PHSS Aseptic Processing Syndicate Workshops 2021

We would like to thank our exhibitors:

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PHARMAGRAPH Pharmaceutical Monitoring Systems

more to come

NEW DATES: 24TH & 25TH MARCH 2021

Keynote Speakers:

Day 1 : QP perspective on challenges in Aseptic processing and bioburden control in product certification and release.

Day 2 : Colin Newbould Contamination control for sterile and Non Sterile products a 'mind-set for the future'.

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Day 1 Workshops : Four 75 min sessions facilitated by two trainers

Workshop 1 Kindly sponsored by Cherwell Laboratories

Environmental classification and Qualification: Suzanne Nutter, Astrazeneca & Graham Steele, Microserve.

This workshop considers a risk based approach and connection between environmental classification, Qualification and routine monitoring for GMP controlled areas. ISO14644-1 is a standard generic for all industries so specific considerations are required on setting sample locations for GMP facilities where data builds through establishing environmental control to a state of control where ongoing data collection and trending inform of continued compliance or deviations.

Workshop 2 Kindly sponsored by Sterility Solutions

Moist Heat sterilisation: Preparation of load patterns and Autoclave cycle qualification. David Hallows GSK & Darren Beckett Sterility Solutions Ltd.

In moist heat sterilisation for loads used in aseptic processing the load pattern presentation, addition of protective packaging can all impact steam penetration, air removal and cycle efficacy. In addition residual water resulting in Wet loads can impact GMP. This workshop considers good practice in load preparation for autoclave Moist sterilisation cycles and associated qualification.

Workshop 3

Isolator barrier technology key points to consider in selection and implementation: API preparation, Filling, Aseptic process Sterility testing; James Drinkwater F Ziel/PHSS and Pharma industry (TBC).

Different products and at different stages of manufacture require different design attributes in Barrier Isolator technology. This workshop considers Isolator designs and attributes for processing an API that forms part of a sterile product, Aseptic process filling of non-hazardous sterile products, Aseptic process filling of toxic (Cytotoxic) products and biologically hazardous products including viral vectors and live viruses. Considerations will be provided on environmental monitoring solutions.

Workshop 4

Aseptic containment strategy (ACS) and cross contamination control: Dr Holger Kranenburg F Ziel GmbH & Colin Newbould Wasdell group.

An Aseptic containment strategy (ACS) must sit alongside a Contamination Control Strategy (CCS). The CCS is an upcoming Annex 1 requirement and relates specifically to manufacture of sterile medicinal products. When sterile hazardous products (Toxic and biological hazards) are aseptically processed containment design attributes need to align patient protection with operator protection and where cross contamination control is required.

The PHSS are developing guidance on Aseptic Containment Strategy and this workshop will cover development of strategies, technical solutions and supporting research that characterises the risk.

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Attendance Fee: £700 + VAT
per delegate to two day attendance

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Workshop 5 Kindly sponsored by micronclean

Cleanroom garment gowning and Cleanroom behaviour. Prof Matts Ramstorp BioTekPro & Steve Marnach DuPont.

We all know operators are the greatest source of bio-contamination in cleanrooms. Also cleanroom gowning can be a contribution to contamination because of material type that shed particles/fibres where degradation in use can increase contamination source. Also reduction of filtration efficiency over time may be a contributing factor to source increase.

Gowning therefore is an important contamination risk mitigation for GMP applications. This workshop considers gowning selection; comparing single use and re-usable, gowning qualification for qualification of operator entry to cleanrooms and controlled areas together with good practice in Cleanroom behaviour that is under scrutiny of regulatory authorities. Examples on MHRA observations on poor cleanroom behaviour will be shared.

Workshop 6 Kindly sponsored by ECOLAB

Manual cleaning and disinfection: Agent qualification and disinfection programs for different areas. Matthew Cokely & Emily Buck ECOLAB.

Manual cleaning and disinfection is one of the fundamental contamination control measures in cleanroom and controlled areas in GMP facilities that support aseptic processing. There are many challenges when considering developing a cleaning/ disinfection program for specific controlled areas including agent selection (BPR status), agent qualification including requirement for rotation, and agent method of application, procedural control and residue management. This workshop considers the many challenges and provides practical guidance with case study examples on developing a cleaning/ disinfection program.

Workshop 7 Kindly sponsored by PHARMAGRAPH

EM risk assessment at DQ/ Design phase of projects: James Drinkwater F Ziel & David Grieves, Pharmagraph.

Setting EM sample locations at the project design phase requires technical integration into process machinery (including filling machines) bed plates that are enclosed by barrier technology; Isolators and RABS. Technical integration can also include controls interfacing through different modes of operation together with HMI (Operator panel) interactions.

The PHSS are developing guidance around setting EM sample location and sample type (airborne and surface) at the design phase for new filling lines. This workshop will explain how the risk assessment models are characterised and applied during design and Mock-up studies at DQ stage.

Workshop 8 Kindly sponsored by MERCK

Single use systems: Dr Paul Beckett & Simone Biel Merck Millipore.

The increase in single use systems and disposable technologies has facilitated process development opportunities for new product types where product contact parts cleaning/ sterilisation for reuse is a challenge together with risk mitigation is required in cross contamination control. The revised Annex 1 recognises the development of such single use 'Closed system' technologies which have specific qualification and GMP compliance requirements. Single use technology has developments in connections and interconnected systems that combine to manage product aseptic processing. This workshop provides a practical insight to the many opportunities and technical solutions that single use systems provide.