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# JOINT SEMINAR BETWEEN ISPE THAILAND-INDONESIA-SINGAPORE AND TIPA 2017

## ***“Cleaning Validation Theory and Practice”***

**Monday 16<sup>th</sup> October 2017 – Tuesday 17<sup>th</sup> October 2017**

**Venue:** 3<sup>rd</sup> Floor, Cattleya 2 Room, Ambassador Hotel Bangkok, 171 Sukhumvit Soi 11, Bangkok 10110, Thailand (BTS Nana Station Exit 3), <http://www.amtel.co.th/>

### **BACKGROUND AND OBJECTIVE**

Cleaning and cleaning validation has become important process in every pharmaceutical manufacturing step. The objective is to ensure patient safety and product quality. Cleaning validation is a requirement of PIC/S GMP. The regulatory approach is set out in Annex 15 PIC/S GMP PE009 - 12 : Qualification and Validation.

Cleaning Validation assures the effectiveness of any cleaning procedure for all product contact equipment by employing a risk based approach associated with cross-contamination. Cleaning validation program should start with the design of cleaning and sampling method, applying the right cleaning agents, choosing the critical process parameter and critical quality attribute and specifying contamination limits/acceptance criteria.

In order to understand the science of cleaning and cleaning validation, ISPE Thailand and TIPA set the seminar for pharmaceutical industry and related fields on Cleaning Validation, Theory and Practice. The objective of the seminar includes:

- Update on current PIC/S GMP PE009-12 (Annexes) 1 October 2015, Annex 15 Qualification and Validation : Cleaning Validation
- Understand the appropriate cleaning method and the right cleaning equipment as well as the factors that influence efficiency and effectiveness of cleaning process
- Determine suitable cleaning agents and cleaning equipment
- Determine suitable sampling techniques and the selection of sampling locations
- Employ appropriate quality risk based approach on cleaning validation
- Learn how to calculate residue limits that meet all necessary regulatory requirements
- Differentiate the principle of cleaning validation for each cleaning process i.e. manual, semi-auto and automatic
- Determine worst case selection/bracketing
- Learning how to apply the principle of cleaning validation in practice

In addition, benefits of the seminar and workshop include interacting and learning from the trainers and delegates. Delegates will have the opportunity to discuss their challenges and problems.

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**SPEAKER:**



## **Maurice Parlane**

2016 ISPE Member of the Year, Director of **ISPE Australasian Affiliate** and Director of **Centre for Biopharmaceutical Excellence**, Australia

Maurice is a professional engineer with 29 years' experience in technical and consulting roles within the biopharmaceutical industry, including 19 years as an industry consultant.

Prior to this; he held senior engineering and manufacturing roles within the Glaxo group of companies.

His core skills and experience are in manufacturing and compliance management; process design and improvement; risk management, validation and operational excellence. Maurice has assisted numerous organizations to establish, improve or scale-up manufacturing operations and GMP compliance in Australasia and Asia Pacific.

He has a Bachelor of Manufacturing Technology alongside Mechanical and Electrical Engineering qualifications. Maurice is a Past President and current Director of the ISPE Australasian Affiliate, and is a member of ISPE's Asia Pacific Regulatory and Compliance Committee and the PQLI Process Validation Committee. He is a course instructor for ISPE's Process Validation training, a technical SME for ISPE International's Guidance Document Committee and a chapter lead in the development of ISPE's Good Practice Guide for Process Validation.



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### AGENDA

Day 1 (Entitled to 6.5 CPE credits)	
08.00 - 08.50	Registration
08.50 - 09.00	Welcome and opening by ISPE Thailand President
09.00 - 10.15	Cleaning Validation Regulatory Requirements Overview of Cleaning Validation Guidelines PIC/S GMP Guidance, Annex 15 Qualification and Validation
10:15 – 10:30	Coffee break
10:30 - 12:00	Cleaning Mechanisms & Agents Cleaning Methods Sampling Methods
12.00-13.00	Lunch
13:00 – 14:45	Worst Case Selection / Bracketing Risk Assessment on Cleaning Validation
14:45 – 15:00	Coffee break
15:00 – 17:00	Acceptance Criteria : How to calculate Limits



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<b>Day 2 (Entitled to 4.75 CPE credits)</b>	
08.00 - 09.00	Registration
09:00 – 10:15	Ultrasonic Cleaning for Tablet Press Tooling Case Study on Cleaning Validation of Oral Solid Dosage
10:15 – 10:30	Coffee break
10:30 – 12:00	Workshop
12.00 - 13.00	Lunch
13:00 – 14:45	How to correctly choose hygienic pumps that are important to use in CIP Case Study on Cleaning Validation on Liquid Dosage
14:45 – 15:00	Coffee break
15:00 – 17:00	Workshop



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### Registration Fees

Type	Day 1, Theory	Day 2, Workshop (Day 1 Registration is required)
ISPE & TIPA Member	2,000	2,000
Non-Member	2,500	2,500

**Remarks:** Day 1, seats are limited to 100 Attendees with first-come, first-served basis  
Day 2, seats are limited to 50 Attendees with first-come, first-served basis  
(Day 1 Registration is required)

### HOW TO REGISTER

- 1. Online Registration** Browse website [WWW.ISPETH.ORG/EVENT-3\\_2017](http://WWW.ISPETH.ORG/EVENT-3_2017), 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](mailto:REGISTER@ISPETH.ORG)

**REGISTRATION CLOSING ON 12 OCTOBER 2017 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.