



Simplify the classification process and remove the need to evaluate the 95% upper confidence limit (UCL) for low sample location numbers (currently required for 2/9 of cleanroom locations).

Review the classification procedure and make it more applicable to cleanroom operation. For example, contamination is not expected to be evenly distributed.

Over the last five years, the ISO Technical Committee 209 has been working on the revision of the basic airborne cleanliness classification, 14644-1 and -2.

Update the standard as required to current reasoning and industry requirements.

Avoid any radical change to the principles of the current ISO cleanliness classes 1-9.

**For more information,
kindly contact our local office:-**

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- ▶ Microbial Air Monitoring Technique –Grade A
- ▶ Microbial Surface Monitoring Technique –Grade A
- ▶ ISO 14644: 2015 Summary and Revision
- ▶ ISO 14698 Bio-contamination Control

Venue: Olive Tree Hotel, Penang

Date: 28th March 2017

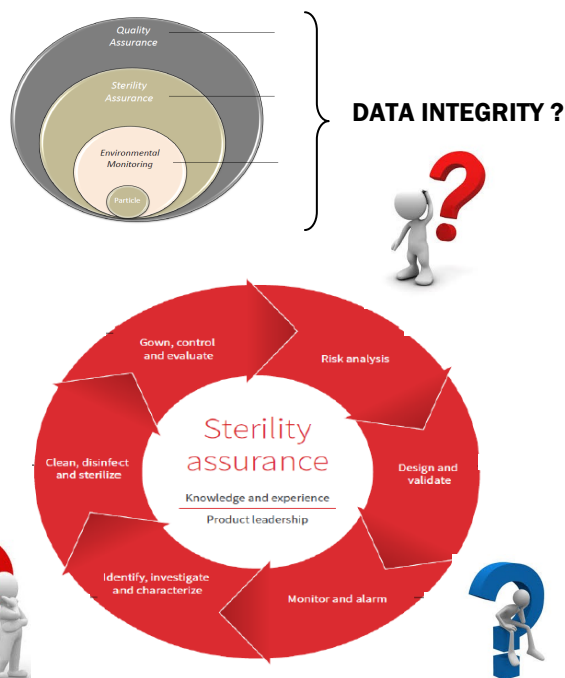
Time: 9.30 am to 4.00 pm



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Environmental Monitoring (EM), particularly in Pharmaceutical manufacturing facilities where the risk of microbial contamination is controlled through aseptic processing, comprises both physical & microbiological test methods. It is a common assumption that if fewer total particulates are present in a cleanroom, it is less likely that airborne microorganisms will be present. This is true only if human operators are the main source of particulate matter in the air. However, it is not possible to clearly distinguish between background total particulate contamination generated largely by mechanical operations and the total particulates contributed by personnel. Thus, it is routine for cleanroom EM programs to consist both a total particulate component & a microbiological component.

The data originated from these EM components provide critical information on how well a stable & suitable environment for the aseptic preparation of medicinal products is maintained.



Speaker Profile



王彩琴 **CHRIS WANG**

PMS China Sr. LS Mkt. Manager
(Asia GMP Expert)

Responsible for the business development of PMS in China Life Science Industry, supporting Asia subsidiaries on GMP regulation compliance.

Chris has 10 more years Pharmaceutical environment monitoring and certification experience, specialized in the risk assessment and compliance consultant

From 2012 to 2016, PMS China Senior Marketing Manager, Responsible for the business development of PMS China LS Industry, being charge of the sterility assurance full circle solution service.

In 2012, Chris have ever been involved in the design and validation of the first unit of Real-time microbial site inspection for China local FDA.

From 2008 to 2012, PMS East China Sales manager. Have been involved in the design and constructions of hundreds of facility monitoring systems for sterile drug manufactories. Have ever trained the environmental monitoring regulations and applications for Shanghai FDA, Anhui FDA and some designing institutes.

From 2004 to 2008, Chris has been in charge of cleanroom consultant service in China pharmaceutical and electronic industries and has ever provided the risk assessment for Roche China, GE healthcare and some other Pharm. companies.

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Registration Fees (GST to be charged upon invoicing):

Early Bird: RM300.00/Pax before 28-2-2017

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RSVP : By 15th March 2017



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