

Agenda PROPAK 2019 Training

Thursday 13th June 2019, At BITEC
Get it Right on User Requirements Specification (URS)

Agenda

TOPIC: Get it Right on User Requirements Specification (URS)		
Date : Thursday 13 th June 2019 Time : 9:00 – 12:00 Venue: BITEC		
Time	Topic	Speaker
9:00 – 10:30	Preparing an effective User Requirements Specification (URS) to streamline with Qualification Task	Dr. Jitaporn Wattanaseree <i>ISPE Thailand Committee</i>
10:30 – 10:45	Coffee Break	
10:45 – 12:00	Practical Examples of URS for Pharmaceutical Machinery	Ms. Wilawan Atiwattananont <i>ISPE Thailand Committee</i>
Note: The training course will be in Thai.		

Speaker:

Dr. Jitaporn Wattanaseree

ISPE Thailand Committee



Dr. Jittaporn Wattanaseree has been working in the field of pharmaceutical and Biopharmaceutical since 1990. Her experiences in pharmaceutical and Biopharmaceutical are over all stages of drug development starting from research to commercialization. Her work records are in the areas of;

- Lecturer and trainer on the topics which related to industrial microbiology/ Biotechnology for Biopharmaceutical Production: Principle & Application, GMP, quality system and etc.
- Institutional networking and technical collaboration initiatives, local and oversea
- Project management:
 - R&D facility and GMP Pilot Plant: Conceptual design , construction, equipment selection and installation supervision
 - Quality control facility: Conceptual design and site construction, equipment selection and installation supervision
 - Relocation and renovation of Clinical research facility
- Good Manufacturing Practice (GMP) and GMP inspection management
- Quality system improvement for WHO PQ of Anti-Retrovirus drugs (solid dosage form)
- Rationalization of pharmaceutical warehouse
- Vaccine research and development
- Vaccine production and quality control
- Biosafety and Biosecurity of Genetic Modification Microorganisms (GMM)
- Human resource development initiatives
- Project management on establishing laboratory animal company, a Public-Private Joint venture company
- Clinical research studies: quality management, regulatory and medical affairs
- Technical collaboration and Scientific affairs

Currently, she is voluntary contributed her experiences and knowledge to Thai society by serving as a board committee member of ISPE Thailand Affiliate. Meanwhile, she also involves herself to other activities such as a technical committee of Biosafety of Genetically Modified Microorganism of BIOTEC, NSTDA, and as a core committee of Thailand towards Excellence in Clinical Trials (ThaiTECT).

She obtained bachelor degree in Medical Technology and master degree in Biochemistry from Mahidol University. After working as university instructor for almost 4 years, she pursued her Ph.D. in Molecular Biochemistry and Biophysics at Yale University, New Haven, Connecticut, USA.



Ms. Wilawan Atiwattananont

ISPE Thailand Committee

Ms. Wilawan Atiwattananont is currently Managing Director of Onimax Co.,Ltd. and Director of Pharmaceuticals and Medical Supply Co.,Ltd (PMS) with more than 20 years of working experience. She holds Professional Mechanical Engineering License from Engineering Council of Thailand. She started her career in Electronic industry and worked in USA and Malaysia before entering Pharmaceutical Industry.

She has extensive experience in Pharmaceutical, Food, Cosmetic, Chemical and Biotechnology Industry, dealing with clients in more than 40 countries. Her scope of work covers Machinery Design and Control System Design, Product Formulation Development, Process Development, Facility Layout Design, Supporting System Design, Material Handling System, Equipment Validation, Cleaning Validation and Computer Validation.

She attended various seminars and trainings in Engineering, Pharmaceutical, Food and Management fields, i.e. PIC/S GMP, Facility Design and Operation, Qualification and Validation, Food Engineering, Food Product Development, Cleanroom Design, Piping Design, Blower Design, Pump Design, Dehumidifier System Design, Water System for Pharma Industry, Lean Manufacturing, Failure Mode and Effect Analysis (FMEA), Measurement System Analysis, Design of Experiment, Six Sigma Statistic, Statistic Process Control and many more.

Wilawan has been ISPE member since 2003 and actively participated in ISPE Thailand Affiliate events since started. In August 2016, she was appointed as ISPE Thailand Committee. Besides committee duty, she has been moderator and adjunct speaker in some ISPE Thailand Seminars.

Since 2017, Wilawan has been elected as Secretary of Thai Automation and Robotics Association (TARA) and has involved in various activities to promote growth of Automation and Robot Utilization for Thailand 4.0, inclusive of Seminars, Exhibitions, Mini-factory Demonstration, Business Matching and advanced course works for university professors/startup/professional in the industry.

Wilawan was a lecturer in Production Technology at Huachiew Chalermprakiat University in 2006-2008 and has been a lecturer in Pharmaceutical Engineering and Advanced Pharmaceutical Process at Silpakorn University from 2016 until now. In addition, she has been speaker for Board of Investment (BOI), Department of Industrial Promotion - Ministry of Industry, Thailand Science Park and Thai-German Institution (TGI).

