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Annual Challenges in Sterile Product Manufacturing Conference

7th June 2018

The Mere Hotel & Spa, Knutsford, Manchester UK

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Challenges in Sterile Product Manufacturing with risk based GMP

The 2018 annual PHSS Challenges in sterile product manufacturing conference will consider the impact of EU GMP Annex 1 revision and GMP guidance where clarity is required.

Following the consultation process on revision of Annex 1 it is clear supportive guidance in GMP will become even more important as new products, advanced technologies and new practices are developed and implemented using a risk based approach.

The balance between prescriptive GMP and QRM (Quality Risk Management) principles will be considered together with a key requirement of the revised Annex 1 to prepare a Contamination control strategy. Presentations will include examples of GMP principles and QRM working together.

The Contamination control strategy is required to define an approach to sterile product manufacturing with product/ process and risk knowledge considering contamination risk mitigation by technical and operational control measures. Such a control strategy should cover the facility, process and environmental control with process monitoring to verify the state of control.

Find out more about the requirements for a Contamination control strategy and solutions to challenges in sterile product manufacturing including:

What is required for a Contamination Control strategy for a Facility? As a new requirement in the revised Annex 1 (Draft but the Control strategy requirement is expected to be upheld).

Grade A continuity from moist heat steriliser to sterile product Aseptic processing line: considering unload of sterilised parts, loading of Transfer cart that maintains Grade A conditions through transfer into RABS aseptic processing line: Details are presented of environmental classification, qualification and routine monitoring of L-UDAF (Localised Uni-Directional Airflow) zones applied at equipment interfaces.

Transfer of pre-sterilised containers via an NTT (No-Touch-Transfer) process into Aseptic process filling lines with protective Uni-directional Airflow classification and qualifications via visualisation smoke studies and particle transfer challenge studies (LR method). Presentation includes an overview of applied risk assessment for Environmental control considering detectability in deviation of Critical Process Parameters (CPPs).

Managing deviations in environmental control state considering impact of proposed new requirements in Annex 1 revision (if upheld). The presentation covers response to positive recovery above alert and action levels and/or change in microflora profile where atypical profiles develop including root cause investigations, CAPAs and change efficacy checks.

Barrier Separation Technology: Isolators and RABS, Definitions, Differences and Types to add Clarity where EU GMP Annex 1 cannot be prescriptive. Presentation includes overview of a new PHSS Technical Monograph 21 of Barrier Separation Technology: Isolator and RABS: Restricted Access Barrier Systems.

Programme

9.00am: **PHSS Chairman & Vice Chair welcome and overview of conference sessions.**

9.05am - 10.00am: **Annex 1 revision update. Key points from EMA consultation process. Pharma industry and regulatory perspective. Discussion session with MHRA.**

10.00am - 11.00am: **Presentation: Challenges in development of a Contamination Control strategy for different product types:**

Speaker: Di Morris GSK GMP Auditor Global Ops. GSK Vaccines. Ex-MHRA GMP senior inspector.

- What is expected to be included in a Contamination control strategy as a GMP requirement outlined in the revised (draft) Annex 1.
- Contamination control strategy for different product types: Sterile non-hazardous, Aseptic-Toxic, Aseptic highly potent (including ADCs), Aseptic sensitising (Hormones).
- Contamination control strategy and linkage to cross contamination.

11.00am - 11.30am: **Coffee and viewing exhibition.**

11.30am - 12.15pm: **Presentation: Case study and consideration of applied methodology in transfer of Moist heat sterilised parts from an Autoclave to RABS Aseptic processing line with Grade A continuity.**

Speaker: Tim Eaton AstraZeneca Macclesfield UK, Specials Specialist.

- Principles of Grade A continuity and implementation of solutions in process operations.
- Definition, Classification, Qualification of Localised Uni-Directional Airflow used as aerodynamic protection of Autoclave unload and loading of Transfer carts and unload of transfer carts into RABS aseptic processing line.
- Transfer cart case study: maintaining sterile integrity of sterilised parts in transfers.

12.15pm - 1.00pm: **Presentation: NTT (No-Touch-Transfer) of pre-sterilised containers into Aseptic process Filling lines: Contamination control qualification studies and supporting risk assessment.**

Speakers: Corinna Maier F Ziel Head of Aseptic processing Technologies & Dr Holger Kranenburg PhD. F Ziel Aseptic technologies: Development, Qualification & Training.

- Environmental control and risk assessment of Critical Process Parameters (CPPs) in NTT step wise transfer process that employs Pressure and Airflow cascades through Grade C>B>A transfers via controlled environments of connected RABS/Isolator zones.
- Smoke study airflow visualisation; Method and results: Data from Case study.
- Application of LR method as a Particle transfer challenge of airflow protection during operational transfer of pre-sterilised containers from one Zone grade to a higher grade.

1.00pm - 2.00pm: **Lunch and viewing exhibition & networking.**

2.00pm - 2.45pm: **Presentation: Contamination Control Strategy.**

Speaker: Dr. Alexander Stoll VP Competence Center Microbiology & Aseptic Technique Quality Management Pharmaceuticals Fresenius Kabi AB).

- Usage of Contamination Recovery Rates (CRRs) as an effective tool for cleanroom monitoring.
- CRRs give accurate data on the cleanroom status and also allow easy comparison of data in between manufacturing sites.
- The influence of cleanroom-processes and cleanroom-design changes on CRRs are shown for a case example.

2.00pm - 2.45pm: **Exhibitor demonstrations in exhibition area: Gowning, EM trend reporting, Enzyme Indicators (EIs) and Biological Indicator (BIs) correlation in H202 decontamination.**

2.45pm - 3.30pm: **Presentation: Understanding of different aspects of protective gowning solutions.**

Speaker: Steve Marnach DuPont Protection Solutions.

- Gowning selection based on requirements; 1) Protecting GMP controlled environments from particle and microbiological contamination. 2) Protecting operators from exposure to hazardous chemicals, hazardous medicinal products and or biohazards.
- Dressing for the right grade of controlled area and process application.
- Gowning performance: Particle filtration/ Shedding, Chemical permeation, Bacterial filtration, tear strength: comparison of different single use gowns.
- To Re-use (Launder/ sterilize) or not to re-use (single use sterile protective gowning).
- Gowning Life cycle and summary of solutions in protection.

3.30pm - 3.45pm: **Coffee/ Tea break in exhibition area.**

3.45pm - 4.30pm: **Presentation: Isolator and RABS definitions, surrounding environments, types in GMP applications for Sterile product processing/ Filling. Outline of New PHSS Technical Monograph 21.**

Speaker: James Drinkwater Chairman of PHSS & F Ziel Head of GMP Compliance. Lead of PHSS Special interest group: Aseptic Processing & Bio-contamination preparing Technical Monograph 21.

- Barrier Separation Technology principles/ differences, Isolators and RABS definitions.
- Meaning of terms: 'Open and Closed' in design, operation and in aseptic processing.
- Barrier technology types and surrounding environments by process application and risks.
- Bio-decontamination methods and process integration: check list of considerations.

4.30pm: **PHSS Chairman's thanks and Vice Chair closing remarks.**

Exhibition area with exhibitors who can provide further knowledge and support with technologies and essential supplies in sterile product manufacturing.

International attendees are encouraged to engage to understand European regulatory perspectives and industry key opinion leader's position on the challenging area of risk based GMP and Revision of EU GMP Annex 1.

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