Meeting The New ISO Cleanroom Standards And Changing EU Guidance

How Will You Comply?

MARCH 02-03 2017
MONTREAL, CANADA

Two day intensive training on:

- Changes to ISO Standards-what does it mean to you?
- Airflow pattern analysis-Why do regulators expect this?
- Methods for airflow pattern analysis-meet ICH Q9 and Q10 Risk based approach
- Establishing risk based sample sites to maintain current industry thinking
- Selection of particle counting instruments/systems/notification systems
- Selection of viable particle sampling/real time microbial detection (New Technology)

And More...

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EVENT ORGANIZED BY:

International Pharmaceutical Academy

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www.ipacanada.com

About the course:

The International Cleanroom Standards (ISO 14644-1 & 2) have been updated, these changes affect the requirements for the classification testing and monitoring of ALL cleanrooms. The classification testing standard has significant changes and includes the requirements for the development of a "Monitoring Plan" based upon risk assessment. How will you comply with these changes?

With changes to number of sampling sites, testing frequencies, particle classification limits and rules it is critical to re-visit your environmental monitoring program.

How will you address the differences between particulate limits for classification and monitoring as changed in the new ISO 14644 parts 1 & 2 and those of current EU Ennex1?

A risk based approach to environmental monitoring is emphasized in the new ISO standard and the current EU Annex 1. As the ISO standards are being updated, PICs supported by EMA is in the process of revising EU Annex 1 to align with ICH Q9 and Q10 risk based approach and current technologies. A risk based approach to sample site selection, considerations for monitoring technology, as well as other risk considerations during environmental monitoring will be discussed in this two day intensive training.

This 2 day course will address:

- Changes to ISO Standards-what does it mean to you?
- Airflow pattern analysis-Why do regulators expect this?
- Methods for airflow pattern analysis-meet ICH Q9 and Q10 Risk based approach
- Establishing risk based sample sites to maintain current industry thinking
- Selection of particle counting instruments/systems/notification systems
- Selection of viable particle sampling/real time microbial detection (New Technology)
- Frequency of monitoring to adequately address risk
- Performance Qualification-First step to assess risk
- Establishing a Risk Based EM Program
- Trend Analysis-What is your EM data telling you?
- Investigating Environmental Monitoring Excursions

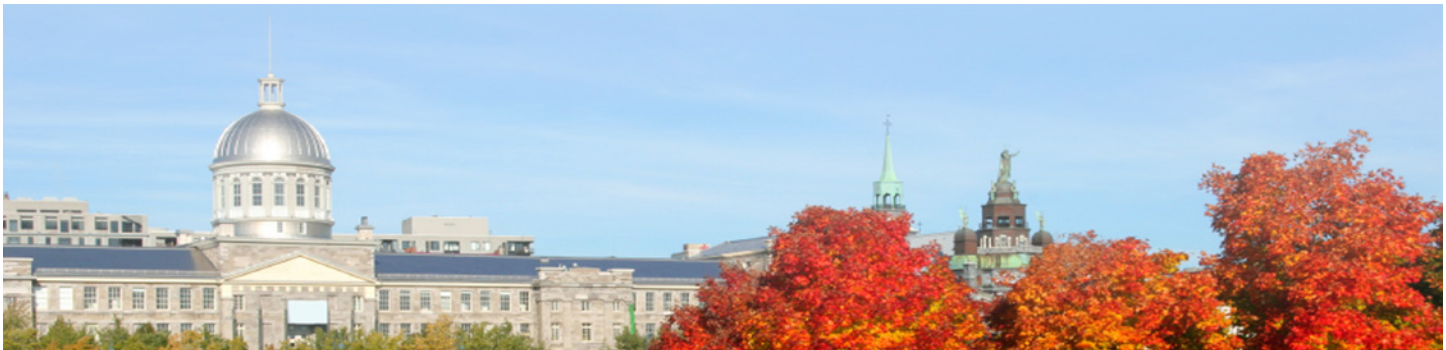
About the speakers:

Ziva Abraham
President and Founder
Microrite, Inc.

Ziva Abraham is the President and Founder of Microrite, Inc., a California based consulting firm. She has over 25 years of academic, research, clinical and industrial experience in microbiology, and quality assurance. Ziva has received her Master's Degree in microbiology with a focus on Mycology and has worked on developing microbial Insecticides using entomogenous bacteria and fungi for her doctoral research. Her career also includes founding and managing clinical laboratories for Maccabi Medical in Israel. She has trained personnel from various industries in microbiology techniques and methods. She uses her extensive experience to teach why assessing risk of microbial contamination should be in the forefront of any company that has products for human/veterinary use. Her experience in clinical laboratories has provided her with the framework to understand the effects of microbial contamination in products from a patient safety perspective.

