ISPE Thailand 1st Seminar/Workshop Year 2018

12th – 13rd February 2018

Ambassador Hotel, Sukhumvit Soi 11, Bangkok, Thailand

Background

Pharmaceutical Industries have continually improved their manufacturing standards in order to deliver quality and safely products to patients. In year 2018, ISPE Thailand Affiliate has come up with interesting topics, which would help industries to raise their quality system. First topic is ***Applied Risk Management for Commissioning and Qualification*****.** The other one is ***Changes to the PIC/S GMP guidance on the manufacture of sterile medicines (Annex 1)*****.** ISPE Thailand Affiliate sets two tracks of the seminars and workshops on these two topics details as follows:

Track 1: Applied Risk Management for Commissioning & Qualification

In pharmaceutical industry, the execution of commissioning and qualification of utilities, systems and equipment is the important part for achieving process validation, which leads to the guarantee of product quality. The difference between commissioning and qualification is that the former is concerned with *Good Engineering Practice (GEP)*, whereas the latter primality verifies facility and systems aspects that can affect product quality.

At present, Quality Risk Management has been applied in Good Manufacturing Practice (GMP) for a total product life cycle process. In this seminar (Track 1), you will understand the benefit of risk based approach define in the ISPE Good Practice Guide, ASTM E2500 and ICHQ9 and will learn how to apply the approach to the commissioning and qualification of utilities, systems and equipment. Besides theoretical point of view, there will be case studies of the commissioning and qualification of HVAC system and equipment in pharmaceutical manufacturing. The objective of the seminar includes:

- Understand and differentiate the principle of commissioning and qualification
- Learn how to develop commissioning and qualification plan for utilities, systems and equipment that affect the quality of product according to PIC/S GMP
- Understand quality risk management related to commissioning and qualification
- Learn how to apply commissioning and qualification based on risk based approach in practice

Who should attend?

- Managers of companies who response for production, quality control and quality assurance
- Operators who involves in facilities and production such as production staffs, engineers etc.
- Consultants who involves in designing or improving the facilities, system and equipment
- Validation teams

Get to know speaker

Pierre Winnepenninckx

Past Chair of ISPE Asia Pacific and Chair ISPE Singapore Conference 2017

With a degree in chemistry and chemical engineering, Pierre combines the scientific mindset with the practical approach of the engineer. Applying analytical skill and practical sense has proved the perfect fit for design and commissioning activities in a field that requires accuracy and productivity. After working in several projects around Europe as consultant for one of the leading pharmaceutical company, he opened his own service company in 2007, and is currently providing services on 3 different projects in Singapore and China. He believes in People skill and manages them at their best, to optimize the available competences. His customer is his concern, whom he advises and supports throughout all project phases, according to identified needs.

Track 2: Changes to the PIC/S GMP guidance on the manufacture of sterile medicines (Annex 1)

Background

The Pharmaceutical Inspection Co-operation Scheme (PIC/S) recently introduced updated versions of both their GMP guide and the associated annexes. There are now 20 annexes to the guide, some are new, some have received little or no change, while others have been significantly updated. ***Annex 1 of PIC/S GMP Guide,*** related to sterile medicines, was one annex to receive considerable revision as part of the update.

Annex 1 was first published in 1971, since then it has undergone a number of targeted updates but, until now it has not undergone a full review. This revision is intended to add clarity, introduce the principles of Quality Risk Management to allow for the inclusion of new technologies and innovative processes and to change the structure to a more logical flow.

The ISPE Thailand Affiliation proposes a two days seminar on ***Changes to the PIC/S GMP guidance on the manufacture of sterile medicines (Annex 1)***, which will enable you to voice your concerns in anticipation of the revision to Annex 1. The objective of the seminar is to discuss all of the changes in Annex 1, clarify the impact on sterile manufacturers and importantly provide constructive feedback to the authors of the Annex 1 draft document. This is a very important opportunity where your expert insight and effort will be most beneficial to the industry. The objective of the seminar includes:

- Update global trend on the manufacture of sterile medicines
- Understand changes to the PIC/S GMP guidance Annex 1 that has an impact on sterile manufactures
- Have opportunities to discuss, share your idea and voice your concerns in anticipation of the revision to the PIC/S GMP guidance Annex 1

References to the new document – Annex 1 Revision

- *Targeted Stakeholders consultation on the revision of annex 1, on manufacturing of sterile medicinal products, of the Eudralex volume 4*
  https://ec.europa.eu/health/human-use/quality/developments/pc_2017_12_sterile_medicinal_products_en
- *White Paper : PIC/S GMP Guide – Annex 1 Revisions & Interpretations*
  https://40rik02ft2xye26xv2i0y0yc-wpengine.netdna-ssl.com/downloads/white-paper-pics-gmp-guide-annex-1-revisions-and-interpretations.pdf
- *New Annex 1 – PIC/S and EU finally arrives*
  https://www.pharmout.net/new-annex-1-eu-pic-s/

The seminar will cover:

Day 1 (Seminar)

- The principles and Quality Risk Management
- The application of Annex 1 to non-sterile product manufacturing
- The focus on sterility assurance and contamination control
- Isolators, RABS and Cleanrooms.
- Special processes such as Blow-Fill-Seal
- Clean room and clean-zone classification and monitoring
- New requirements for WFI
- Sterilisation
- Process simulation and media-fills
- Single use systems

Day 2 (Working groups to look at the following areas in details.)

