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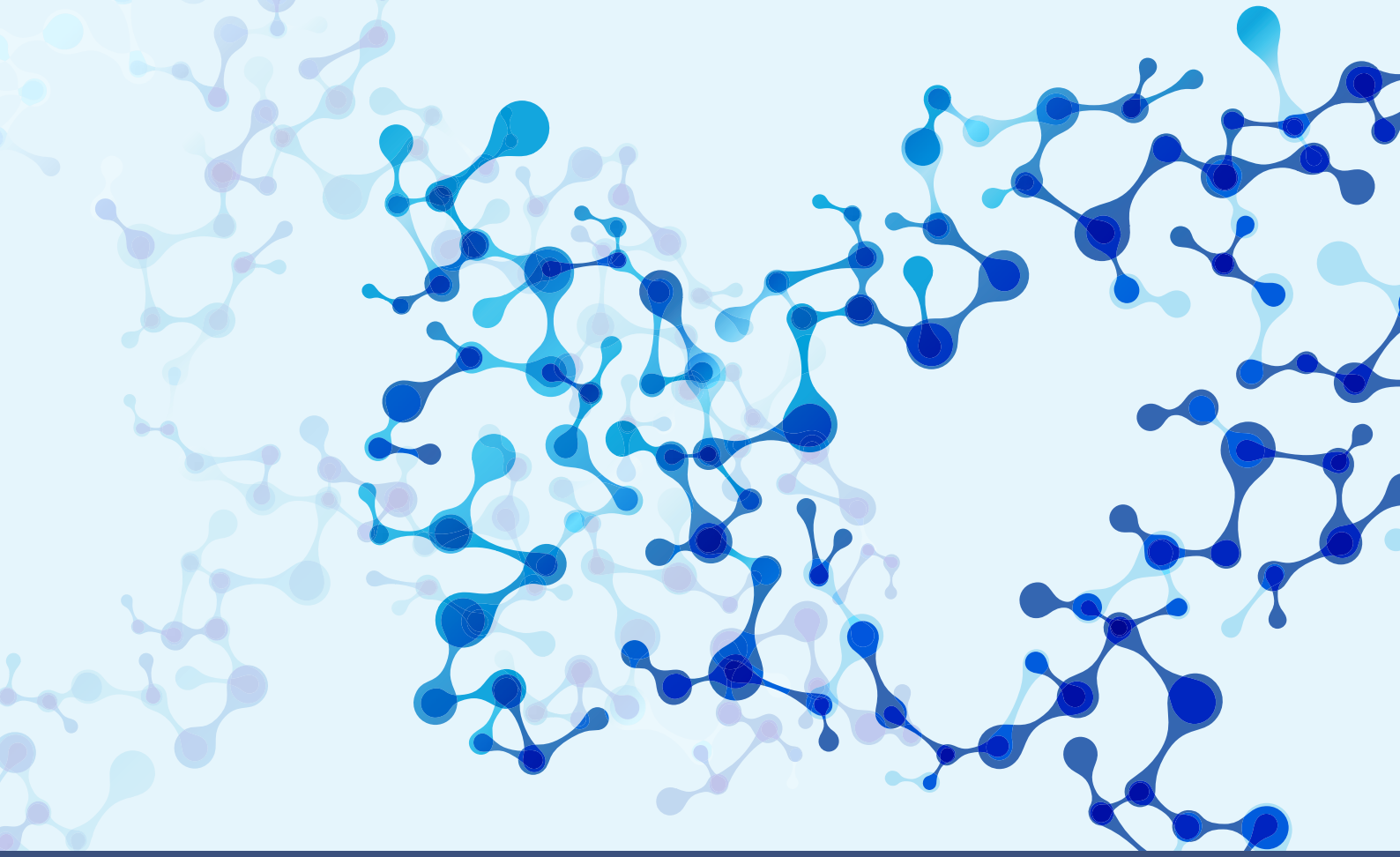
PHSS Annual Members Conference 2014



Speakers and Exhibitors Networking Dinner
Thursday 11th September
(Venue TBC)

Conference & Exhibition Day
Friday 12th September
(Close by 3.30pm)

Conference Venue
University College London UCL, School of Pharmacy

book online phss.co.uk/events

Processing challenging Pharmaceutical, Biopharmaceutical and Therapy products to GMP:

Managing compliance, control, monitoring and efficiency challenges

As new Biological products, challenging toxic products and Cellular/ Gene therapies (ATMPs) are developed there are increasing challenges in GMP compliance. With more complex products that have increased efficacy and efficiency in targeted delivery systems the challenges in processing and GMP compliance with a focus on patient safety require new strategies, technologies and practice.

The regulatory, product and processing environments are changing and it is important to keep up with these trends.

Today we have to balance the use of Closed and Open system processing technologies, technique and practice to manage risks and interfaces processing large and small batches and for therapies essentially 'one product, one batch, one patient'.

There is a need to think more strategically on how to approach processing of such products to manage quality, safety, efficacy and patient safety with GMP compliance.

