NEW ANNUAL EVENT

3rd & 4th April 2019

The Mere Knutsford, Manchester UK

£700 + VAT per delegate for two day attendance

phss
over 25 years of advancing pharmaceutical and healthcare sciences

PHSS Aseptic Processing Workshop Syndicates 2019

The PHSS Aseptic processing workshops are run as a syndicate where simultaneously four workshops per day are run with four groups of attendees moving through each workshop in sequence. The workshop training is completed over two days so in total eight workshops are completed for each attendee.

Workshops will each be limited to 20 attendees, with a total of 80 attendees per day.

Each training day starts with a Keynote presentation for all attendees below the four training syndicate groups are formed.

Workshops will have a lead trainer with support trainers (1 or 2) and are intended to be practical guidance where equipment is used for hands-on/ demonstration to increase learning and engagement.

Sponsors support workshops with equipment and specialists in the technology or consumables used in the training.

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WORKSHOP SYNDICATES DAY 1

Keynote presentation: MHRA speaker (TBC)
Status of Data integrity challenges in sterile product manufacturing: A GDMP Inspectors point of view.

Workshop 1: Moist heat sterilization – autoclaving loads, avoiding wet loads.

Leader: Alan Heavey Sterilization Solutions Ltd – Consultant

Sponsor: Steritech

Workshop 1 content: Moist heat sterilization is a well-developed process in sterile product manufacturing but with the increase in aseptic processing where sterilisation is applied to wrapped components that support the manufacturing process today we still see challenges with avoiding 'Wet loads'. This workshop will discuss the key aspects of air removal, steam quality and penetration together with practical sessions on preparing a load pattern for autoclaving to avoid wet loads.

Workshop 2: VHP/ vH2O2 applied to barrier technology, loads and feeder bowls. Consideration to 'fragility of VHP', science and process knowledge.

Leader: James Drinkwater PHSS Chairman & Head of GMP Compliance F Ziel GmbH

Support trainer: Simon Rowlands – VHP Specialist STERIS Life sciences

Sponsor: STERIS Life Sciences

Workshop 2 content: VHP/ vH2O2 is a technology that has been applied in the Pharma industry for many years but we have got to the position where the MHRA posted a Blog on Fragility of VHP that has promoted debate on the lack of understanding of the science and process leading towards over claiming efficacy, poor process in bioburden/ protected soiling management and poor load pattern set-up and risks of surface exclusion to the bio-decontamination process.

VHP/ vH2O2 has excellent attributes with a broad spectrum efficacy and ability for residuals to break down to safe components of oxygen and water but there are limitations in penetration of microbial contaminations layers (clumped spores) and through protective soiling like fatty acids from skin contact. In addition the oxidising potential of H2O2 can impact biological products even at low residual levels below 1ppm. VHP process Fragility is considered by lack of knowledge to manage the strengths and limitations of VHP/H2O2 bio-decontamination and apply good practice. This workshop presents the key science, bio-decontamination process and qualification considerations together with practical sessions for setting up load patterns for material transfer or Isolator loading.

Workshop 3: Barrier Technology; Isolators and RABS: Glove Management and Good aseptic technique related to 'First air principles': considering glove selection, integrity testing (visual and physical), response to detected glove leakage post filling in Grade A environments.

Leader: Corinna Hinken Head of Aseptic technologies F Ziel GmbH

Workshop 3 content: Barrier separation technology has become an expectation in Aseptic processing to separate people from process. Isolators have contamination control attributes that are not absolute so there are risks to manage and good aseptic technique is still required. This workshop considers contamination risk management from the 'weakest link' in the Isolator barrier with a Glove management strategy based on a Life cycle approach and good aseptic practice in contamination risk mitigation that all operators should respect.

Workshop 4: Aseptic-Containment in GMP considering process solution technologies and gowning to balance patient and operator safety/ risk.

Support trainer 1 Aseptic – Containment: Dr Holger Kranenburg Aseptic technologies containment F Ziel Gmbh

Workshop 4 content: Aseptic – Containment requires new approaches to Isolator barrier designs and operating principles that combine contamination control requirements with containment attributes.

This workshop covers the risks in processing hazardous or toxic products that require Aseptic-containment and developing process solutions and qualification methods. In addition, operator and maintenance gowning are important aspects of the personnel protection strategy that also require contamination control in GMP facilities as part of a Contamination control strategy.

SEE OVER FOR DAY 2 >

WORKSHOP SYNDICATES DAY 2

Key note presentation: Blind compliance encourages bad science

Speaker: Gordon Farquharson – Critical Systems Ltd / Convenor of ISO TC2019 WG1

Workshop 5: Single use systems including Pre-Use and Post Use (PUPSIT) sterilising filter integrity testing: practical setup for application in barrier technology including QRM considerations.

Workshop 5 content: Increasingly single use systems are used in sterile product manufacturing, in particular to support aseptic processing of new biological and therapeutic products where cross contamination control is paramount. One area of application of single use systems is in filling processes to integrity test the product filter pre and post use; so called PUPSIT. The requirement of PUPSIT has been reinforced in the revision of Annex 1 that applies QRM principles. The workshop will consider the development of single use systems and in particular focus on technical solutions for integrating into Isolator barrier technology.

Workshop 6: Environmental Monitoring Risk based programs and contamination excursion management: monitoring technologies, setting sample locations by review of contamination risks – practical exercise. Root Cause Analysis to contamination event: Recommended steps and case study exercise.

Leaders: Mike Davies & Ian Symonds – PHSS Aseptic processing special interest group (ex GSK)

Support trainer 1: EM technologies: John Wallingford Pharmagraph monitoring systems

Sponsors: Pharmagraph & PMS

Workshop 6 content: Environmental monitoring data in Aseptic processing provides the data based evidence that the manufacturing environment was under control during process operations and increasingly provides more rapid results, so proactive measures can apply.

One challenge that is a constant is how to respond to microbiological excursions in a monitoring program with good practice in completing Root cause investigations, so corrective and preventative actions can be taken to prevent reoccurrence.

This workshop considers the approaches to developing Environmental monitoring programs, what technologies and methods are used (including Rapid Micro Methods; RMM) and what is good practice in response to a contamination event or out of trend results in monitoring data. Workshop includes a worked exercise.

Workshop 7: Airflow characterisation – visualisation in controlled zones: CFD (Computational Fluid Dynamics in design), LR Method with smoke particle challenge and particle counting tracking to study contamination control. Smoke visualisation studies – good practice in study design and application.

Leader: James Drinkwater PHSS Aseptic processing special interest group

Sponsor: F Ziel Gmbh

Workshop 7 content: Airflow as a contamination control and protective measure is one of the key approaches in GMP for contamination control within controlled areas and together with pressure differentials airflow pattern (uni-directional or turbulent) and in cascade (between areas) requires characterisation to be qualified as a control measure. This workshop considers the different methods to characterise airflow including CFD in design, Smoke studies to qualify the operational state and the LR Method to provide a smoke particle challenge where airborne contamination transfer requires control with particle counters used to track compromise of protection or map particle movements.

Workshop 8: Manual disinfection in contamination control of classified/ controlled GMP areas.

Speaker: Matthew Cokely – ECOLAB Life Sciences

Workshop 8 content: Manual disinfection is fundamental in any environment contamination control program and requires qualified agents, delivery systems and methods under procedural control. Cleaning and disinfectant residuals require management to prevent cross contamination. The Biocides directive further challenges agent selection and continued use.

This workshop provides an update on current best current practice in manual disinfection and includes practical recommendations on agent selection, qualification and methods of application for target efficacy and residual management in a GMP contamination control strategy.