ISPE Thailand 2nd Seminar 2019

Effective Auditing of Pharma Cleanroom HVAC, and other Critical Utility Systems

9th – 10th May 2019 At Convention Hall C Room

Ambassador Hotel, Sukhumvit Soi 11, Bangkok, Thailand

Background

Effective auditing of Manufacturing and Quality systems and assets is an essential part of all quality management systems (QMS). The regulations and GMPs clearly require that we evaluate and audit our operations in several ways:

- Annex 15 'Qualification and Validation' clearly requires a process of audit and review of designs against the URS and GMP requirements and best practice. This is called Design Qualification (DQ) or enhanced design review.
- Internal self-inspection and audit is an essential part of continuous improvement.
- We are required to audit suppliers (Contract manufacturers, APIs suppliers, and providers of materials and components).
- We need to prepare for regulatory inspections and B2B audits.

Inspectors & Auditors are often short of time and may not be expert in every part of a manufacturing and quality operation. To help guide attendees the course will include:

- The GMP requirements for HVAC and important Critical Utility Systems.
- The importance of effective Commissioning & Qualification.
- Some important industry trends and best practices.
- Guidance on common issues and problems (what to look for!).
- How to sense problems.
- Questions to ask.
- Planning ahead of the audit.

Outline of the course:

This 2-day training course will provide a practical approach and guidance on effective ways to plan and undertake audits of manufacturing facilities (cleanrooms) and critical utilities including pharmaceutical water (PW & WFI), pure steam for sterilisation, compressed gases, and stand-by power systems.

The course will comprise educational material, training sessions, and references. There will be plenty of time to ask questions and raise issues of concern. The technical aspects of the training will be equally applicable to prospective assessments in DQ and audits of plans in operation.

The main content of the course will be:

- The role and importance of effective Commissioning and testing of Pharma HVAC Systems
    - NEBB best practices.
    - Using tests in ISO 14644-3 and IEST RP006 test methods.
    - Leveraging commissioning data for qualification – How to avoid duplication of testing.
    - Monitoring performance.
    - Auditing systems.

- General requirements for auditing:
    - Industry and regulatory trends and developments.
    - Planning an audit.
- For auditing each type of system:
    - What documentation should be requested. Data, Drawings, diagrams, etc.
    - What visual inspection access should be requested?
    - Audit check-lists.
    - Common faults, problems and issues – things to look for.
    - Guidance on understanding technical drawings P&IDs, layouts, etc.
    - Getting information from 'deviations' or 'quality events', EM data and information, change control, and operational failures.

Who should attend:

This course is intended for inspectors, auditors, quality assurance professionals (including qualification and validation) and subject matter experts including commissioning & qualification engineers and technicians. It would also be of interest to consultants and providers of technical products and engineering systems who want to understand how the installations are likely to be inspected and audited.

Get to know speaker

Mr. Gordon J. Farquharson

Gordon Farquharson, B.Sc.(Hons), C.Eng. is a Chartered Consulting Engineer with more than 35 years experience of quality & safety critical processes and facilities used by industries such as Healthcare, Life Science, Micro-electronics, etc. He is Principal and Managing Director of Critical Systems Ltd, an international consultancy firm with partnerships with PharmOut Pty Ltd, a consulting business based in Australia, FactoryTalk based in Thailand, and CM Plus Corporation of Japan.

He has focused on technologies such as isolators, barrier technology, mini-environments, critical utility systems and bio-containment applications. He has been responsible for the development of technical solutions in product development, primary manufacturing and device and dosage form manufacturing.

Standards and regulatory compliance issues in the Pharma/Life Science sectors are a major interest and responsibility. In this context he has a high degree of expertise in the practical interpretation & application of EU/PIC-S/WHO GMPs and US FDA cGMP requirements. Experience with the variation in expectations gives him an ability to dovetail the differing regulatory requirements. In recent years, he has been heavily involved in the development of the new regulatory guidance and standards. In particular, he is active working on CEN/ISO Cleanroom & Contamination Control Standards, WHO GMP guidance and ISPE Baseline Guides. He is Chairman of BSI's LBI 30 Committee and of CEN Technical Committee 243, and was Convenor of WG1 and a UK expert working on the ISO TC209 and CEN TC243 family of contamination control standards that provide the platform for contamination control standardisation and practice in this millennium. He has worked with the EMA in London to help update and improve the cleanroom classification and monitoring requirements in Annex 1 of the EU and PIC/S GMPs and has contributed writing WHO's Pharmaceutical water GMP Guidance and the revision of the WHO GMP guidance on sterile products.