Agenda PROPAK 2019 Training

Friday 14th June 2019, At BITEC

Supplier Audit and How to create C&Q documents

Agenda

TOPIC: Supplier Audit and How to create C&Q documents		
Date : Friday 14th June 2019 Time : 9:00 – 12:00 Venue: BITEC		
Time	Topic	Speaker
9.00 – 10.00	A practical approach to apply risk management on supplier audit	Dr. Mukdavan Prakobvaitayakit <i>Deputy Managing Director The Government Pharmaceutical Organization (GPO)</i>
10:00 – 10:30	Coffee Break	
10:30 – 12:00	How to create commissioning and qualification document	Mr. Paranpornras Gewatthanin <i>Quality and Validation Manager Pharmafac Group</i> Mr. Santirat Phoodai <i>Quality and Validation Supervisor Pharmafac Group</i>
Note: The training course will be in Thai.		



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Speaker:



Dr. Mukdavan Prakobvaitayakit

Deputy Managing Director

The Government Pharmaceutical Organization (GPO)

Education :

- Doctor of Philosophy degree in Pharmacy from the Faculty of Pharmaceutical Science, Chulalongkorn University, Bangkok. (2004)
- Master of Science in Pharmacy from the Faculty of Pharmaceutical Science, Chulalongkorn University, Bangkok. (1992)
- Bachelor degree of Science in Pharmacy with 2nd class honors from the Faculty of Pharmaceutical Science, Chulalongkorn University ,Bangkok (1988)

Certification :

- NEBB Cleanroom Performance Testing (CPT) Certified Technician from National Environmental Balancing Bureau (NEBB),USA (Examination passed on March 3-6,2014)
- Certified Pharmaceutical Industry Professional; CPIP from International Society for Pharmaceutical Engineering (ISPE)(April 30, 2013-April 30,2016)

Job Experience :

- Deputy Managing Director (Oct1,2015-Current), The Government Pharmaceutical Organization.
- Director of Quality Assurance Department (Oct1,2013-Sep,2015), The Government Pharmaceutical Organization.
- Quality Assurance Manager ,Rangsit Manufacturing Plant (February 4 ,2010-Sep 30,2013), The Government Pharmaceutical Organization.
- Director of Pharmaceutical Production 4 Division (October 16,2006 – Feb 3,2010), The Government Pharmaceutical Organization.

Training :

- 2018 Facilities of the Future Conference, by ISPE , in Bethesda , Maryland ,USA (20 - 22 Feb 2018)
- 2017 UNICEF–UNFPA–WHO meeting, at WHO, Copenhagen, Denmark (18 -21 September 2017)
- ISPE 2017 Asia Pacific GAMP® Data Integrity Conference , in Singapore (13-14 Nov. 2017)
- Training at Mylan, India for Technology transfer course (June 17,2012 – June 20, 2012)
- Consultative Meeting of the UN Prequalification of Diagnostic, Medicines at WHO, Switzerland (April2,2011-April7,2011)
- Meeting with Manufacturers WHO Prequalification in a New Decade at WHO, Denmark (July26,2010-July 27,2010)



Facilitator/Speaker :

- ISPE Annual Meeting & Expo 2018, Philadelphia, Pennsylvania, 6 Nov 2019, “2018 Facility of the Year Awards (FOYA)”
- DITP/ ISPE THAILAND /AND TPMA Seminar and Workshop Bangkok, Thailand – Jun 3-5,2014, “Cost Effective URS for Compliance PIC/S GMP”
- Asean Life Sciences Conference and Exhibition 2013 /ISPE Seminar Bangkok, Thailand –July 20,2014 “Quality by Design (QbD) and Process Analytical Technology (PAT)”
- UNFPA/ WHO/ fhi360 Workshop Bangkok, Thailand – November 9, 2012 Update on WHO Prequalification of Medicines Programme for Regulators and Manufacturers“WHO Prequalification of Medicines Programme as viewed by Thai authorities and manufacturers



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Mr. Paranpornras Gewatthanin

*Quality and Validation Manager
Pharmafac Group*

Education :

2002 - 2006 King Mongkut's Institute of Technology Ladkrabang
Bachelor's Degree in Environmental Resource Chemistry of Science
WORKING SUMMARY

Job Experience :

