

## WORKSHOP:

# “An Oral Solid Dosage Plant Design”

Monday 18<sup>th</sup> – Tuesday 19<sup>th</sup> October 2010, Siam City Hotel, Bangkok

## BACKGROUND AND OBJECTIVE

The seminar will focus on case studies on manufacture of oral solid forms with Low to Moderate Active Pharmaceutical Ingredients. This type of plant is probably the most common in Thailand and a number of companies are planning to build new plants. A practical course for 2 days to provide information for design companies, contracting companies, construction companies and owners and engineers from pharmaceutical companies about how to run a project to build a new oral solid dose (OSD) facility to meet PICS regulations and to use industry best practice (based on ISPE publications)

## AGENDA

This two day seminar will cover the following principles and important topics:-

- **Project Management** - Customer and Supplier relationships – responsibilities and activities of the pharmaceutical company and responsibilities and activities provided by the design companies, contracting companies, construction companies.
- **The Vision** - Case studies describe what a suitable plant might look like based on a typical OSD process consisting of : dispense, wet granulation, fluid bed drying, compression,
- **User requirements** - Developing the key user requirements for the plant to meet production and regulatory requirements covering the product/process, room/facility & systems, including contamination control, critical utilities, processing equipment and control systems.
- **Risk Assessment** - Introduce the concept of system impact to manage qualification
- **The Design Phase** - Design Reviews – the importance of key design reviews leading to an approved design. Examples of key design points covering the building, HVAC, critical utilities, processing equipment and control systems.
- **The Build phase** – key points of build/install
- **The Commissioning Phase** – use of the correct documentation, concept of GEP, Testing, IQ, OQ, PQ – what to test and record
- **Handover** - Final Reports, Ongoing Operation and Change control

The seminar includes Workshop sessions – to consolidate the design review process concentrating on the facility and the utilities (HVAC) The workshop sessions are designed to provide practice with the important management tools of:

- Project Management
- User Requirements Specification
- Design Review
- Risk Assessment
- Qualification and Validation

## WHO SHOULD ATTEND

Managers and Engineers from Pharmaceutical Companies  
Managers and Engineers from Design and Contracting Companies

**DAY 1**

<b>9:00</b>	<b>Start of morning session</b> <b>Welcome and introductions</b>
<b>9:05</b>	<b>Keynote: Thailand perspective and opportunities for OSD manufacturing</b> – OSD Production in Thailand & Asean – Importance of Regulations <b>Speaker:</b> Mr. Paiboon Amatamahathana, Thai FDA
<b>10:00</b>	<i>Coffee Break</i>
<b>10:30</b>	<b>Project Management: Good Practices for success and compliance of pharmaceutical projects</b> – Project Framework (Customer & Supplier Responsibilities) – User requirements – Specification & Design Reviews – Build phase – Commissioning & qualification – Project Documentation & Change Control <b>Speaker:</b> Mr. Raymond Mikrut, Foster Wheeler
<b>12:00</b>	<i>Lunch</i>
<b>13:00</b>	<b>Start of afternoon session</b> <b>User Requirements Specification: Case study (Facilities &amp; Utilities)</b> – The process & capacity – The building – Contamination control – Environmental conditions – Critical utilities – Regulatory requirements <b>Speakers:</b> Dr. Anthony Margetts, Factorytalk co., Ltd. Dr. Mark Tang, Telstar Solutions (Thailand) Co., Ltd.
<b>14:30</b>	<i>Coffee Break</i>
<b>15:00</b>	<b>Start (resume main conference) Good Practice for GMP: Update and clarifications for OSD manufacturing</b> – GMP aspects of Facility Design – Practical Points for Facility compliance and Project compliance – Microbiology <b>Speaker:</b> Ms. Linda Ambrose, Ambrose Consulting Ltd.
<b>16:30</b>	<i>Closure</i>

**DAY 2**

<b>9:00</b>	<b>Design Review Workshop: Track 1 - Facilities</b>	<b>Design Review Workshop: Track 2: HVAC</b>
	<ul style="list-style-type: none"> <li>– Facility case study and information</li> <li>– Design review in groups</li> <li>– Group Feedback</li> </ul>	<ul style="list-style-type: none"> <li>– HVAC case study and information</li> <li>– Design review in groups</li> <li>– Group Feedback</li> </ul>
	<b>Trainer:</b> Foster Wheeler	<b>Trainer:</b> Dr. Anthony Margetts, Dr. Mark Tang
<b>10:20</b>	<i>Coffee Break</i>	
<b>10:40</b>	<i>Cont.</i>	<i>Cont.</i>
<b>11:30</b>	<i>Lunch</i>	
<b>12:30</b>	<b>Design Review Workshop: Summary of findings and main points (Expert panel discussion)</b>	
<b>13:00</b>	<b>Risk Assessment Workshop: Optimizing the effort of compliance (Expert panel discussion)</b> <ul style="list-style-type: none"> <li>– Risk framework</li> <li>– Impact assessment</li> <li>– Critical parameters</li> <li>– Risk review as part of Design reviews</li> <li>– Examples</li> </ul> <b>Speaker:</b> Dr. Anthony Margetts, Factorytalk	
<b>14:30</b>	<i>Coffee Break</i>	
<b>15:00</b>	<b>Validation: A framework for project and compliance control</b> <ul style="list-style-type: none"> <li>– Specification and verification</li> <li>– Risk Assessment &amp; Design reviews</li> <li>– Good Engineering Practice</li> <li>– Commissioning &amp; qualification</li> <li>– Testing – what to test and record</li> </ul> <b>Speaker:</b> Dr. Anthony Margetts, Factorytalk	
<b>16:30</b>	<i>Closure</i>	

