

ISPE China Informer 中国简讯

ISPE 中国办事处 ISPE China Office

Tel: +86 21-5116 0265
 Fax: +86 21-5116 0260
 Email: china@ispe.org
 Add: 上海市静安区陕西
 北路 66 号科恩国际中心
 2302 室, 200041
 Suite 2302, Wise Logic
 International Center
 No.66 North Shanxi Road
 Shanghai, China
 200041



In this issue, we have:

- [ISPE China Training 2010](#) *hot!*
- [ISPE has published the Chinese version of GAMP® 5](#) *hot!*
- [Two Technical Documents and Seven Knowledge Briefs Released](#) *hot!*
- [ISPE-CCPIE China Conference 2009 was successfully held 26 - 28 October in Shanghai](#)
- [ISPE at Universities in China](#)
- [Communities of Practice Updates](#)
- [Share Your Expertise](#)
- [ISPE Member of the Year](#)
- [ISPE Chinese Website updating notice](#) *Notice*

ISPE China Training 2010 *hot*

As a curriculum designed to meet needs of the Chinese pharmaceutical industry, a series of ISPE China Training events will be held in March, April, and May 2010 in Beijing, Shanghai, Guang-dong with topics as below:

ISPE China Trainings 2010			
Topic	Instructor	Time	Venue
GAMP	TBD	March to April	Beijing, Shanghai
HVAC for Pharmaceutical Facilities	Gordon Farquharson	24-25 May	Beijing
HVAC for Pharmaceutical Facilities	Gordon Farquharson	27-28 May	Shanghai
Sterile Drug Manufacturing Facilities	Gordon Farquharson	31May - 1June	Guangdong
Pharmaceutical Water	Gordon Farquharson	3 - 4 June	Guangdong
C&Q, Facility Design...More are at planning stage			

About Instructor:

**Advertisement-Broadcast
your company brand
to the world!**

Advertising ISPE website,
Pharmaceutical Engineering
magazine and ISPE technical
guides to expand your market!
Please click [here](#) or Contact
jliu@ispe.org. You could also find
opportunities to sponsor ISPE
training, annual
conference and other
membership events in China.



Gordon Farquharson was the instructor for "Sterile Drug Manufacturing Facilities" and "Pharmaceutical Water Systems" which were held in Beijing and Shanghai in 2009 which gained excellent feedback from attendees. Mr. Farquharson received **ISPE's Distinguished Achievement Award 2009**. Recipients are considered to be Members of ISPE's "Hall of Fame."

Vote for your favorite topic!

For more training topics voting, please refer to <http://www.zoomerang.com/Survey/?p=WEB229ZNLJTMKE>

ISPE Online Learning *hot!*

ISPE Online Learning page has been recently updated and includes dozens of opportunities for learning at your convenience. Please click http://www.ispe.org/multimedia/galleries/online-seminar-files/TBLOnlineCatalog_09.pdf to download the online learning catalog. You will find topics that match your areas of interest such as sterile, water, GAMP, API, etc.

You may purchase Webinars and Online Learning courses via credit card or contact ISPE China Office for assistance:

Send an email to china@ispe.org with the item number # and payment transaction for transaction for the live and recorded webinars. (Please note that the exchange rate is fixed at 7.3 in order to cover the tax incurred in China) Login instructions for the live webinars will be emailed to the purchaser three times and recorded webinar download instructions will be sent to customers once payment is confirmed and the order processed.

Chinese version of GAMP® 5 has been published! *hot!*

Language barrier?

Worrying if you can fully understand the English version of GAMP® 5?

Concerned about having a contrast of GAMP® 5 English vs. Chinese?

Chinese version of GAMP® 5 has been published!

Order the Chinese version of GAMP® 5 now!

The Chinese version of GAMP® 5 was reviewed by a dedicated review team of pharmaceutical industry experts who utilized their rich experience for their review and translation. You are sure to have a better understanding of GAMP® 5 after reading this version.

Please contact China@ispe.org to order this new industry guide.