- Pharmaceutical Quality System (PQS) - Highlights the specific requirements of the PQS when applied to sterile medicinal products
- Personnel Guidance on the requirements for specific training, knowledge and skills. Also gives guidance to the qualification of personnel
- Premises - premises design and guidance on the qualification including the use of barrier technology (Isolators and RABS). Viable and non-viable environmental and process monitoring

- Equipment - guidance on the design and operation of equipment
- Utilities - Guidance on requirements of utilities, water, air and vacuum
- Production and technologies – guidance on approaches for aseptic and terminal sterilisation
- Guidance for lyophilisation and Blow Fill Seal (BFS)

Who should attend?

- Managers of companies making sterile products
- People who are interested in voicing your concerns in anticipation of the revision to Annex 1

Get to know speaker

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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Monday 12th February, 2018 : SEMINAR (Entitled to 6.0 CPE credits for each track)

Time	Track 1	Track 2
	Applied Risk Management for Commissioning & Qualification	**Changes to the PIC/S GMP guidance on the manufacture of sterile medicines (Annex 1)**
	Speaker : Pierre Winnepenninckx **Room : Cataleya 2 Ambassador hotel**	**Speaker : Gordon Farquharson** **Room : Orchid 1 Ambassador hotel**
09:00 – 10:30	- Fundamental of Commissioning & Qualification (C&Q) - The relationship between ASTM E2500, ICHQ9, ISPE Guide - Risk-Based Approach defined in the ASTM & ICHQ9	- The joint EMA and PIC/S revision process explained : • Drafting • Review by regulators • Draft publication for public scrutiny & comment • Submission & consideration of comments by the EMA & PIC/S • The ISPE international reviews, comments, and comment submission process - Some important principles in the revision: • The scale & scope of revision (15 to 50 pages) • How the principles of QRM are embodied • Application scope of Annex 1 to non-sterile product manufacturing
10:30 – 11:00	Break	
11:00 – 12:00.	- Bridging the differences between traditional C&Q and the risk-based ASTM verification practices/science based approach - How to apply Risk-Based Approach for the delivery of facilities, systems and equipment	- The focus on sterility assurance & contamination control - Isolators, RABS & Cleanrooms - Special processes such as Blow-Fill-Seal
12:00 – 13:00	Lunch	
13:00 – 15:00	- Case Study : C&Q on HVAC system	- Clean room & clean-zone classification and monitoring - New requirements for WFI - Sterilisation
15:00 – 15:30	Break	
15:30 – 17:00	- Case Study : C&Q on systems and equipment	- Process simulation and media-fills - Single use systems

Tuesday 13th February, 2018 : WORK SHOP (Entitled to 3.0 CPE credits for each track)

Time	Track 1	Track 2
	Applied Risk Management for Commissioning & Qualification	**Changes to the PIC/S GMP guidance on the manufacture of sterile medicines (Annex 1)**
	Speaker : Pierre Winnepenninckx **Room : Cataleya 2 Ambassador hotel**	**Speaker : Gordon Farquharson** **Room : Orchid 1 Ambassador hotel**
09:00 – 10:30	Workshop exercise on C&Q of HVAC system	- Pharmaceutical Quality System (PQS) - Highlights the specific requirements of the PQS when applied to sterile medicinal products - Personnel Guidance on the requirements for specific training, knowledge and skills also gives guidance to the qualification of personnel.
10:30 – 11:00	Break	
11:00 – 12:00.	Discussion on C&Q of HVAC system Critical Quality Attributes and from there walking through the risk assessment will be discussed	- Premises - premises design and guidance on the qualification including the use of barrier technology (Isolators and RABS). Viable and non-viable environmental and process monitoring.
12:00 – 13:00	Lunch	
13:00 – 15:00	Workshop exercise on C&Q of process equipment	- Equipment - guidance on the design and operation of equipment - Utilities : Guidance on requirements of utilities, water, air and vacuum.
15:00 – 15:30	Break	
15:30 – 17:00	Discussion on C&Q of process equipment Critical Quality Attributes and from there walking through the risk assessment will be discussed	- Production and technologies – guidance on approaches for aseptic and terminal sterilisation. - Guidance for lyophilisation and Blow Fill Seal (BFS)

Registration Fee

TRACK 1 : Applied Risk Management for Commissioning & Qualification		
Type	**Day 1,** Seminar	**Day 2,** Workshop (Day 1 Registration is required)
ISPE & TIPA Member	2,000	2,000
Non-Member	3,000	3,000
Remarks: Day 1, seats are limited to 120 Attendees with first-come, first-served basis Day 2, seats are limited to 60 Attendees with first-come, first-served basis **(Day 1 Registration is required)**		

TRACK 2 : Changes to the PIC/S GMP guidance on the manufacture of sterile medicines (Annex 1)		
Type	**Day 1,** Seminar	**Day 2,** Workshop (Day 1 Registration is required)
ISPE & TIPA Member	2,000	2,000
Non-Member	3,000	3,000
Remarks: Day 1, seats are limited to 80 Attendees with first-come, first-served basis Day 2, seats are limited to 40 Attendees with first-come, first-served basis **(Day 1 Registration is required)**		

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-1_2018 , 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 8 FEBRUARY 2018 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.