He is a founding member, management committee member, past Chairman, and Honorary Member of the UK Pharmaceutical & Healthcare Sciences Society (formerly Parenteral Society), and was Editor in Chief of the European Journal of Parenteral & Pharmaceutical Sciences. He is also active in ISPE, the R3 Nordic Association, and PDA. He is a past chair of the ISPE European Education Committee and was voted ISPE International Member of the year 2001, UK Affiliate Member of the year in 2008, and recipient of the Richard B Purdy Distinguished Achievement Award 2009. He was a member of the PDA Science Advisory Board (SAB) and is an honorary senior lecturer at UCL (London) and the University of Manchester PEAT & PIAT programmes.

He lectures and teaches extensively, is an author of many papers, and contributor to books on cleanroom and isolator technology, as well as practical engineering interpretation of GMP philosophies.

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Agenda of ISPE Thailand 2nd Seminar 2019

Topic : Effective Auditing of Pharma Cleanroom HVAC, and other Critical Utility Systems

Date : 9th – 10th May 2019

Venue : At Convention Hall C Room Ambassador Hotel, Sukhumvit Soi 11, Bangkok, Thailand

Thursday 9th May, 2019 (Entitled to 6 CPE and CEC credits)

Day 1: Pharma HVAC Systems		Speaker
08.00-08.50	Registration	
08.50-09.00	Welcome and opening	*ISPE Thailand President*
09.00-10.30	**Pharma HVAC Systems** • GMP drivers. • Identifying critical parameters. • Design Review (DQ). • Commissioning. • Qualification.	*Gordon Farquharson*
10.30-11.00	Coffee break	
11.00-12.00	• Auditing Systems • Common faults, problems and issues – things to look for. • Guidance on understanding technical drawings P&IDs, layouts, etc	*Gordon Farquharson*
12.00-13.00	Lunch	
13.00-14.30	• NEBB practices and methods. • Test methods in ISO 14644-3. • Test methods in IEST RP006	*Gordon Farquharson*
14.30 -15.00	Coffee break	
15.00 -17.00	• Learn how to choose the required tests and sequence of testing. • What data can we take from Commissioning into Qualification (to avoid retesting)?	*Gordon Farquharson*

Friday 10th May, 2019 (Entitled to 6 CPE and CEC credits)

Day 2: Other Critical Utility Systems		Speaker
08.00-09.00	Registration	
09.00-10.30	**General Auditing requirements and best practices** • What documentation should be requested. Data, Drawings, diagrams, etc. • What visual inspection access should be requested? • Audit check-lists. • Common faults, problems and issues – things to look for. • Guidance on understanding technical drawings P&IDs, layouts, etc. • Getting information from 'deviations' or 'quality events', Monitoring data and information, change control, and operational failures.	*Gordon Farquharson*
10.30-11.00	Coffee break	
11.00-12.00	**Pharma Water Systems** • What documentation should be requested. Data, Drawings, diagrams, etc. • What visual inspection access should be requested? • Audit check-lists. • Common faults, problems and issues – things to look for.	*Gordon Farquharson*
12.00-13.00	Lunch	
13.00-14.30	**Pure steam for sterilization** • What documentation should be requested. Data, Drawings, diagrams, etc. • What visual inspection access should be requested? • Audit check-lists. • Common faults, problems and issues – things to look for.	*Gordon Farquharson*
14.30 -15.00	Coffee break	
15.00-17.00	**Compressed gas Systems & Standby power systems** • What documentation should be requested. Data, Drawings, diagrams, etc. • What visual inspection access should be requested? • Audit check-lists. • Common faults, problems and issues – things to look for. **Standby power systems** • GMP requirements. • Understanding different systems. • Testing system operation. • What documentation should be requested. Data, Drawings, diagrams, etc. • What visual inspection access should be requested? • Audit check-lists. • Common faults, problems and issues – things to look for.	*Gordon Farquharson*

Registration Fee

Seminar 9th - 10th May 2019	Registration Fee
ISPE/TIPA Member	4,000 Baht
Non-member	6,000 Baht

Note :

1. The registration fee is for 2 days seminar (9th - 10th May 2019)
2. Member applies to member of ISPE and TIPA only.
3. Seats are limited to **120 participants** with first come-first served basis.

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/EVENT-2_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.