**RESERVATION:**

**“An Oral Solid Dosage Plant Design”**

Monday 18<sup>th</sup> – Tuesday 19<sup>th</sup> October 2010, Siam City Hotel, Bangkok

**VENUE:** 6<sup>th</sup> Floor, Kamonmart Room, Siam City Hotel:

477 Si Ayuthaya Road, Bangkok 10400: [www.siamhotels.com](http://www.siamhotels.com) - BTS: Phayathai Station

**FEES:** The fee is due upon reservation and includes seminar documentation, lunch and coffee breaks.

(Prices INCLUDE VAT 7%) - No Deduction of Withholding Tax.

ISPE Member **4,815** Baht/ delegate

Non-ISPE Member **5,885** Baht/ delegate

**HOW TO RESERVE:** *Seats are limited: First-come-first-serve-basis*

<b>STEP 1 FILL-IN</b>	<b>STEP 2 PAYMENT</b>	<b>STEP 3 SUBMIT</b>	<b>STEP 4 CONFIRM</b>
Fill-in the attached reservation form with your details	Transfer to: <b>Siam Commercial Bank,</b> Branch: Samyaek Faichai Account Current  <b>Account Name:</b> Thai Pharmaceutical Manufacturers Association  <b>Account Number:</b> 036-2-64381-1	Submit your reservation form along with bank slip or a copy of cheque  <b>Email to:</b> sth@factory-talk.com  <b>or fax to:</b> 02-630-4527  <b><u>LATEST BY MONDAY, OCTOBER 11TH, 2010</u></b>	ISPE Thailand will confirm the received of our reservation to the given contact person to ensure that your seat is reserved.

**SEMINAR SPEAKERS:**

**MR. RAYMOND MIKRUT - Project Manager for Foster Wheeler**

Raymond Mikrut involved in Project Management since 1983 after graduating from college. Raymond Mikrut has specialized in Pharmaceutical/Biotech project implementation since 1991. He has a strong understanding of the overall project management approach together with overall regulatory requirements for pharmaceutical projects.

**MR. SOON ENG GUAN - Section head, Pharmaceutical Process Engineering, Foster Wheeler**

He has more than 12 years of experience in the Pharmaceutical industry, with the first 7 years spent in the USA pharmaceutical contract manufacturing as a chemist/ Process engineer involved in cytotoxic product and vaccine in fill/finish facilities.

**DR. TONY MARGETTS - Associate Consultant, Factorytalk Co., Ltd.**

Dr. Tony Margetts has more than 20 years in Pharmaceutical Manufacturing Industry. Dr Tony Margetts recently relocated to South East Asia and operates as an Associate Consultant for Factorytalk Co., Ltd. His experiences include leading teams for new product introductions including medical devices, gaining FDA pre-approval inspection of manufacturing sites and he is also Chairman of editorial team for GAMP 5

**DR. MARK TANG - Managing Director, Telstar Solutions (Thailand) Co., Ltd.**

His technical positions are the Head of Regulatory Affairs (Thai FDA) and cGMP Specialist and Project Scientist for Pharmaceutical Projects. Previously, at M+W (Thailand) Ltd. in Bangkok, Thailand, his last management position was the Operations Manager, Projects Director and Head of Business Development. His technical positions are the Head of Regulatory Affairs (Thai FDA) and cGMP Specialist and Project Scientist for Pharmaceutical Projects.

Previously, at Alpha Therapeutic Corp./Grifols USA LLC/Baxter Inc. in Los Angeles, California U.S.A., my last management position was the Project Manager and Senior Principal Scientist for Alpha-1 Anti-Trypsin (AAT) (Aralastâ). His technical positions were in Pharmaceutical (GMP) Manufacturing /Validation/ Quality Project Management, R & D and QC Laboratory (GLP) Management, Regulatory Affairs (U.S. FDA) Technical Correspondence and Pre-Approval Inspection.