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Challenges in Sterile Product Manufacture

PHSS Conference 8th June 2017
Venue: The Mere, Knutsford, UK

This major PHSS conference will focus on clarity of issues in GMP in sterile product manufacturing with consideration to EU GMP Annex 1 revision.

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Three presentations will be provided:

Key note: Regulatory speaker: Andrew Hopkins MHRA Expert GDMP Inspector and leader of EU GMP Annex 1 EMA/ PICS revision groups. An inspector's point of view on revision of Annex 1 and issues that require clarity in GMP.

Pharma industry speaker: Brian Cullinan: Associate Director, Engineering Projects, Alexion Pharma Ireland – Aseptic Filling of rare disease medicine in pre-sterilised containers: Project case study and learning.

Supplier presentation: Dr Paul Beckett; Technology Manager Filtration, EMEA, Merck Life Science PUPSIT (Pre-Use and Post Use Integrity Testing) of Product sterilising grade filters: Configurations for Aseptic process Filling in Barrier Separation technology (Isolators and RABS).

Three Discussion sessions will be provided considering Clarity of GMP

Group 1 Discussion issues:

- Annex 1 revision: How will clarity in GMP cover new product types, new technologies and new practice without being prescriptive?
- Grade A Air supply: Localised aerodynamic protection by Grade A Air supply is applied outside Capper zones, how is Grade A air supply to be classified/ monitored?
- Cross Contamination: Requires different approaches possibly including; Cleaning validation, decontamination before introduction of a different product, dedicated facilities and Single-Use-Systems/ Disposables. In this complex area how do we balance operator safety, patient safety and product quality (efficacy and sterility) with GMP?
- Rapid Micro Methods are still difficult to apply when all GMP references relate to CFUs. Is the technology still not mature enough and what are good current applications for RMM?
- Cleaning and Disinfection are often confused with limited guidance in GMP how do we improve knowledge and practice?

Group 2 Discussion issues:

- PUPSIT; Pre-Use and Post-Use Integrity testing of Product sterilising grade filters; Is PUPSIT always required in GMP or is there justification for alternatives?
- EM sample incubation regimes; considering it is now known Dual incubation of the same media plate reduces recovery at the higher temperature and new published research points towards a more targeted approach for Media, temperatures and more targeted characterisation is it expected there should be a change from old generic regimes?
- EM: Process monitoring is a new term to be introduced in the revision of Annex 1; what does Process Monitoring entail?
- Aseptic Holds; apply to sterilised components used in Aseptic manufacturing and Controlled areas. How do you qualify Aseptic holds?
- Process simulation trials (PSTs), Media fills and campaigns; how do you specify a Media fill/ PST for a campaign to cover interventions, duration and risks to product sterility. Is 'Piggy backing' a viable approach to Media Fills?

Group 3 Discussion issues:

