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PHSS India I-SIG 2014 Conference series; Mumbai & Goa

Mumbai 19/20 November & Goa 21/22 November 2014

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Mumbai: Evening networking event with key note speaker and dinner, 19 November.

Conference day 20 November; theme: Regulatory GMP Compliance challenges and improved control to avoid deviations.

Venue: Hotel in Mumbai: To be confirmed.

Goa: Evening networking event with key note speaker and dinner, 21 November.

Conference day 22 November; theme: Process design and control for GMP Compliance.

Venue: Hotel in Goa: To be confirmed.

The PHSS India special interest group: I-SIG for education in GMP/ GDP welcome all to attend this 2014 Conference series covering key aspects of GMP compliance, control, process design, operations and deviation management – High profile key note speakers and in depth technical panel discussions to extend the learning experience and knowledge exchange ….not one to miss to keep informed about addressing current challenges, understanding new trends, best practice and latest developments.

The evening networking events include a high level guest speaker (Indian FDA invited) followed by dinner and a network opportunity between attendees, speakers and exhibitors.

The back to back I-SIG Conferences in Mumbai and Goa have different content but are set around a common challenge of GMP compliance and improved control/ design to avoid deviations and regulatory non-conformance.

There is a relatively low cost fee for attendance to these high level events, 6000 INR, with attendance independent of the requirement to be a member of the PHSS, a not for profit educational society. There are extra benefits to becoming a PHSS member (full membership fee 6000 INR, students 2500 INR), please ask for details.

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.

PHSS I-SIG Conference event schedule: Mumbai

Mumbai evening networking event on Wednesday 19 November starts at 6.30pm with a welcome from the PHSS Chairman and member of the PHSS I-SIG Board of Directors followed by the Key note speaker (India FDA invited) covering key aspects of GMP compliance in India. Networking dinner and close by 9pm.

Mumbai Conference Thursday 20 November: opens for registration at 9.0am with coffee and refreshments and a first chance to view exhibitions.

Conference starts at 9.30am with a welcome and overview from the PHSS Chairman and Member of the I-SIG Board of Directors. The Conference closes at 4.30pm.

Presentation 1: 9.30am – 10.30am
Control strategies in GMP compliance.

Di Morris; Pharmaceutical Solutions Principle consultant: ex MHRA GMP inspector.

An ex-MHRA GMP inspector's point of view on developing requirements of Control strategies, currently referenced in EU GMP Annex 2 for biological products and now under increasing discussion related to manufacture of sterile medicinal products. Consideration will be given to the PHSS White paper on manufacture of sterile products, drugs and drug substances.

A Control Strategy sets out the approach and rationale taken to control product quality, efficacy and patient safety in manufacture of sterile Pharmaceutical/ Drug products (and substances). Product quality, efficacy and patient safety can be compromised by contamination as microbiological, chemical, another product(s) or other biological entities.

A control strategy and risk control measures (technical and organizational) are required to prevent such compromise.

A Control Strategy should be considered to include:

- Manufacturing control strategy; based on product type, demand, process and risk.
- Quality control strategy; based on understanding of risk with control of Critical Quality Attributes (CQAs) in a manufacturing process meeting regulatory requirements.
- Contamination control strategy including cross contamination control that may include requirements for containment/ product segregation.

Break for viewing exhibition, networking and refreshments. 10.30am – 11.15pm.

Presentation 2: 11.15am – 12.15pm
Facility design for Aseptic manufacturing plants, requirements, challenges of overdesign and consideration towards the ideal design.

Jean Dennis Mallet; Principle consultant of NNE Pharmaplan and ex-Head of Afssaps French regulatory GMP inspectorate.

This presentation addresses the key questions:

'Is Indian industry over designing the Aseptic Manufacturing Plants it builds?'

'Is it possible to over play Aseptic operations?'

It is clear under design leads to poor process and non-conformances difficult to resolve with CAPAs – Corrective and Preventative Actions without process improvements to establish regulatory acceptance.

It is not so clear that over design can also lead to challenges in regulatory compliance and operations with over complexity, challenging operations (and operator understanding) and issues of non-robustness and un-planned process interruptions that are difficult to manage for GMP compliance.

This presentation considers the challenges of 'Over design' in India, covering regulatory expectations (history and current requirements) and what would be considered the ideal design for the ideal Aseptic manufacturing facility?

- Brief history of the development of sterile GMP guidances (from 1963 to 2014)
- Current guidances America – Europe Japan and India – A comparison
- Recent trends in regulatory expectations – Some FDA findings
- Changes brought by the 2008 European Annex 1 on vial capping
- An ideal design for an ideal aseptic facility ?

Each bullet point will be closed by a quick summary in relation with the "overdesign" issue.

Break for viewing exhibition, networking and refreshments. 12.15pm – 1.30pm.

