Training Course

Practical Implementation of Process Validation
Lifecycle Approach

Date : 18 – 19 July 2024
Venue : Ambassador Hotel, Bangkok, Thailand

OVERVIEW

Lifecycle Process Validation (PV) remains one of the most important and commonly misunderstood topics in the pharmaceutical industry. How many lots should we make? Are we taking enough samples? Do we need to use statistics in our protocols? The real question may be: are we even focusing on the right questions?

Participants will focus on the practical application of the lifecycle approach to all stages of PV to gain valuable knowledge and insight on the regulations, guidance, and best practices currently utilized across the industry.

OBJECTIVE What You Will Learn

Participants will focus on the practical application of the lifecycle approach to all stages of PV to:

- Understand the importance of product and process understanding and patient requirements.
- Know how to apply QRM tools for PV.
- Recognize opportunities to leverage process design information to establish a process validation strategy and a process performance and product quality monitoring program.
- Understand the challenges to the application of an entirely science- and risk-based approach.
- Understand a variety of approaches to applying specific expectations of the lifecycle approach to PV including number of sampling, acceptance criteria and determining the number of batches for PPQ/PV.
- Understand the differences in expectations among various major world markets.
- Learn various approaches for deciding which attributes and parameters should be evaluated at a heightened level during PV stage 3.
- Understand new expectations for routine process monitoring.

- Understand the process validation lifecycle and the importance of maintaining an effective pharmaceutical quality system.
- Apply process performance and product quality monitoring system elements to identify opportunities for continual improvement.
- Minimize chance of validation failures by learning about adequate preparation in process understanding and ancillary systems.
- Acquire tools to prepare for a smooth validation execution.
- Understand implications of validation deviations.
- Maximize and be able to apply your understanding of ICH terminology including the principles of a science- and risk-based approach to the process validation lifecycle.
- Recognize the value of the requirements of management's responsibilities within the PQS.

WHO SHOULD ATTEND

- This course is relevant to individuals involved in process validation of products and processes in all sectors of the pharmaceutical industry – small and large molecules, innovators, generics, and lifecycle management.
- Specific job functions including:
  - Development, manufacturing, engineering, quality, validation compliance, and scientific professionals with intermediate level experience in development, manufacturing, engineering, validation, quality, technology transfer and those wishing to understand the concept of process validation as a lifecycle.

TRAINING DATE & TIME

Date : 18-19 July 2024
Time : 09.00 – 17.00
Venue : Ambassador Hotel, Bangkok, Thailand

For pharmacists who attend this course will receive **11.5 CPE accredits**

REGISTRATION FEE

For ISPE Member 8,000 THB

For Non ISPE Member 12,500 THB

AGENDA

TOPIC: Practical Implementation of Process Validation Lifecycle Approach
SPEAKER: Mr. Maurice Parlane
DATE: 18th- 19th July 2024
LOCATION: Ambassador Hotel, Bangkok Thailand

COURSE OUTLINE

DAY 1: THURSDAY 18TH JULY 2024		
TIME	**TOPIC**	**NOTE**
8:50 – 9:00	Opening Remark by ISPE Thailand President	*Mr. Totsapon Santitewagun*
9:00 – 10:30	**Overview of Stage 1: Process Development** • Regulatory Climate and Surrounding Changes in Process Validation • Process Validation Basics US and EU	
10:30 – 11:00	Coffee Break	
11:00 – 12:00	**Stage 1: Process Development (cont.)** • QRM Applied to PV • Developing Understanding of QbD to Develop Robust Control Strategies (PV Stage 1)	
12:00 – 13:30	Lunch	
13:30 – 15:00	**Stage 2: Performance Qualification / Process Validation** • Equipment and Qualification	
15:00 – 15:30	Coffee Break	
15:30 – 17:00	**Stage 2: Performance Qualification / Process Validation (cont.)** • Statistics for PV • Readiness for Process Performance Qualification (PPQ) / PV	

DAY 2: FRIDAY 19TH JULY 2024		
TIME	**TOPIC**	**NOTE**
9:00 – 10:00	**Stage 2: Performance Qualification / Process Validation (cont.)** • Acceptance Criteria, Number of Batches, Sampling Plan • Acceptance Criteria and Sampling Plans for PPQ	
10:00 – 10:30	Coffee Break	
10:30 – 12:00	**Stage 3: Continued Process Verification / Ongoing Process Verification** • Process Validation / PPQ Execution	
12:00 – 13:00	Lunch	
13:00 – 14:30	**Stage 3: Continued Process Verification / Ongoing Process Verification (cont.)** • Process Validation / PPQ Execution Validation CIP Recipe	
14:30 – 15:00	Coffee Break	
15:00 – 17:00	**Stage 3: Continued Process Verification / Ongoing Process Verification (cont.)** • CPV / OPV for Existing Products	

GET TO KNOW SPEAKER

Mr. Maurice 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 and is a member of the Guidance Documents Committee. He is an ISPE PV Instructor and was named ISPE Member of the year in 2016.

REGISTRATION FEE

ISPE Official Training Course 18th - 19th July 2024	Registration Fee
ISPE Member	8,000 Baht
Non-member	12,500 Baht

Note : 1. The registration fee is for 2 days training (18th – 19th July 2024)
2. Member applies to member of ISPE only.

Hotel and Travel

Ambassador Hotel, Sukhumvit Soi 11, Bangkok, Thailand (BTS NANA)
http://ambassador.bangkokshotels.com/en/
Travel : http://www.amtel.co.th/location/

HOW TO REGISTER

1. **Online Registration** Browse website https://www.ispeth.org/event/ispeth-pv/, 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 evident i.e. payslip to email REGISTER@ISPETH.ORG

REGISTRATION CLOSES ON 15 JULY 2024 OR WHEN ALL SEATS ARE FULLY RESERVED (LIMITED TO 40 SEATS).

FIND OUT MORE INFO & CONTACT US: WWW.ISPETH.ORG
EMAIL: REGISTER@ISPETH.ORG T: +6688-090-4664

PAYMENT METHOD

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.