Two Technical Documents and Seven Knowledge Briefs Released! *hot!*



HVAC Good Practice Guide - released October 2009

HVAC systems can be critical systems that affect the ability of a pharmaceutical facility to meet its objective of providing safe and effective product to the patient. The ISPE Good Practice Guide on HVAC provides designers and the project team with suggestions to help determine the user requirements and the functional design that define the facility's objectives. It also provides options to be considered in creating a design that has low lifecycle cost and that is sustainable.

Oral Solid Dosage Forms Baseline Guide, Second Edition - released November 2009

This revision - the latest ISPE publication reviewed by the US FDA - updates content from the original Oral Solid Dosage Forms Baseline® Guide to current industry standards, practices, and regulatory requirements. Specifically, it addresses the latest interpretation of GMP requirements, as well as a risk-based approach to regulatory compliance relating to the design, construction, and validation of the OSD manufacturing facility.

Seven new Knowledge Briefs released in November:

- Forecasting for Clinical Trials
- Best Practices in the Sponsor-Provider Partnership to Optimize the Clinical Trials Development Process
- Clinical Supply Chain Logistics of Small Molecules vs. Biologics - A Provider's Perspective
- Packaging Material Selection: Things to Consider
- Recent Evolution of Clinical Trial-Related Regulatory Environment in Belgium
- Containment Hierarchy of Controls
- Technology Solutions for Challenges in Cold Chain Supply Management

ISPE Members: Free

Please find purchasing and other detailed information about Knowledge Briefs at:
http://www.ispe.org/cs/resource_library_section/knowledge_briefs/BestPracticesClinicalTrials

[ISPE-CCPIE China Conference 2009 came to a successful conclusion!](#)

With the theme of Facilitating Internationalization of China Pharmaceutical Industry, ISPE-CCPIE China Conference 2009 was successfully held in Shanghai from 26-28 October, with around **400 participants**.

The officers from SFDA and US FDA shared their insights of new China GMP and FDA/EU GMP. After the fantastic keynote presentations, 6 industry tracks with tailored addresses of technical and practical issues were held paralleled on Oct26-27. The topics are: HVAC and Environmental Control、GAMP、Cleaning Validation、Pharmaceutical Water、Application of C&Q、Sterile Drug Manufacturing Facilities.

The officers from SFDA and US FDA shared their insights of new China GMP and FDA/EU GMP. After the fantastic keynote presentations, 6 industry tracks with tailored addresses of technical and practical issues were held paralleled on Oct26-27. The topics are: HVAC and Environmental Control、GAMP、Cleaning Validation、Pharmaceutical Water、Application of C&Q、Sterile Drug Manufacturing Facilities.

On Oct.28, a part of the delegates visited 7 most state-of-art pharmaceutical facilities in Shanghai and Suzhou. That's an integral part of the Conference and very welcome by both Chinese and foreign participants.

According to the feedback from delegates, **95% of them felt the overall quality of this conference is very good / excellent.**



Views from conference delegates:



JiLiang Tang, Shanghai Institute of pharmaceutical industry; Professor, Pharmaceutical Industry Automation Research and Design

Congratulations on the success of ISPE-CCPIE CHINA CONFERENCE 2009! This was a perfect platform of learning and communication for the Chinese pharmaceutical industry. We were exposed to a tremendous amount of valuable experience and knowledge from both Chinese and foreign experts. The six topics selected by the conference were very helpful, since “HVAC”, “Water”, “Sterile”, “GAMP”, “Cleaning” and “C&Q” are exactly **six key problems that have the most significant relationship with the quality of pharmaceutical production.**

As automation levels of pharmaceutical industry production rise in China, the problems regarding good automated manufacturing practices, and computerized and automation system have been attracting more and more attention from pharmaceutical enterprises. How to carry out the correct and reasonable validation of computerized and automation systems, and facilities and instruments in pharmaceutical production according to the requirements of GAMP have been urgent tasks of pharmaceutical engineering and quality supervision in China. So, how to provide effective training and application guidance about GAMP may also become one of more important works of ISPE in China.