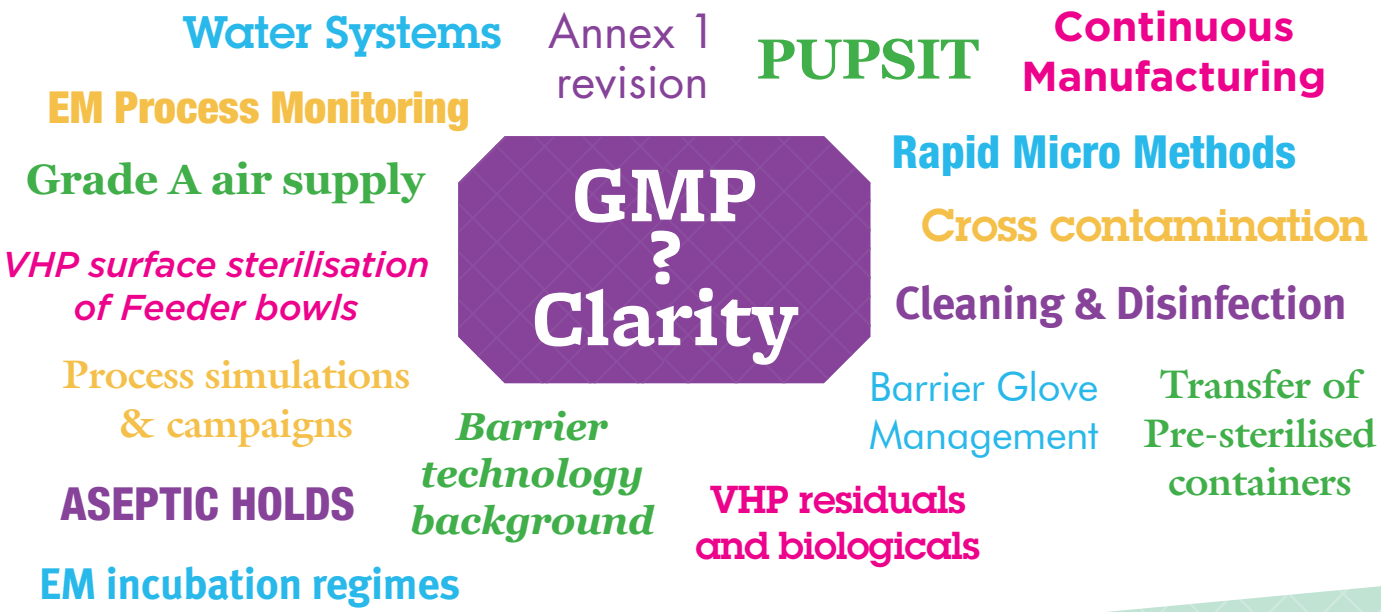
- Barrier technology surrounding environments; is there consensus in background environments required for Open system Aseptic processing and Closed systems Aseptic processing for Isolators and RABS and is the GMP minimum Grade D for Isolators acceptable for Aseptic Process Filling considering QRM?
- Transfer of Pre-sterilised Containers into a Filling Line: Alternative technology of de-bagging/ No-Touch-Transfer (NTT) as a different approach without a Tub surface decontamination step e.g. ebeam, VHP, is now starting to be implemented but has the NTT technology been running ahead without full consideration to GMP and clarity in regulatory expectation?
- Continuous Manufacturing requires different approaches to qualify campaigns with short turnaround times; how do we qualify Continuous manufacture with GMP?
- VHP/vH202 surface sterilisation of Feeder bowls: Is a pre-VHP/ vH202 moist heat sterilisation (Autoclave step) required for stopper contact parts e.g. Feeder bowls, before assembly into an Isolator and subsequent VHP/ vH202 bio-decontamination or can VHP/ vH202 be justified alone to provide surface sterilisation (In-Place)?
- VHP residuals and Biological product bio-compatibility; There is little specific reference in GMP relating to bio-compatibility of bio-decontamination agents and biological products, in particular the most commonly used process VHP/vH202. Analytical methods are now developed to characterise Bio-compatibility. How should GMP deal with these bio-compatibility challenges?
- Barrier Technology Glove Management: As the most vulnerable element of a Barrier system how do we manage the risks of integrity compromise during Aseptic processing and what is regulatory expectation for Glove management in Isolators and RABS?

Program: Challenges in Sterile product manufacture – Clarity of GMP

9.00am - 9.15am	Welcome and overview of conference sessions from PHSS Chairman, James Drinkwater and PHSS Vice Chairperson Jenni Tranter
	Morning conference moderator; Jenni Tranter
9.15am - 10.00am	Presentation: Andrew Hopkins MHRA Annex 1 and Clarity in GMP
10.00am - 10.45am	Presentation: Brian Cullinan Aseptic filling of rare disease medicine
10.45am - 11.45am	viewing exhibition, demonstrations, networking, coffee break
11.45am - 12.45pm	Discussion session 1: Clarity in GMP; Facilitator Tim Eaton; Astra Zeneca Sterile manufacturing specialist
12.45pm - 1.45pm	Lunch and viewing exhibition
1.45pm - 2.30pm	Presentation: Dr Paul Beckett: PUPSIT (Pre-use & Post-use integrity testing)
2.30pm - 3.30pm	Discussion session 2: Clarity in GMP: Facilitator: Ian Symonds GSK Head, Aseptic Strategy and Intelligence, Pharma Ops, Global Functions
3.30pm - 3.45pm	Afternoon break
3.45pm - 4.45pm	Discussion session 3: Clarity in GMP: Facilitator: James Drinkwater: PHSS/F Ziel followed by PHSS Chairman's thanks and 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 with the challenging area of risk based GMP, European regulatory perspectives and industry key opinion leaders.



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