Morgan Polen
Member of IEST's US Technical Advisory Group to ISO/TC 209 Cleanrooms
Microrite, Inc.

Morgan Polen has been involved with cleanrooms and contamination control since 1984, working in over 40 countries involved with projects ranging from cleanroom design, construction, validation, monitoring program development, particle counter design and product management for cleanroom related products and systems. Addressing monitoring and control solutions in a wide variety of clean industries such as pharmaceutical, medical device, semiconductor, data storage, aerospace, defense, automotive, optical and others. Morgan is a member of IEST's US Technical Advisory Group to ISO/TC 209 Cleanrooms and Associated Controlled Environments, participating in the process of adapting the latest cleanroom standards.



Day 1 Course Agenda

Day 1 - Thursday March 02, 2017

8:00 AM – 8:30 AM

Registration and continental breakfast

8:30 AM – 10:00 AM

Changes to ISO Standards-What does it mean to you?

- Understanding the changes to ISO 14644 parts 1 and 2
- How long do you have to comply with the new ISO Standard?
- How will it affect you current EM program?
- What has changed in the standard that may affect your current EM program?

10:00 AM - 10:15 AM

Mid-morning Refreshment Break

10:30 AM – 12:00 PM

Airflow Pattern analysis-Why do regulators expect this?

- Role of Airflow visualization studies (smoke studies) in:
  - Confirming airflow parameters, direction and uniformity to mitigate contamination risk and assess and define critical control points
  - Establish a visual representation of airflow conditions during normal operations and media fills
  - Assess airborne particles and microbial contamination risk to product

12:00 PM - 1:00 PM

Networking Lunch

1:00 PM - 2:00 PM

Methods of airflow pattern analysis-meet ICH Q9 and Q10 risk based approach

- Benefits of performing airflow analysis during static and dynamic conditions
  - Simulation of interventions to assess and prevent risk during aseptic processing
- Equipment considerations to visualize airflow from source to return
- Why type of smoke generating equipment and placement of video equipment is important in order to assess risk
- Residue considerations; cleaning after completion of airflow visualization studies

2:00 PM - 3:00 PM

Establishing a risk based sample sites to maintain current industry thinking

- Use airflow visualization to assist in establishing sample locations which are risk based and can influence product risk
  - Sample site locations in relationship to placement of probes, plates, fixtures, particle counters and active air samplers
  - Particle monitoring
  - Active air sampling
  - Passive air sampling

3:00 PM – 3:15 PM

Mid-Afternoon Refreshment Break

Day 1 Course Agenda

Day 1 - Continued

3:15 PM – 4:00 PM

Selection of particle counting instruments/systems/ notification systems

- Type of particle counter
- Installation of particle counter and sampling probe location
- Operator notification/interface
- Data: Reporting, retention and security

4:00 PM – 4:45 PM

Selection of viable particle sampling/ real time microbial detection (New Technology)