ISPE at Universities in China

Sanofi-Aventis in BUCM

Sanofi-Aventis group visited Beijing University of Chinese Medicine (BUCM) on Tuesday, 1 December. During the visit, industry experts from Sanofi-Aventis introduced some overall information about the global pharmaceutical industry and career development within it. Moreover, internship requirements and expectations for BUCM were highlighted during their visit. Student representatives and teachers had a face-to-face meeting with experts from Sanofi - Aventis, and both felt this visit was very successful.

ISPE at Nankai University

On the occasion of the 90-year anniversary of Nankai University, ISPE Greater China SC members, Jason Tang (Chairman of ISPE China), Leslie Chang (GSK Tianjin), and Qi Ying (NNE Pharmaplan) were invited by NKUCP to participate in the "University Education, Professional Education and Biomedical & Pharmaceutical Industry" Round Table Summit on 16 October, 2009.

Jason Tang conducted a speech on "Professional Education for Biomedical and Pharmaceutical Industry". Senior management representatives from Tianjin Zhongxin Pharmaceutical, Tianjin Jinyao Pharmaceutical, Novartis Biopharmaceutical Research, GlaxoSmithKline Tianjin and Novo Nordisk Beijing were also there for an inspiring and innovative question and answer session.

Communities of Practice (COP) Updates

Various ISPE Communities of Practice (COPs) are being asked to participate in the development of the *GAMP Good Practice Guide: Calibration Management* revision and review of the draft is currently underway. The revision of *Calibration Management* will take account of the changes in the industry over the years since publication of the original Guide and will align with the new concepts in ASTM E2500, ICH8/9/10, the *GAMP Good Practice Guide on the Validation of Process Control Systems*, and the new *ISPE Baseline® Guide on the Science and Risk-Based Approach for the Delivery of Facilities, Systems, and Equipment* (currently in development).

In an effort to address the industry's need for specific guidance on how to attain consistency in the transport of the products requiring specific parameters to maintain safety, efficacy and quality of the medicinal product during transportation from the manufacturer to the consumer, various ISPE COPs are being asked to participate in the development of *ISPE Good Practice Guide: Cold Chain Management*.

To learn more about how to benefit from COPs, please go to www.ispe.org/cops and click the button to the right labeled "**Login to COPs**".

Share Your Expertise

ISPE is accepting proposals from pharmaceutical professionals for content that can be included in a variety of its educational resources. ISPE is currently accepting proposals for webinars, conferences, Annual Meeting sessions, training, *pharmaceutical Engineering Magazine*, Knowledge Briefs, E-Letters, technical documents, and more. Submissions are expected to shed light on current, topical issues and address knowledge gaps within the pharmaceutical science and manufacturing industry.

In exchange for sharing knowledge, submitters will have the opportunity to network with and learn from fellow subject matter experts; gain additional experience and develop new skills; receive recognition from industry colleagues; and contribute to innovation while improving the efficiency of pharmaceutical industry processes.

Contributions can be made by downloading the ISPE Proposal Form at www.ISPE.org/education. Call Ginger Phillips, ISPE Director of Continuing Education, at tel: +1-813-739-2271 with questions.



ISPE Member of the Year

Max Santa Member

Jason Tang



Jason Tang (Chairman of ISPE Greater China Steering Committee) has won "ISPE the Member of the Year 2009", which honors the ISPE Member who made the most significant contribution to the Society during the past year. For more information about ISPE international news, please refer to:

<http://www.ispe.org/ISPE%20Announces%202009%20Membership%20Award%20Winners%20at%20Global%20Annual%20Meeting>

ISPE Chinese website updating notice ^{Notice}

The Chinese website will be updated and restructured start from January, 2010. Updating notice will be sent out once the new system has finished upgrading.

Thank you for your attention!

ISPE 中国办事处 ISPE China Office

Tel: +86 21-5116 0265

Fax: +86 21-5116 0260

Email: china@ispe.org

Add:上海市静安区陕西北路 66 号科恩国际中心 2302 室, 200041

Suite 2302, Wise Logic International Center

No.66 North Shanxi Road Shanghai, China 200041