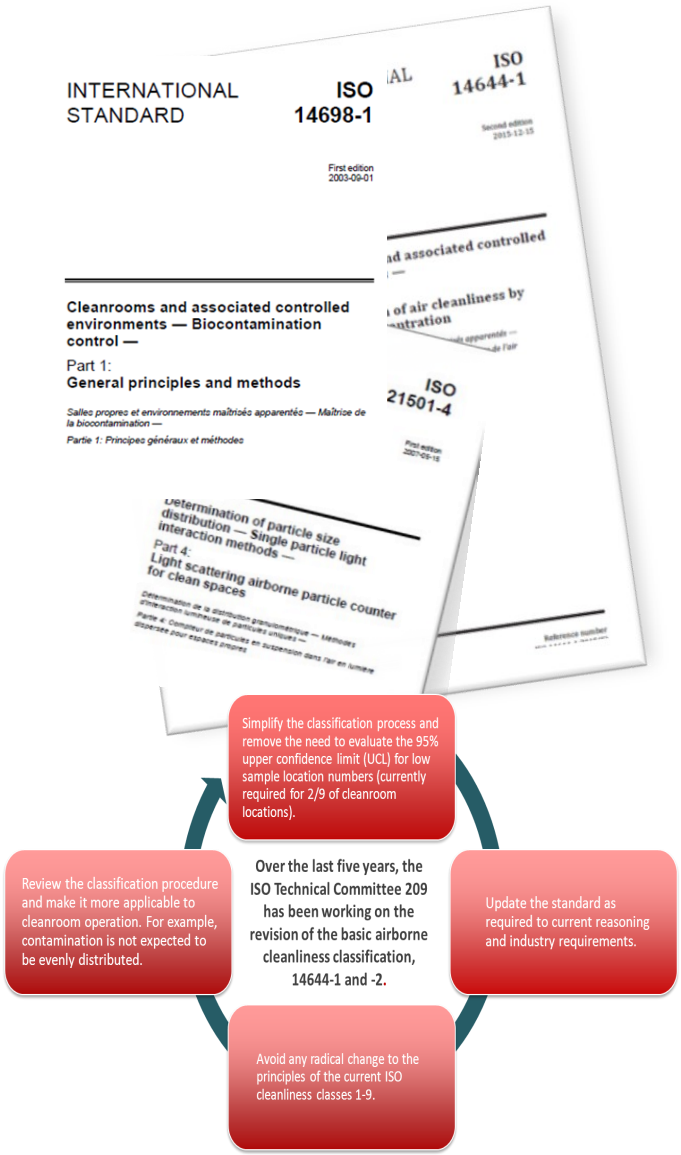

For more information, contact your local office:

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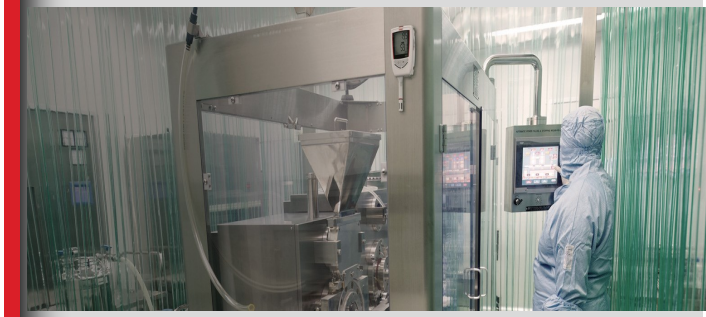

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- Data Integrity & PMS Compliance Solutions
- Microbial Air Monitoring Technique in Grade A
- Microbial Surface Monitoring Technique in Grade A
- ISO 14644: 2015 Summary and Revision
- ISO 14698: Biocontamination Control

Venue: Hotel Bangi-Putrajaya

Date: 30th March 2017

Time: 9.30 am to 4.00 pm

Who Should Attend:

- **Microbiology Manager**
- **QA / QC Manager**
- **Validation Manager**
- **Production Manager**
- **Engineering Manager**

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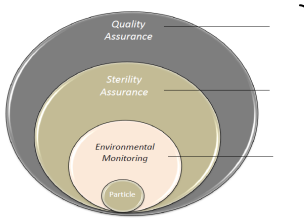
Environmental Monitoring (EM), particularly in Pharmaceutical manufacturing facilities where the risk of microbial contamination is controlled through aseptic processing, comprises both physical & microbiological test methods. It is a common assumption that if fewer total particulates are present in 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.



DATA INTEGRITY ?

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 regulation compliance.

Chris has more than 10 years Pharmaceutical environment monitoring and certification experience, specialized in the risk assessment and compliance consultant. From 2012 to now, 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

Regular Price: RM450.00/Pax after 28-2-2017

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RSVP : By 15th March 2017

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