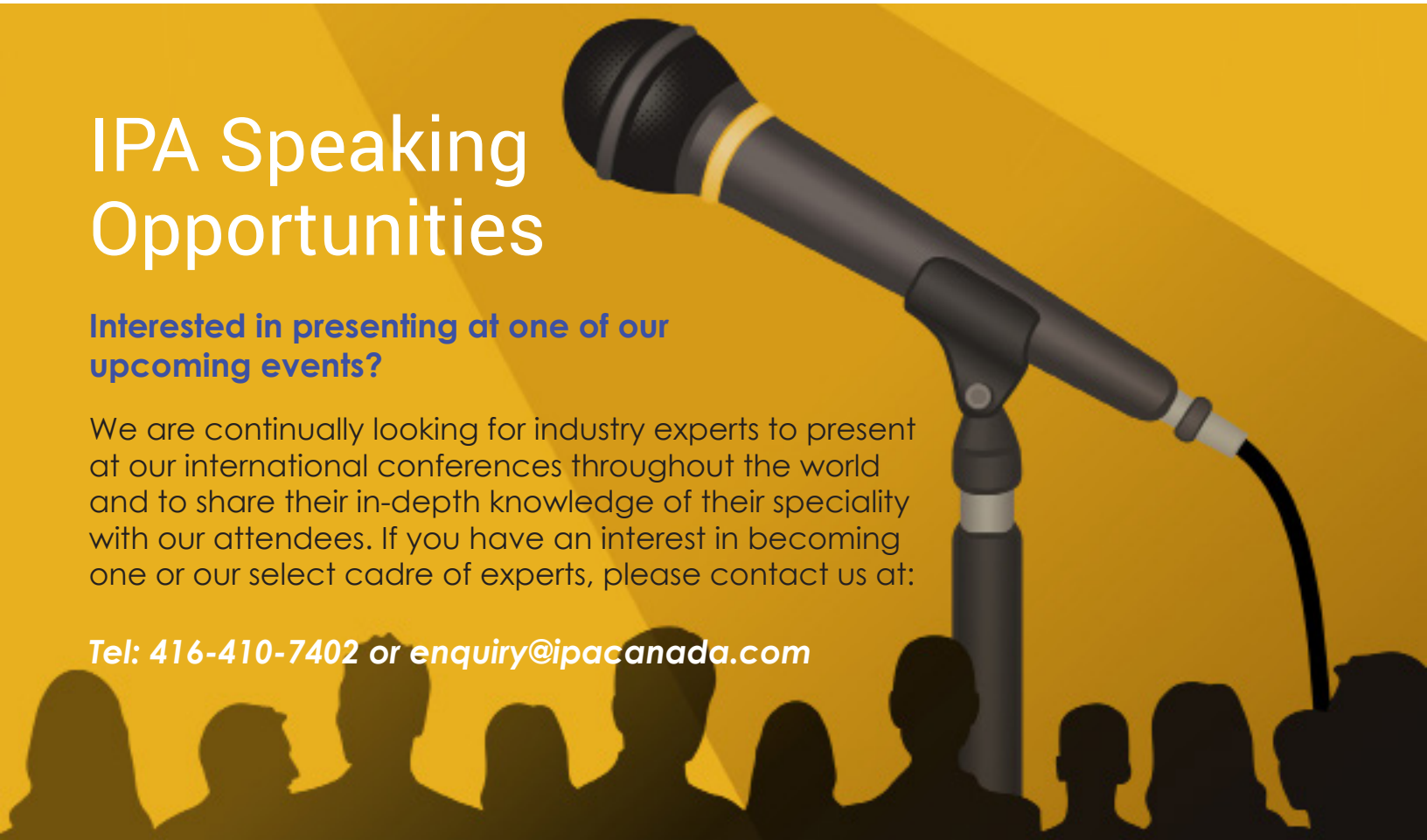
- New technologies are being addressed in changing guidances, understand type of viable particle counter updated technologies
- Continuous monitoring of viable particles-benefits and challenges

4:45 PM – 5:00 PM

Questions and Answers and discussions

5:00 PM

Conclusion of Day 1



IPA Speaking Opportunities

Interested in presenting at one of our upcoming events?

We are continually looking for industry experts to present at our international conferences throughout the world and to share their in-depth knowledge of their speciality with our attendees. If you have an interest in becoming one or our select cadre of experts, please contact us at:

Tel: 416-410-7402 or enquiry@ipacanada.com

Day 2 Course Agenda

Day 2 - Friday March 03, 2017

8:00 AM – 8:30 AM
Networking and Continental Breakfast

8:30 AM – 9:15 AM
Frequency of monitoring to adequately address risk

- Understand the requirements for cleanroom classification testing per the new ISO standard and changing EU Annex 1 and those for routine environmental monitoring
- Use product type and risk to patient to establish a reasonable frequency for monitoring

9:15 AM – 10:00 AM
Performance qualification-First step to address risk

- Setting limits for sterile and non-sterile using a myriad of guidances-evaluation of the applicability of each guidance
- Value in performing a baseline study before establishing action levels for environmental monitoring
- Planning a disinfection and cleaning strategy; why chemical kill and physical removal are equally important
- Establish length of microbiological PQ of environment and gases to collect relevant data evaluate hot spots that may pose risk to product; and which risk assessment tools can be used
- Know the operational risks before performance qualification testing

10:00 AM - 10:15 AM
Mid-morning Refreshment Break

10:15 AM – 12:00 PM
Establishing a Risk Based EM Program

- Strategy for reasonable monitoring without overkill
- Operational risks during monitoring: common errors in choice of media, management of media, and incubation
- Revising limits-errors to avoid
- Key elements of an EM procedure-cannot generate good data without a sound procedure
- Adequate data recording-first component for assessing risk
- Managing EM data for purposeful trending
- Microbial identification
    - What is objectionable in your product?

12:00 PM - 1:00 PM
Networking Lunch

1:00 PM - 3:00 PM
Trend Analysis- What does the data mean?

