

ISPE Thailand 4th Seminar Year 2019

Best practices, tools & techniques for Root Cause Analysis & effective CAPA

11th – 12th December 2019

Ambassador Hotel, Sukhumvit Soi 11, Bangkok, Thailand

Background

Recently the *Parenteral Drug Association (PDA)* and the *International Society for Pharmaceutical Engineering (ISPE)* has signed a *Memorandum of Understanding (MOU)* confirming their plans to continue to advance practical approaches for quality culture. The first product of this collaboration is the **Root Cause Analysis (RCA)** guide. The organizations selected Root Cause Analysis as the first topic in this undertaking as root cause analysis forms a significant part of any organization's continuous improvement program.

Root Cause Analysis (RCA) is a defined process that seeks to explore all of the possible factors associated with an incident by asking what happened, why it happened and what can be done to prevent it from happening again. In other words, by getting to the bottom of an incident at the root, the action can be taken to fix it permanently. RCA, however, continues to be a topic observed by regulators as something the pharmaceutical industry does poorly. The most common failings include poor investigative techniques, not reaching true root cause, which then causing ineffective **Corrective and Preventive Action (CAPA)**.

Outline of the course

This 2-day training course will provide *best practices, tools and techniques* for RCA that have shown to be effective for the pharmaceutical industry, *strategies* for assessing criticality and reaction to events/problems, *guidance* for implementing effective CAPA system.

The course will include some background on the tools and techniques that are effective in conducting better root cause investigation and CAPA. The examples and their use will be provided as an exercise where attendees will be able to participate in a simulated incident and investigation, putting these tools and techniques into practice.

In addition, attendees will hear from Thai FDAs to give insight on their inspections and collaboration efforts regarding RCA and CAPA concerns. The actual industry example will be raised with their advices on how to establish a reliable and sustainable quality system in order to meet the regulatory requirements.

Course Modules

- Refresh Quality Risk Management (QRM) principles
- Fundamentals and Tools of Risk Management
- Global regulatory concerns – Management of Incidents and Deviations
- Strategies for assessing criticality and reaction to events
- Corrective and Preventive Action (CAPA) management
- Root Cause Analysis – What makes a good RCA
- RCA Techniques and Tools
- Thai regulatory concerns and advices
- Case Studies & Exercises
- Further references

Take Back to Your Job

- An understanding of the common failures in RCA and CAPA under GMP
- Details of best practices, tools and techniques for RCA that have been shown to be effective for the Pharmaceutical Industry
- Strategies for running an effective CAPA system
- Worked examples for the use of RCA tools
- Developing your skills in conducting RCA
- Being able to build RCA into your standard work – as continuous improvement
- Reducing workloads on quality assurance by focusing on critical incidents
- Working on exercises together with the speakers for better understanding
- Fruitful discussion on questions/issues you may have in this area

Who should attend?

This course is intended to be useful to anyone in Pharmaceutical Industry involved in investigating/identifying the *true* root causes of problems or incidents and involved in CAPA system. It is also useful for those who concern on continuous improvement and are interested to implement RCA into their standard work.

The speakers will guide you step by step the practical approach that you can apply to problems solving in your work as well as decision making with risk based.

Get to know speaker



Maurice B. Parlane

New Wayz Consulting Ltd
Principal/Director

Maurice Parlane is Principal of New Wayz Consulting Ltd in New Zealand and a Director of CBE Pty Ltd in Australia. He is a professional engineer with 30 years' experience within the biopharmaceutical industry, including 20 years as an industry consultant providing support to manufacturing and compliance management; validation and operational excellence projects in Australasia and the Asia Pacific region. Prior to this, he held senior engineering and manufacturing roles within the Glaxo group of companies. He has a Bachelor of Manufacturing Technology (Hons) as well as mechanical and electrical engineering qualifications.

