleary, B.CS, M.B.A. is the Director of Product Development at Novatek International. Previously holding the position of Program

Manager and Lead SOFTWARE Engineer for the core LIMS and Environmental Monitoring software programs. Susan has 20 years of experience in designing, developing, implementing and managing large scale LIMS, Quality Management, and Validation Management software implementations. Susan works with pharmaceutical, biotech, and medical device companies and specializes in data integrity, and working with clients to streamline their procedures and manage their data more effectively for LIMS, Environmental Monitoring, Cleaning Validation, and Quality Management Systems

Enrique Riis, Ellab

Enrique Riis is Senior Sales Manager at Ellab A/S in Denmark, which provides thermal validation pharmaceutical industries from Ellab's offices in Denmark and the United States. Enrique Riis has a B.Sc. in Global Business Engineering and a Graduate Diploma in Business Administration.

Jana-Cathrien Müller, Atec Steritec GmbH

Jana-Cathrien Mueller works since beginning of 2020 as sales manager at Atec Pharmatechnik GmbH, Germany. Atec manufactures pharmaceutical processing equipment, such as formulation systems, vessels, CIP/SIP systems, clean room lifts, component processing systems (stoppers, caps, combi-seals etc.), and sterile transfer solutions.
Previously, Jana-Cathrien Mueller worked for GEA Group as project engineer and manager for pharma and healthcare solutions, mostly in API processing.
Jana-Cathrien Müller is holding a master degree in Biotechnology and Process Engineering.

Lars- Eric Ellow, Key2Comnpliance

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