- USP <1116>; how does it apply during trending
- Trending excursions vs. organisms-the key to foresee risk to product and patient
- Using data trends to identify facilities, gowning, cleaning and other deficiencies
- Key element of an EM summary report to assess risk to product and patient

3:00 PM – 3:15 PM
Mid-Afternoon Refreshment Break

Day 2 Course Agenda

Day 2 - Continued

3:15 PM - 4:15 PM

Investigating Environmental Monitoring Excursions

- Developing and action plan when an excursion occurs
  - Planning an investigation-information to be collected
  - Three step approach-Estimated cause(s), Probable cause(s), Root cause
  - What are corrective actions and how effective are they
  - When is it appropriate to use EM data as a product release criterion?

4:15 PM – 5:00 PM

Questions and Answers and discussions

5:00 PM

Conclusion of Program

Sponsorship & Exhibition Opportunities

Interested in Exhibiting or Sponsoring at this event? Contact us at 416-410-7402 or enquiry@ipacanada.com

Who Should Attend:

Why attend?
This program is set up to eliminate the confusion between regulatory requirements, inspectors' expectations and the changes to ISO standards and upcoming EU Annex 1 changes. FDA observations, warning letters and case studies will be used to clarify regulatory expectations for sterile and non-sterile facilities.

Which industries does this workshop apply to?
Pharmaceuticals, Biotechnology, Medical Device, In Vitro Diagnostics, Food, Beverage, Pharmacies and Technology Companies

Who will benefit?
QC Microbiology, Quality Assurance, Regulatory, Training, Validation, Facilities, and Certification Personnel and Technology Companies

Course Venue:

Holiday Inn Montreal Aeroport- Airport

6500 Cote De Liesse Montreal, Quebec H4T1E3 Canada
Tel: 1-514-739-6440

Website: http://www.ihg.com/holidayinn/hotels/us/en/montreal/yulcd/hoteldetail

Hotel Accommodation:

Guests are responsible for their own accommodations.

IPA has arranged a special room rate for attendees at the Holiday Inn Montreal Airport (Conference Venue). To reserve a room at our group rate, please call the hotel directly at 514-739-6440 and state that you are attending IPA event.

Complimentary shuttle available to and from **Pierre-Elliott Trudeau International(YUL) airport.**
Distance: 4.35 MI/7.0 KM WEST to Hotel. Complimentary Shuttle Available. 24 hour airport shuttle is available. Driving directions: from the airport follow signs for 520 East (Cote de Liesse EST/EAST). From the 520 EST/EAST, take exit 5 Hickmore. Stay on the Cote-de-Liesse service road and hotel will be on your right-hand side.

Nearby Hotel:

Crowne Plaza Montreal Airport

6600 Cote De Liesse, Montreal Quebec - H4T 1E3, Canada | Phone: 1-514-344-1999 | http://www.ihg.com
Guests are responsible for their own accommodations. Please call the hotel directly.
Note: The Crowne Plaza Montreal Airport hotel offer a 10 km radius complimentary shuttle bus from 7AM - 9PM week-days. For more information, please call the hotel directly.

REGISTRATION FORM

Meeting The New ISO Cleanroom Standards And Changing EU Guidances

March 02-03, 2017 | Montreal, Canada

Early Bird: Till January 06, 2017	CAD $788 + HST
Discounted Price: January 07, 2017 to January 31, 2017	CAD $888 +HST
Regular Price: February 01, 2017 to March 02, 2017	CAD $988 +HST
Academia / Government at all time (Save Over $250.00)	CAD $688 +HST

Group Discount: Special group rates available for 3 or more registransts. Some restriction applies., please contact us by email: enquiry@ipacanada.com or Call: 416-410-7402

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For registration or any further information, please contact us at:

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420 Highway 7 East, Box 82022,
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www.ipaevent.com

Fax:
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Cancellation/Substitutions Policy:

All cancellations are subject to a CAD $150.00/person processing fee. To receive cancellation credits for attendance at an upcoming course, IPA must be notified of the cancellation in writing (by email, mail or fax) up to 3 weeks prior to the program start date. Cancellations submitted less than 3 weeks prior to the event will not be qualified for refund or credit.

Substitution of delegate/s with the member/s of the same organization is permitted at any time with no penalty.

IPA reserves the right to postpone an event, prior to which time all the registered attendees will be notified a minimum of 2 weeks in advance. IPA shall not be responsible for any air fare, hotel or transportation costs incurred by registrant/s.