



ISPE®

Thailand
Affiliate



JOINT MEETING BETWEEN ISPE THAILAND AND TIPA 2017 “Cleanroom Testing & Certification”

Tuesday 2nd May 2017 – Wednesday 3rd May 2017

Venue: 1st Floor, Convention A-B Room, Ambassador Hotel Bangkok, 171 Sukhumvit Soi 11, Bangkok 10110, Thailand (BTS Nana Station Exit 3), <http://www.amtel.co.th/>
(Special room rates are available for seminar participants)

BACKGROUND AND OBJECTIVE

HVAC problems can be difficult to fix or improve, not like a small piece of equipment. To prove cleanroom is built as intended use, it cannot be done by visual check. A cleanroom can fail one although it looks very nice by our own eyes. To prove a cleanroom, we need to do cleanroom testing and the right cleanroom testing must follows international standards ISO / IEST / NEBB. Most important, cleanroom must be designed for the right cleanroom testing otherwise we cannot ensure the cleanroom meets the requirements.

So we have to know how a cleanroom is tested and certified before we can design the cleanroom and qualify the cleanroom.

The program will be benefit for the design team who wants to do the best design, the validation team who wants to perform the right cleanroom qualification, the service team who wants to maintain the cleanroom at validated state. Also In a regulated pharmaceutical facility, someone in Quality Assurance must sign off on the cleanroom test reports. Although they do not test, they must know if the testing procedure is correct and as per SOP's

Many problem cases will be presented e.g. improper airflow measurements, HEPA Filter mismatched installation for leak testing, Clean-up time ambiguity, etc.

SPEAKER:

Mr.Dan C. Milholland, NASA Consultant

RATE PER PERSON FOR 2 DAYS

Type	Early-Bird 20 MAR -20 APR 2017	Standard AFTER 20 APR 2017
ISPE & TIPA Member	4,280	5,350
Non-Member	5,350	6,420

Remark:

- Prices include 7% VAT
- Attendees are limited with first-come, first-served basis.



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AGENDA

Day 1		Speaker
08.00-08.50	Registration	
08.50-09.00	Welcome and opening	ISPE Thailand President
09.00-10.30	What is a cleanroom? How do they work? The basic cleanroom design <ul style="list-style-type: none"> • What does it require to maintain particle control in the room • HEPA filters and how they work • Room pressurization and airflow 	Dan C. Milholland
10.30-10.45	Coffee break	
10.45-12.00	Cleanroom standards (present and history) <ul style="list-style-type: none"> • IEST • Federal Standard 209 • ISO 14644 • NEBB • Annex 1 	Dan C. Milholland
12.00-13.00	Lunch	
13.00-14.30	Regulatory requirement for cleanroom testing & certification	Thai FDA
14.30 -14.45	Coffee break	
14.45-16.30	Why do we test cleanroom performance periodically? Four primary test <ul style="list-style-type: none"> • Filter Integrity • Airflow • Room Pressure • Particle counts per ISO 14644 or Annex 1 (Procedure, Instrumentation, Acceptance Criteria, Report)	Dan C. Milholland
16.30-16.45	Q&A	
16.45	Closure	



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Day 2		Speaker
08.00-08.50	Registration	
08.50-09.00	Welcome and opening	ISPE Thailand President
09.00-10.30	<p>Other tests (Secondary test)</p> <ul style="list-style-type: none"> • Temperature & Humidity and use of building Management System • Airflow Visualization • Recovery • Lighting • Sound <p>(Procedure, Instrumentation, Acceptance, Report)</p>	Dan C. Milholland
10.30-10.45	Coffee break	
10.45-12.00	<p>Prior to cleanroom testing and certification</p> <ul style="list-style-type: none"> • Site preparation for new build • Building and Room Commission, Testing, Adjusting and Balancing (TAB) work 	Dan C. Milholland
12.00-13.00	Lunch	
13.00-14.30	<p>Other interested issues</p> <ul style="list-style-type: none"> • Is airflow velocity uniformity necessary (Video – need internet connection) • The history of why 0.01% is considered a leak • Measuring accurate velocity readings at work height origin of 90 fpm +/- 20% (0.45 m/sec +/- 20%) • Testing dehydrogenation tunnels ambient and at temperature 350 °C • PTFE media vs. traditional glass media 	Dan C. Milholland
14.30 -14.45	Coffee break	
14.45-16.30	<ul style="list-style-type: none"> • Environmental monitoring –viable and non-viable • Trend data –alert and action limits • Monitor FDA website to see recent 483 violations • Particle counts per ISO 14644 or Annex 1 (https://google2.fda.gov/search) • Review of NEBB and CETA’s role in USO 797 • USP 797 is being revised. Where does it stand 	Dan C. Milholland
16.30-16.45	Q&A	
16.45	Closure	



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SPEAKER BIOGRAPHY

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MR. DAN C. MILHOLLAND

He is the cleanroom expert in USA. He has more than 35 years of experience in cleanroom and contamination control. He was the working group of US cleanroom standards e.g. IEST and Federal Standard 209 and served US Expert Council for ISO 14644. He consulted for NASA for multiple space missions and he is the NEBB Cleanroom Instructor and Committee to certify cleanroom certifiers which is world recognized accreditation program in cleanroom certification.

He completed both his undergraduate and graduate studies at North Carolina State University where he was awarded a Master's degree in biochemistry.

Milholland began in the air filtration business in the mid-1970's as a service manager for a company that sold air filters. That experience was the springboard for founding Biocon in November 1980.

- Awarded the IES Maurice Simpson Technical Editors Award in 1994 and the IEST Willis J. Whitfield Award in April 2002
- Consulted at NASA for Mars samples containment design
- Served on the Expert Council for United States for ISO 14644-1
- Presented to the FDA for the "Barrier Users Group Symposium"

Since selling his company in 1999, Dan has remained active as a consultant in the contamination control industry.



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WAYS TO REGISTER OR ENQUIRY

1. Fill-out this form with your details
2. E-mail to info@tipa.or.th or fax to **TIPA 02-713-5593**
3. Make a payment with your chosen for payment below

Latest by Tuesday, April 25th, 2017

CONTACT DETAIL:

Mr. Ms. Dr. Others(_____)

First Name: _____

Last Name: _____

Job Title: _____

Pharmacy License Number: _____

Email: _____

Tel: _____ Fax: _____

Management Level: Senior Middle Junior

FOR TAX INVOICE: *Please provide us the official NAME and ADDRESS for Tax Invoice*

Company: _____

Branch: _____

Address: _____

TAX ID : _____

Type	Early-Bird	Standard
ISPE &TIPA Member	<input type="radio"/> 4,280 Baht	<input type="radio"/> 5,350 Baht
Non-member	<input type="radio"/> 5,350 Baht	<input type="radio"/> 6,420 Baht

FEES: The following rates INCLUDE VAT 7%

To join ISPE Thailand as member, please visit ISPE Thailand's Website: www.ispeth.org or call 0-2630-4525

Mode of payment:

TRANSFER

Transfer to THAI INDUSTRIAL
PHARMACIST ASSOCIATION

ACCOUNT NO: 042-282-031-1

SIAM COMMERCIAL BANK (SCB)

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SWIFT CODE: SICOTHBK

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CANCELLATION & SUBSTITUTION POLICY:

Notice of withdrawal must be given in writing at least 7 working days (latest by 25 Apr 2017) before the commencement of the event. No refund of fees will be made for cancellations on or after 25 Apr 2017 or "no show" participants. Substitutions are acceptable in writing to the organizer; however, non-members substituting for members must pay the difference in fees prior to the event.