Presentation 3: 1.30pm – 2.30pm
Contamination and Cross Contamination control.

James Drinkwater; PHSS Chairman and F Ziel (Germany) Head of Aseptic processing technologies & GMP compliance.

Contamination control and Cross contamination control in controlled areas used for Aseptic manufacturing, terminally sterilized sterile product manufacturing and applicable to non-sterile products manufacture.

Controlling contamination is one of the biggest challenges in GMP compliance. Contamination can prevent product release and causes difficult root cause investigations in deviation events.

Often GMP non-conformance is a result of lack of understanding, poor interpretation and management of environmental monitoring data with inappropriate responses to events.

This presentation covers key aspects of Bio-contamination control, monitoring and deviation management with consideration from key points from the new PHSS Bio-contamination technical monograph 20 – a guidance document covering the bio-contamination life cycle: 1) Bio-contamination characterization and risk profiling. 2) Bio-contamination control, Strategy, Principles, control attributes, guidance on best practice. 3) Monitoring of controlled environments including Rapid Micro Methods. 4) Deviation management: best practice in root cause investigations and Corrective and Preventative Action (CAPA) implementation/ efficacy checks.

Improved contamination control is also considered through a new holistic design and environment monitoring initiative detailed in the PHSS Bio-contamination monograph 20. The new initiative is called: Bio-contamination Risk Profiling and Proactive Response (RPPR).

- Key aspects of Bio-contamination characterization, as micro-flora groups and risk profiling relative to products, process and patient safety.
- Contamination control and cross contamination control – Key considerations in facility design and in Aseptic manufacturing employing Barrier technology: Isolators and RABS; Restricted Access Barrier Systems.
- Monitoring: Requirements in classification and routine monitoring, selecting risk based sampling locations for critical processes, EM sample handling and processing including EM incubation regimes. Also a perspective in developing applications in RMM – Real time Bio-count monitoring systems for controlled environments.
- Deviation management: Process flow to manage deviations, check lists of recommended areas to cover in Root cause investigations and implementation of CAPAs.

Short break for change over to afternoon Technical panel discussions.

Afternoon session technical panel discussions:

Panel discussion A: Control Strategies.

Panel discussion B: Facility and process design.

Panel discussion C: Contamination and cross contamination control.

Technical panel; to include all speakers, member of PHSS I-SIG Board of Directors and invited Indian key opinion leaders in field of manufacturing to GMP.

Panel discussion A: 2.45pm – 3.15pm
Control Strategies.

Panel discussion questions:

- When do Control strategies apply and why are they needed now?
- Do all regulatory authorities expect Control strategies to be put in place?
- Can a company write a Control strategy retrospectively for an existing process?
- Where do we get guidance of what should be included in a Control Strategy for manufacture of Sterile Medicinal, drug products and substances?

Short 15 minute break for change overs.

Panel discussion B: 3.30pm – 4.00pm
Facility and process design.

Panel discussion questions:

- Why is over design occurring?
- Is overdesign of concern to regulatory authorities?
- How do we avoid over design if we have been subject to regulatory citations?
- If we find our plant is subject to over design what paths do we take: accept and proceed as change is too difficult or modify to meet a more appropriate design?

Panel discussion C: 4.00pm – 4.30pm
Contamination and cross contamination control.

Panel discussion questions:

- Open question to attendees to discuss issues in a Contamination event that has been experienced at the attendee's area of operations/ interest.
- USP <1116> indicates a greater level of acceptable microbiological contamination than EU GMP Annex 1 levels and different incidence rates for Isolator barrier and conventional cleanrooms – is this OK?
- What is the difference between Contamination and Cross contamination?
- If a Sterility tests fails but my media fill and environmental monitoring results are OK can I retest the product for release if this repeat Sterility test passes?

PHSS I-SIG Conference event schedule: Goa

Goa evening networking event on Friday 21 November starts at 6.30pm with a welcome from the PHSS Chairman and member of the PHSS I-SIG Board of Directors followed by the Key note speaker (India FDA invited) covering key aspects of GMP compliance in India. Networking dinner and close by 9pm.

Goa Conference Saturday 22 November: opens for registration at 9.0am with coffee and refreshments and a first chance to view exhibitions.

Conference starts at 9.30am with a welcome and overview from the PHSS Chairman and Member of the I-SIG Board of Directors. The Conference closes at 4.30pm.

Presentation 1: 9.30am – 10.30am
Developments in Aseptic Filling Technologies.

Wenzel Novak PhD (TBC); Groninger, Germany: Director of Pharmaceutical Development.

With changing and new pharmaceutical products profiles, more aseptically filled products and the need for process flexibility filling technology is developing to meet these challenges

Considering different dose forms: Vials, Syringes, Cartridges Filling platforms and solutions need to be flexible to meet product and market demands.