Maurice is past president and current director of the ISPE Australasian Affiliate. He is the co-lead of ISPE's Asia Pacific Regulatory and Quality Harmonization committee and leader of the Process Validation Team. He is a member of the Guidance Documents and PQLI Committees. Maurice is an ISPE Instructor for PV, Technology Transfer and QbD, and was named ISPE Member of the year in 2016.



Achiraya (Ink) Praisuwan,

Thailand Bureau of Drug Control,
Thai Food and Drug Administration
GMP Lead Inspector Ministry of Public Health

Ms Achiraya Praisuwan is currently a GMP Lead Inspector at the Inspectorate Unit, Division of Postmarketing Control, Bureau of Drug Control of the Food and Drug Administration in Thailand. She is a professional pharmacist with a doctor of pharmacy degree from the faculty of pharmaceutical science, Naresuan University, Thailand. Achiraya has relevant experiences in domestic and overseas GMP inspections, handling of products quality defects, and GDP/GSP inspection at vaccine distribution channels. She has been a speaker on Data Integrity and Data Management at ISPE Thailand Affiliate Seminar, a speaker on Current Challenges to GxP Compliance at ISPE Philippines Affiliate 2018 Annual Meeting, a principle investigator on a WHO-USP Project on Quality of Antimalarial Medicines in the GMS Countries, a Temporary Advisor to WHO on the national regulatory authority observed audit in Hyderabad and New Delhi.

Best practices, tools & techniques for Root Cause Analysis & effective CAPA	
Wednesday 11th December, 2019	
08:30 – 09:00	Registration
09:00 – 09:15	Opening Remark by <i>Mr. Totsapon Santitewagun (ISPE Thailand President)</i>
09:15 – 10:30	Refresh Quality Risk Management Principles Fundamentals and Tools of Risk Management
10:30 – 11:00	Coffee Break
11:00 – 12:00	Differentiate Incidents and Deviations
12:00 – 13:30	Lunch
13:30 – 15:00	Workshop on Incidents and Deviations
15:00 – 15:30	Coffee Break
15:30 – 17:00	CAPA Management & Global Regulatory Concerns Industry guidance (ISPE+PDA)

Best practices, tools & techniques for Root Cause Analysis & effective CAPA	
Thursday 12th December, 2019	
08:30 – 09:00	Registration
09:00 – 10:30	Thai FDA Concerns and Expectations on Thai Pharmaceutical Industry Incident Management & CAPA in by <i>Ms. Achiraya Praisuwan (GMP Inspector, Thai FDA)</i>
10:30 – 11:00	Coffee Break
11:00 – 12:00	Root Cause Analysis (RCA) & Problem Solving What makes a good RCA RCA Tools
12:00 – 13:30	Lunch
13:30 – 14:00	RCA Tools
14:00 – 15:00	Workshop on RCA
15:00 – 15:30	Coffee Break
15:30 – 16:30	Workshop on RCA (continued)
16:30 – 17:00	Summary and Wrap up

Note: *Wrap up in Thai by Dr. Sasivimol Kittivoravitkul on both days*

Registration Fee

ISPE Thailand Event 4 th Year 2019 11 th - 12 th December 2019	Early Bird Registration Fee Before 22 November 2019	Registration Fee After 22 November 2019
ISPE/TIPA Member Academia/ Government	3,000 Baht	4,000 Baht
Non-member	5,000 Baht	6,000 Baht

Note :

1. The registration fee is for 2 days seminar (11th - 12th December 2019)
2. Member applies to member of ISPE & TIPA only.
3. Seats are **limited to 120 attendees**. In the case that the registration is over 120, we reserve the right to allocate the seats as appropriate.

Hotel and Travel

Conference Hotel: Ambassador Hotel, Sukhumvit Soi 11, Bangkok, Thailand

<http://ambassador.bangkokshotels.com/en/>

Travel : <http://www.amtel.co.th/location/>

How to register

HOW TO REGISTER

1. **Online Registration** Browse website <https://www.ispeth.org/ISPETHailandEvent4-2019>, 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

REGISTRATION CLOSES ON 9 December 2019 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.