ISPE Thailand 3rd Seminar 2018

Contamination Risk Assessment in Pharmaceutical Cleanrooms & How to use Airflow Visualization (Smoke Studies) to troubleshoot Cleanroom Contamination issues

29th – 30th October 2018 At Convention Hall C-D Room

Ambassador Hotel, Sukhumvit Soi 11, Bangkok, Thailand

Background

Day 1 : Contamination Risk Assessment in Pharmaceutical Cleanrooms

Cleanrooms are highly controlled environments where the air quality is monitored to ensure the extreme standards of cleanliness required for the manufacture of pharmaceutical, electronic and healthcare goods. ***Contamination controls*** is the primary consideration in cleanroom design, especially in the pharmaceutical facilities where contamination risk is concerned. However, contamination risk levels differ in aseptic, and non-sterile and terminally sterilized products. Within the non-sterile products risk levels vary per mode of administration. In terminally sterilized products, contamination for a terminally sterilized medical device may differ from a terminally sterilized drug product. Contamination risk in a non-sterile drug product may be different for a healthy patient as compared to an immunocompromised patient or children.

Contamination risk assessment initially begins with understanding the nature of a product, release specifications and which organisms are objectionable. In some medical device manufacturing, particulate contamination could also be objectionable because of the electronics involved.

The manufacturing facility is designed to mitigate and reduce contamination risks. Facility controls vary depending upon final product requirements. Contamination may also result due to inadequate cleanroom/RABs/Isolator/design and maintenance. Similarly, if a risk based approach is not adopted right from the beginning, contamination risks can occur due to utilities, raw materials, excipients, process and also inadequate testing.

With ICH Q9, Q10, ISO and EU all aligned on a risk based approach; it is time to explore performing a real risk assessment to control contamination in your product.

In this seminar (Day 1), you will understand the evolution of contamination control technology and will experience common misunderstood design/integration mistakes in cleanrooms and barrier/isolation technology. The limitation-of-Risk (LR) method which can be used as an engineering tool in risk assessment for the identification, minimization and evaluation of potential airborne risks, and for the identification of adequate monitoring points will be discussed. Besides theoretical point of view, there will be case studies and investigative methods for finding contamination sources.

<u>Day 2</u> : Air Flow Visualization techniques and technology: How to avoid common mistakes and misunderstandings related to smoke studies.

Understanding airflow patterns in cleanrooms and controlled environments is an important aspect in contamination control. Personnel, equipment and material flow can influence airflow and affect contamination levels in even the most well designed cleanrooms. Air flow visualization studies, sometimes referred to as smoke studies are useful in providing a visual representation of air flow in cleanrooms. These tests can also be useful in troubleshooting cleanroom contamination issues from undetected air patterns that limit a cleanrooms ability to provide adequate contamination control.

Though considered an optional test as listed in ISO 14644-3, Airflow Direction Test and Visualization is an expected test by pharmaceutical inspection authorities.

- The US FDA "Guidance for Industry Sterile Drug Products Produced by Aseptic Processing Current Good Manufacturing Practice" "Air pattern analysis should be conducted at the critical area to demonstrate unidirectional airflow and sweeping action over and away from the product under dynamic conditions. The studies should be well documented with written conclusions, and include evaluation of the impact of aseptic manipulations (e.g., interventions) and equipment design."
- GMP Annex 1 States that "air-flow patterns are to be demonstrated that they do not distribute particles from sources including, personnel, operations or machines into zones of higher product risk."
- USP 1116 suggests the use of Airflow Visualization techniques to evaluate air flow patterns under dynamic conditions and must include the evaluation of personnel movement for all aseptic manipulations.

The type of equipment and material used in creating the airflow visualization vapor or smoke is as important as the techniques used. As these test require the use of Tracer Particles generated and released into the cleanroom, clean air devices and areas adjacent to these areas, care should be taken in choosing the desired size and material of these Tracer Particles. The Tracer Particles should be of suitable size and volume as to visually represent the air moving through the cleanroom or clean space being tested.

Improperly conducted air flow visualization studies or the use of equipment that may not be suitable for conducting these studies may lead to a misleading conclusion related to airflow in critical areas. As the various pharmaceutical inspection authorities expect these studies to be conducted under dynamic conditions, simulations of actual processing operations it is important to understand the complexities related to doing dynamic smoke studies.

This seminar (Day 2) will discuss the various methods and techniques of air flow visualization as well as provide examples of improperly tested facilities including FDA 483 Observations and warning letters related to airflow visualization.

The objective of the seminar includes:

- Understand the principle of contamination control in cleanrooms
- Learn how to perform contamination risk assessment in cleanrooms
- Learn air flow visualization techniques
- Know the expected tests of air flow visualization by pharmaceutical inspection authorities
- Learn how to avoid mistakes and misunderstandings related to design/disintegrate cleanrooms and barrier/isolation technology as well as smoke studies

Get to know speaker

Morgan Polen

Morgan Polen is a senior cleanroom and contamination control consultant for Microrite, inc. (www.microrite.com) Morgan has provided cleanroom and contamination control solutions since 1984 in all industries that require cleanrooms and controlled environments. His hands on approach has enabled companies to resolve complex contamination issues in cleanrooms and controlled environments in over 40 countries. His work in identifying contamination sources and regulatory discrepancies in areas such as; cleanroom design, construction, operations, product and facility cleaning, Electrostatic Charge/Discharge remediation, Airborne Molecular Contamination identification, cleanroom suitability, mold source investigations and others.

