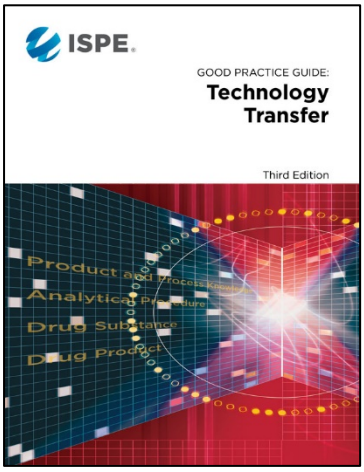
In Depth ISPE Thailand Training Year 2019

Pharmaceutical Technology Transfer

9th – 10th May 2019 At Room Garden 1

Ambassador Hotel, Sukhumvit Soi 11, Bangkok, Thailand



Practical Application of Technology Transfer (T19)

Technology transfer (TT) includes knowledge transfer and the application of science and risk-based principles including ICH Q8, Q9, Q10, Q11, to support the business requirements from both Sending and Receiving units for drug substance, drug product and analytical procedures.

Technology transfer occurs in many circumstances involving for example active pharmaceutical ingredients (APIs), finished dosage forms and analytical methods. TTs may occur between development and manufacturing sites or to contract manufacturing organizations (CMOs). This course identifies criteria for successful technology transfer and provides examples and tools for industry and regulators to use when conducting and evaluating technology transfer activities.

Course Modules

- Introduction to Technology Transfer
- Knowledge: What is it?
- Planning & Success Criteria
- Quality Risk Management
- Phases of the Transfer Process, including Validation
- Analytical Procedures Transfer
- Drug Substance Transfer
- Drug Product Transfer

Take Back to Your Job

Understand technology transfer planning and success criteria including

- Forming the transfer team and developing the charter
- Consolidating knowledge for transfer and developing a technology transfer proposal
- Identifying risks, conducting a risk assessment and developing technology transfer plan
- Executing the transfer
- Developing the process (procedure) qualification
- Finalizing the transfer and performing the review

Who Should Attend

This course is intended to be useful to anyone involved in technology transfer whether in relation to commercial transfer between manufacturing sites or transfer to manufacturing from development or within development but will be particularly relevant to professionals with technology transfer responsibilities, including regulatory compliance associates, process development scientists, facilities engineers, validation and quality assurance specialists, manufacturing managers, and regulators.

Get to know speaker

Bruce S. Davis

Global Consulting
Principal

Bruce Davis, Principal, Global Consulting is a professional engineer, and has many years' experience in the pharmaceutical industry and a wide international knowledge, and operates a consultancy in QbD, Engineering, Process Validation and reducing Human Error. He is an Associate to NSF-DBA, the training & consultancy Company. He previously worked at AstraZeneca, where he had a number of responsibilities, including managing international engineering, and this extended to provision of sterile facilities.

Davis has been a member of ISPE since 1991, and is a member of the United Kingdom Affiliate. He has held the position of Chair of ISPE International Board of Directors and has been active in supporting ISPE, including leading the team writing the original Sterile Baseline® Guide and its current update. He also led ISPE's case study for practical implementation of Quality by Design (QbD) and is currently co-chairing the team updating ISPE's Technology Transfer Guide.

Davis also facilitated the change to qualification to enable science and risk-based principles to be adopted. Previous experience includes the position of past secretary to ASTM E55.03 Committee on General Pharmaceutical Standards and leading the team that set up a distance-learning course, for a UK university, involving some 40 webinars.

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 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.

Agenda of in depth ISPE Thailand Training in year 2019

Topic : Pharmaceutical Technology Transfer Training Course
Practical Application of Technology Transfer (T19)

Date : 9th – 10th May 2019

Venue : At Room Garden 1 (1st Floor) Ambassador Hotel, Sukhumvit Soi 11, Bangkok, Thailand

Day 1: Thursday 9th May, 2019

Time	Reference	Topic
08.00-09.00	Registration	
09.00-09.10	Welcome and opening by *ISPE Thailand President*	
09.10-10.00	M0	Introduction & Objectives
10.00 – 10.30	M1	Introduction to TT Guide
10.30 – 11.00	Morning Break	
11.00– 11.30	M2	Regulatory Aspects
11.30 – 12.00	H1	Breakout 1 – issues arising from what you have heard so far
12.00 – 13.00	Lunch	
13.00 – 14.00	M3	Knowledge and quality aspects (for both Transfer & Management):
14.00 – 14.30	H2	Breakout 2 - Cause effect matrix (use of tools)
14.30 – 15.00	Afternoon Break	
15.00 – 16.00	M2	TT Planning & Success Criteria
16.00 – 16.45	H3	Breakout 3 - Fishbone & Success criteria
16.45 – 17.00		Questions and wrap up Day 1

Day 2: Friday 10th May, 2019

Time	Reference	Topic
09.00 – 09.30		Review of Day 1
09.30 – 10.15	M5	Quality Risk Management
10.15 – 10.30	H4	Breakout 4 - FMEA
10.30 – 11.00	Morning Break	
11.00– 11.15	H4 – cont'd	Breakout 4 - FMEA
11.15 – 12.00	M6	Phases of Transfer Process
12.00 – 12.30	H5	Breakout 5 - Project Proposal
12.30 – 13.30	Lunch	
13.30 – 14.00	H5 - cont'd	Breakout 5 - Project Proposal
14.00 – 14.30	M7	Analytical Procedures TT
14.30 – 15.00	Afternoon Break	
15.00 – 15.30	H6	Breakout 5 - Analytical
15.30 – 16.15	M8 & M9	Drug Product TT (and Drug substance)
16.15 – 16.30	M10	Summary & Conclusion
16.30 – 17.00		Questions, actions & wrap-up

Registration Fee

In Depth Pharmaceutical Training 9th - 10th May 2019	Registration Fee
ISPE Member	8,000 Baht
Non-member	12,000 Baht

Note :

1. The registration fee is for 2 days seminar (9th - 10th May 2019)
2. Member applies to member of ISPE only.
3. Seats are limited to **50 attendees**. In the case that the registration is over 50, we reserve the right to allocate the seats as appropriate.
4. Part of the registration fee is supported by ISPE Thailand Affiliate & Thailand Center of Excellence in Life Sciences (TCELS) with the intention to train the attendees as the trainers for Thai pharmaceutical industry.

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 http://ispeth.org/ IN_DEPTH_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 4 MAY 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.