Developed filling solutions with a clear pathway to regulatory compliance must be considered to achieve the goal of faster to market for products in the increasing competitive market.

This presentation considers some of the latest developments at large and small batch scale filling operations.

- Current challenges in Filling products aseptically.
- Filling Aseptic and Toxic products.
- Aseptic filling of Freeze dried products.
- Increasing use of Single Use Systems and pre-sterilized containers.
- Requirements in Flexible Filling Platforms.
- Perspective on the future in filling technology.

Break for viewing exhibition, networking and refreshments. 10.30am – 11.15pm.

Presentation 2: 11.15am – 12.15pm

Jean Dennis Mallet; Principle consultant of NNE Pharmaplan and ex-Head of Afssaps French regulatory GMP inspectorate.

Facility design for Aseptic manufacturing plants, requirements, challenges of overdesign and consideration towards the ideal design.

This presentation addresses the key questions:

'Is Indian industry over designing the Aseptic Manufacturing Plants it builds?'

'Is it possible to over play Aseptic operations?'

It is clear under design leads to poor process and non-conformances difficult to resolve with CAPAs – Corrective and Preventative Actions without process improvements to establish regulatory acceptance.

It is not so clear that over design can also lead to challenges in regulatory compliance and operations with over complexity, challenging operations (and operator understanding) and issues of non-robustness and un-planned process interruptions that are difficult to manage for GMP compliance.

This presentation considers the challenges of 'Over design' in India, covering regulatory expectations (history and current requirements) and what would be considered the ideal design for the ideal Aseptic manufacturing facility?

- Brief history of the development of sterile GMP guidances (from 1963 to 2014)
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- An ideal design for an ideal aseptic facility?

Each bullet point will be closed by a quick summary in relation with the "overdesign" issue.

Break for viewing exhibition, networking and refreshments. 12.15pm – 1.30pm.

Presentation 3: 1.30pm - 2.30pm

Key operational aspects of using Barrier Isolator Technology.

James Drinkwater; F Ziel (Germany) Head of Aseptic processing technologies & GMP compliance.

There is increasing use of Isolator technology, particularly in Aseptic processing applications where particulate and microbiological contamination control is required in 'Open processing' stages where products are openly exposed to the manufacturing environment. Also some toxic/ biological products require containment and cross contamination control and such applications require special features in Isolator design and operation.

- Understanding the contamination control attributes of Isolators for different processing applications – strengths and limitations.
- Isolator and Glove leak integrity – how this relates to operations, associated risk in deviations and what actions to be taken in failed leak tests.
- Key operational aspects of Gaseous disinfection (GD-VHP) of Isolator barriers and transfer load surface decontamination. Including GMP non-conformance issues to avoid.
- Overcoming the GMP Compliance challenges of Isolators to ensure a clear pathway into compliant operations.

Short break for change over to afternoon Technical panel discussions.

Afternoon session technical panel discussions:

Panel discussion A: Developments in Aseptic Filling Technologies.

Panel discussion B: Facility and process design.

Panel discussion C: Operational aspects of Isolator Barrier Technology.

Technical panel; to include all speakers, member of PHSS I-SIG Board of Directors and invited Indian key opinion leaders in field of manufacturing to GMP.

Panel discussion A: 2.45pm – 3.15pm

Developments in Aseptic Filling Technology.

Panel discussion questions:

- What filling pump types are available for different product types?
- With a small high value batch how do you avoid product losses/ waste and maintain high accuracy in filling?
- How is managing the risks of glass container breakage managed in filling machine design/ process operations?

Short 15 minute break for change overs.

Panel discussion B: 3.30pm – 4.00pm

Facility and process design.

Panel discussion questions:

- Why is over design occurring?
- Is overdesign of concern to regulatory authorities?
- How do we avoid over design if we have been subject to regulatory citations?
- If we find our plant is subject to over design what paths do we take: accept and proceed as change is too difficult or modify to meet a more appropriate design?
- How do you decide product segregation requirements for a facility/ process?

Panel discussion C: 4.00pm - 4.30pm

Operational aspects of Isolator Barrier technology.

Panel discussion questions:

- When do you select an Isolator in preference to RABS barrier technology?
- What is the significance of leaks in Isolators and gloves during Aseptic manufacturing?
- Are Isolators avoided in India due to lack of understanding (perceived risk in qualification) of Gaseous Disinfection with VHP of the Barrier system?
- What pressure control regime and background environment is required for an Isolator Barrier in Aseptic manufacturing of an Aseptic and Toxic product?

4.30pm. Thanks and Conference close by PHSS Chairman and member of the PHSS I-SIG Board of Directors.

Extra time will be possible with speakers for those that have specific questions that are preferred to be asked 'One on One'.