Morgan has provided consultation to companies in a wide variety of clean industries such as; pharmaceutical, medical device, semiconductor, data storage, aerospace, defense, automotive, optical, agricultural, food and others. Morgan is a board member of the Institute of Environmental Science and Technology and is an internationally recognized Subject Matter Expert for Contamination Control in High Technology Manufacturing.

Morgan Polen

Email: morgan@particleMP.com Mobile: +1.408.892.1138

Senior Cleanroom and Contamination Control Consultant

Agenda of ISPE Thailand 3rd Seminar 2018

Topic : Contamination Risk Assessment in Pharmaceutical Cleanrooms & How to use Airflow Visualization (Smoke Studies) to troubleshoot Cleanroom Contamination issues

Date : 29th – 30th October 2018

Venue : At Convention Hall C-D Room Ambassador Hotel, Sukhumvit Soi 11, Bangkok, Thailand

Monday 29th October, 2018 (Entitled to CPE credits)

Day 1: Contamination Risk Assessment in Pharmaceutical Cleanrooms		**Speaker**
08.00-08.50	Registration	
08.50-09.00	Welcome and opening	*ISPE Thailand President*
09.00-10.30	**The Evolution of Contamination Control Technology :** Cleanroom Technologies from Flow Benches, Open Cleanrooms & the Development of Barrier/Isolation Technology	*Morgan Polen*
10.30-10.45	Coffee break	
10.45-12.00	**Common misunderstood design/integration mistakes in Cleanrooms & Barrier/Isolation Technology**	*Morgan Polen*
12.00-13.00	Lunch	
13.00-14.30	**The Limitation-of-Risk (LR) method of Risk Assessment** • Risk Identification • Minimization • Evaluation of Potential Airborne risks • Identification of Monitoring Points	*Morgan Polen*
14.30 -14.45	Coffee break	
14.45-16.30	**Case Studies & Investigative methods for finding contamination sources** • Contamination Control Strategy : *What it is & Why every cleanroom needs one*	*Morgan Polen*
16.30-17.00	Q&A	

Tuesday 30th October, 2018 (Entitled to CPE credits)

Day 2: Airflow Visualization (Smoke Studies) to troubleshoot cleanroom contamination issues		Speaker
08.00-09.00	Registration	
09.00-10.30	**Purpose of Air Flow Visualization** • Air Flow Basics **Common Errors Associated with Smoke Studies** • Summary of Inspectors Comments • Examples of BAD Smoke Studies • Case Studies	*Morgan Polen*
10.30-10.45	Coffee break	
10.45-12.00	**Evolution of Contamination Control** • Horizontal Flow, Open Cleanrooms, RABS • Standards? Guidance and Updated Regulatory Views on Smoke Studies	*Morgan Polen*
12.00-13.00	Lunch	
13.00-14.30	**Tracer Particles:** • Tracer Particle Size • Tracer Particle Visible Duration • Tracer Particle Contamination Concerns	*Morgan Polen*
14.30 -14.45	Coffee break	
14.45-16.30	**Smoke Study Process** • Smoke Study Protocol • Smoke Study Report • Videos, Raw Videos, Summary Videos & Data Integrity	*Morgan Polen*
16.30-17.00	Q&A	

Registration Fee

Seminar 29th - 30th October 2018	Registration Fee
ISPE/TIPA Member	4,000 Baht
Non-member	6,000 Baht

Note :

1. The registration fee is for 2 days seminar (29th - 30th October 2018)
2. Member applies to member of ISPE and TIPA only.
3. Going green in this seminar with electronic presentation handout i.e. handout will be made available before the seminar in downloadable PDF file

Hotel and Travel

Conference Hotel : Ambassador Hotel, Sukhumvit Soi 11, Bangkok, Thailand

http://ambassador.bangkokshotels.com/en/

Travel : http://www.amtel.co.th/location/

How to register

HOW TO REGISTER

1. **Online Registration** Browse website http://ispeth.org/EVENT-3_2018 , fill-in delegate details and click submit
2. **Confirmation** ISPE staff will confirm your registration status via email. If not receive email within 2 working days after submitted the form, please contact our staff.
3. **Payment** Make a payment to reserve your seats and capture/ scan transferred evidents i.e. payslip to email REGISTER@ISPETH.ORG

REGISTRATION CLOSES ON 24 OCTOBER 2018 OR WHEN ALL SEATS ARE FULLY RESERVED.

FIND OUT MORE INFO & CONTACT US: WWW.ISPETH.ORG EMAIL: REGISTER@ISPETH.ORG
T: +6688-090-4664

PAYMENT

Payment must be received prior to the event otherwise the reservation will be cancelled. All payments should be made in Thai Baht.

BANK > KASIKORN BANK, LAD PRAO 67 BRANCH
ACCOUNT > ISPE FOUNDATION
NUMBER > 027-8-46566-7
SWIFT CODE > KASITHBK
BANK ADDRESS > 2347 LADPRAO 67, WANGTHONGLANG, BANGKOK, THAILAND 10310

TERMS AND CONDITIONS

All fees stated include luncheons, refreshments and documentation. It does not include the cost of accommodation and travel.

SUBSTITUTION / CANCELLATION

Substitute delegates are not allowed. Cancellations must be received in writing at least 10 business days before the start of the event.