This conference considers the challenges to address, strategies, new technologies and practice developing to meet the new challenges...not one to miss.

Exhibition and Networking

New technologies and equipment required to meet the current challenges are presented in an exhibition with specialists on hand to help explain the benefits, technical and compliance aspects.

The PHSS Annual Members Conference Hosts are:

- UCL School of Pharmacy via link with the Qualified Person; Q3P training course provided by UCL.
- PHSS support and encourage participation in the Q3P course provided by UCL and offer support to QPs after qualification via the society and collaborations.

Conference Friday 12 September:

Processing challenging Pharmaceutical, Biopharmaceutical and Therapy products to GMP:

Registration, first access to exhibition and coffee from 9am at UCL School of Pharmacy

9.30am: Welcome, Introduction.
George Skye's Award announcement and release of PHSS Bio-contamination 20 Monograph:
James Drinkwater PHSS Chairman

9.45am – 10.30am: A senior GMP inspector's point of view on GMP compliance challenges in processing new products and recurring non-conformance findings in Aseptic processing.
Andrew Hopkins MHRA senior inspector

10.30am – 11.15am: Implementing a new strategy of Bio-contamination control and monitoring within controlled environments.
Considering a holistic approach to use measurable data and proactive risk management.
Ian Symonds Head, Aseptic Strategy & Intelligence Governance & Advocacy Global Quality GSK Barnard Castle & PHSS Bio-contamination special interest group

11.15am – 12.00pm Break for viewing exhibition, networking and refreshments.

12.00pm – 12.45pm: A holistic operator centric approach to avoid human errors and increase compliance.
with SOPs (Standard Operating Procedures) efficient by 15%, a training system which is not a learning system, batch records that contain 50% of non-critical data, is it a surprise to face with human errors? Are deviations always the fault of the operator? Moreover, are deviations real deviations, or simple events? We have probably attained a limit in the way we design our quality systems. It is probably time to change our paradigm and enter a new way of thinking compliance, to generate sustainable gains.
Oliver Depardieu Partner: OXO Consulting Belgium & Xavier DUBURCQ, Pharm D, Ph. D Group Business Development Director, Life Sciences; **Altran London**

12.45pm – 1.45pm: Lunch and viewing of Exhibition.

The afternoon sessions will be in two streams:

Stream A

Control Strategies: Contamination Control and Monitoring.
Moderator: Mike Davies: GSK, Director, Aseptic Quality Assurance EU&EMAP Global Quality GSK, Worthing UK

Stream B

Biotech and GMP Compliance Challenges.
Moderator: Simon McEwen Oxford Bio-Manufacturing & PHSS Management committee

Stream A: Control Strategies; Contamination Control and Monitoring.

A1: 1.45pm – 2.30pm: Control Strategy for Contamination and Cross contamination control in manufacture of Sterile Medicinal products.

There are developing requirements for Control strategies (a current regulatory requirement EU GMP Annex 2) for Biological product manufacturing and increasing discussion what Control strategies should include in Manufacturing of Sterile Medicinal products to GMP (EU GMP Annex 1). This presentation considers the key aspects of a Control strategy with a focus on the elements of contamination/ cross contamination control in manufacturing controlled zones processing environments that may impact product quality, efficacy and patient safety.

Di Morris Pharmaceutical solutions - GMP Consultant & ex-MHRA inspector.

Short 15 minute break for change overs.

A2: 2.45pm – 3.30pm: Microbiological EM sample incubation regimes.

One area covered in the PHSS Bio-contamination Monograph 20 is incubation regimes for environmental monitoring samples. There is a need to focus on best recovery of samples from controlled environments and new research indicates a change of practice based on a 'selected temperature' methodology for target areas improves recovery. This presentation considers a strategy of managing EM sample incubation through qualification, routine monitoring and investigations into deviations.

Mike Davies Director, Aseptic Quality Assurance EU&EMAP Global Quality GSK, Worthing UK & PHSS Bio-contamination special interest group.

Stream B: Biotech and GMP compliance challenges

B1: 1.45pm – 2.30pm. Challenges in Biotech manufacture related to contamination and cross contamination control.

Biotech processing has unique challenges, often involving complex process interactions with products, processes, controlled environments and operators/ scientists. The presentation discusses the challenges and approaches to manage the risk for GMP compliance and patient safety.

(TBC)

B2. 2.45pm – 3.30pm. Developments in Aseptic processing for Biological/ ATMP products.

New biological and therapeutic products require Control strategies, technologies and solutions for contamination and cross contamination control. This presentation covers the latest developments and considerations in Aseptic processing considering Closed and Open systems processing, single use systems and Barrier Separation Technology. Containment solutions are considered that support operator protection and cross contamination control in a GMP setting.

James Drinkwater PHSS Chairman & F Ziel GmbH Head of Aseptic Processing Technologies and GMP Compliance.

Conference close & thanks by session moderators 3.30pm.