

WORKSHOP:

“Facility Design & Operation for Compliant Pharmaceutical Manufacture”

Wednesday 19th May 2010, The Montien Hotel, Surawongse, Bangkok

BACKGROUND AND OBJECTIVE

A number of Pharmaceutical Companies here in Thailand are planning new facilities or refurbishment projects. New facilities are normally provided by construction firms as turn-key projects. This involves delivery of management, design, construction, installation and commissioning services. It is therefore timely to keep up to date with best practice, new requirements and industry trends.

AGENDA

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

- Recent GMP requirements
Our GMPs continually evolve and develop. It is very important that we keep ourselves fully updated. In response to the revision of Annex 1 of the PIC/S GMP, a number of important issues have arisen that have needed clarification and explanation. To help inspectors and industry, PIC/S has recently published a document providing guidance on interpretation of some of these changes. We will review this guidance document to understand what it says and the impact.
 - PIC/S Annex 1 Interpretation guidance (published February 2010) - overview of the scope and impact of this?
 - Particle monitoring systems.
 - Grade A air supply for vial capping.
- Energy saving & sustainability considerations workshop---is there a conflict with our GMPs?
This is a high profile subject these days as we strive to meet greenhouse gas targets, and perhaps more immediately reduce our energy consumption to save money. This workshop session will explore ways we might consider to achieve these objectives and see if they are GMP compatible. We will consider volume set-back, temperature reductions, and so on.
 - HVAC for sterile products.
 - HVAC for non-sterile products.
 - Pharma water systems.
- Containment and segregation.
It has been clear for a long time that Beta-lactams need to be separated from other product families. However the extent of separation isn't clear when we consider hormones or other highly active molecules. Do we need separate buildings, segregated departments, or just dedicated equipment? We will look at the requirements, critical issues, and best practice.
 - What our cGMPs say.
 - Current Practice for Potent compounds.
 - ISPE's guidance on "Assessing the Containment Performance of Pharmaceutical Equipment".
 - Segregation techniques – Rooms and Isolators.

SEMINAR SPEAKERS (The presentation will be in English)

Mr. Gordon Farquharson, Critical Systems Ltd.

VENUE: Pimanthip Room, The Montien Hotel: 54 Surawongse Road, Bangkok 10500

Mr. Gordon Farquharson

Principal Consultant
Critical Systems Ltd
United Kingdom



We are very lucky to have as our speaker for the day Gordon Farquharson who is the most recent recipient of the ISPE Distinguished Achievement Award.

When receiving this award Gordon stated the following :- ISPE has been an essential part of my life for more than 25 years as a business resource, an unparalleled technical network, and the foundation of real friendships around the world.

Gordon Farquharson is a chartered consulting engineer with 30 years experience of quality & safety critical processes and facilities used by industries such as healthcare, life science, micro-electronics, etc. He is principal consultant with Critical Systems Ltd.

In recent years he has focused on technologies such as isolators, barrier technology, and mini-environments, critical utility systems and 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 pharmaceutical/life science sectors are a major interest and responsibility. In this context he has a high degree of expertise in the practical interpretation and application of EU/PIC-S/WHO GMPs and US FDA cGMP requirements. Experience with the variation in expectations gives an ability to dovetail the differing regulatory requirements together. 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 and 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 is 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 standardization and practice in this millennium. He has recently worked with the EMeA 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 completed writing WHO's new pharmaceutical water GMP guidance.

He is a founding member, management committee member, past chairman, and honorary member of the UK Parenteral Society, and is active in ISPE, the R3 Nordic Association, and PDA. He is a past chair of the ISPE European Education Committee and was voted ISPE Member of the year in 2001. He is a member of the PDA Science Advisory Board (SAB) and is an honorary senior lecturer at UCL (London). He lectures and teaches extensively, is an author of many papers, and contributor to books on cleanroom and isolator technology.