- 2018 – Present QUALITY AND VALIDATION MANAGER – Professional Quality Development
- 2012 – 2018 QUALITY AND VALIDATION MANAGER – Pharmafac Plan Technology
- Devising and establishing a company's quality procedures, and standards and specifications;
 - Reviewing customer requirements and making sure that they are met;
 - Defining quality procedures in conjunction with operating staff;
 - Setting up and maintaining controls and documentation procedures;
 - Making suggestions for changes and improvements and how to implement them;
- 2009 – 2012 QUALITY SYSTEM AND VALIDATION SUPERVISOR – Pharmafac Plan Technology
- Oversees and manages validation staff to conduct qualification and validation studies for equipment, utilities and facilities.
 - Manage the successful execution of projects by working effectively with teams and cross-functional groups.
 - Interface with the FDA in local and customers during site audits to respond to qualification and validation related questions.
 - May be directly or indirectly involved in investigation and root case analysis for incidents reported on validated systems.
 - Provide technical assistance, as needed, for engineering troubleshooting.
 - Consulting the validation & qualification activities to interested people.
 - Provide validation & qualification knowledge to students and interested people.
- 2009 – 2012 VALIDATION OFFICER – Betagro Group
- To create/develop the validation system together with related party, to gather information on new related technologies, and then to publish them on both hard media and electrical media and make sure they are accessible
 - To apply the validation system to real use together with related parties both in and outside the organization, and make sure the system functions normally and up to the academic standard
 - To keep in check of the validation system in case there is any change on the system, together with related parties both in and outside the organization
- 2006 – 2009 TECHNICAL SERVICE AND SUPPORT – Liquid Purification Engineering International
- Service & supporting the technical, regularly to maintain and provide training to ensure smooth and reliable operation that includes engineering support to plan, manage, and execute the start- up, commissioning, and validation of system engineering, assist in the creation of validation master plans of purified water plant for pharmaceutical industry.



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- Responsible for the project validator will write and execute validation protocols, such as Installation, Operational, and Performance Qualification (IQ, OQ, PQ) etc.
- Documentations for system operation & maintenance manual.
- Water treatment system basic & operation trainer more than 20 companies.

Area of Experiences :

- Project management: assure the construction quality control, commissioning, qualification, validation of facilities and utilities system
- Good manufacturing practice consultancy, design, preparation, implementation and management
- Direct impact of facility and utility system commissioning and qualification involved
- No-impact of facility and utility system commissioning involved
- Process machine commissioning and qualification and validation in sterile and non-sterile medicinal field.
- Commissioning, Qualification, Validation consultancy, design, preparation, implementation, and management
- Air bio-decontamination by hydrogen peroxide
- Quality management system consultancy
- Technical and Scientific affairs
- Academic lecture and coaching

Teaching Experiences :

- Basic principle and operational of water treatment system
- Basic principle and operational of GMP utilities system in pharmaceutical use
- Project Management in Pharmaceutical industry
- Conceptual design of PREMISE (e.g. HVAC, PW, etc.) in pharmaceutical field
- Impact assessment
- Principle of process gases in pharmaceutical industry
- Cleanroom validation
- Principle of purified water system in cosmetic field
- Principle of pharmaceutical water and steam
- Cleaning and passivation
- Sanitization for microbiological control
- Validation and qualification



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Mr. Santirat Phoodai

*Quality and Validation Supervisor
Pharmafac Group*

Education:

2009 - 2012 Faculty of Engineering, Maharakham University
Bachelor's Degree of Engineering Program in Biological Engineering

Job Experience :

2018 – Present Quality and Validation Supervisor– Professional Quality Development Co., Ltd., Pharmafac Group

2014 – Present Quality and Validation Supervisor– Pharmafac Plan Technology Co., Ltd., Pharmafac Group

- Oversees and manages validation staff to conduct qualification and validation studies for Equipment, Utilities and Facilities.
- Manage the successful execution of projects by working effectively with teams and cross-functional groups.
- Interface with the FDA in local and customers during site audits to respond to qualification and validation-related questions.
- May be directly or indirectly involved in investigation and root case analysis for incidents reported on validated systems.
- Provide technical assistance, as needed, for engineering troubleshooting.
- Consulting the validation & qualification activities to interested people.
- Provide validation & qualification knowledge to students and interested people.

2012 – 2014 Upstream Process Engineer – National Biopharmaceutical Facility, Industrial Park center, King Mongkut's University of Technology Thonburi (KMUTT)

- Generated Protocol, Standard operating procedure (SOP) and Work Instruction (WI) for the production.
- Qualifications (IQ, OQ and PQ) & Validation of Machine and Equipment follow to Validation Master Plan.
- Management and Control the Machine that are used to production process in compliance with GMP.
- Perform Preventive Maintenance (PM) and Calibrated (CAL) of Machine and Equipment.
- Service Qualifications (IQ, OQ and PQ) to an outside agency.

Area of Experiences:

- Project management: assure the construction quality control, commissioning, qualification, validation of facilities and utilities system.
- Good Manufacturing Practice consultancy, design, preparation, implementation and management.
- Good Distribution Practices, requirements and implementation.
- Direct impact of facility and utility system commissioning and qualification involved.
- Process machine commissioning and qualification and validation in sterile product field.
- Vaccine production and Animal product by Cell Culture technique (Vero cell).
- GMP/PICs for Biological product and Sterilized product.
- Cleanroom standard follow up ISO-14644 standard.
- Contamination tests for Compressed gases follow up ISO-8573 standard.



- ISO 9001:2015 Understanding and Implementation.
- Computerised system compliance: Practical computerised system validation.
- Data Analytics and big data

Teaching Experiences:

- Bioprocess Engineering Basic Concept
- Principle of Microbiology in Cleanroom & Pharma Industry
- Pharmaceutical Cleanroom Commissioning Qualification and Validation (CQV)
- Radiopharmaceuticals and Fundamentals of Nuclear Pharmacy
- Preventing and Troubleshooting Mold-Related