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Upcoming Events

ISPE –CCPIE China Training 2010^{hot!}

ISPE-CCPIE China Training 2009 was successfully held in Shanghai and Beijing in June 2009 with a total of 250 participants. The attendees are highly satisfied with the overall quality of the courses.

ISPE will cooperate with CCPIE again in 2010 to hold several trainings regarding hot topics in the industry. The proud recipient of ISPE’s Richard B. Purdy Distinguished Achievement Award in 2009, Gordon Farquharson will bring Sterile and HVAC course; meanwhile, one of the most welcomed speakers on ISPE-CCPIE China conference 2009 Tracy L. Clemmer will deliver a fantastic GAMP® course.

For more information about ISPE Events in China, please visit: www.ispe-event.org.cn which will be open on 10 March, 2010 available for online registration.

For registration form downloads, please visit: <http://www.ispe.org.cn/10-event.html>.

Course	Course 1 GAMP 5	Course 2 HVAC for Pharmaceutical Facilities	Course 3 Sterile Manufacturing Facilities
Instructor	Tracy L. Clemmer	Gordon Farquharson	Gordon Farquharson
Tianjin	12-13 April	24-25 May	27-28 May
Shanghai	5-6 July	31 May-1 June	N/A
Shenzhen	N/A	N/A	3-4 June

Facilitating Internationalization of China Pharmaceutical Industry — ISPE-CCPIE China Conference 2010^{hot!}

ISPE-CCPIE China Conference 2009 was successfully held in Shanghai in October 2009 with around 400 participants. 95% of them are satisfied with the overall quality of this conference. To further facilitating Internationalization of China Pharmaceutical Industry and understand more about WHO, new GMP regulation in China and Europe & USA, ISPE will cooperate with CCPIE again in 2010 to hold the ISPE-CCPIE China Conference 2010 in Beijing in October. Conference this year will focus on Cleaning Validation, PQLI, Technology Transfer from R&D to Production, Solid Dosage Forms, Sterile Drug Manufacture, Commissioning and Qualification. Facility Tour will also be organized as part of the conference.

- ✓ **Theme:** facilitating Internationalization of China Pharmaceutical Industry
- ✓ **Date:** 27-29 October 2010
- ✓ **Venue:** China National Convention Center (CNCC), Beijing

For more information about ISPE Events in China, please visit: www.ispe-event.org.cn which will be open on 10 March, 2010 available for online registration.

ISPE Singapore Conference

The annual ISPE Singapore Conference will be held from 6–8 June 2010 at Suntec Singapore. With the theme of “Celebrating Growth and Continuous Innovation”, this will be the 10th edition of the conference. The program for the conference will feature two workshops focused on Cleaning Validation and HVAC Sustainability.

More information regarding the conference and any enquiries may be directed to Vincent Lee at Vincent.lee@reedexpo.com.sg.

More information about ISPE global events, please visit: <http://www.ispe.org/globalcalendar> .

Technical Knowledge

Online Learning: Live and Recorded Webinars

New GMP Online Course

- ✓ USFDA GMP Inspection Approach for Facilities and Equipment Systems
- ✓ ISPE Annual Meeting Session Recordings Available Online

Recorded Webinars

If you are unable to take part in a live presentation, a recorded version will be available within five business days from original broadcast date. Please visit www.ISPE.org/OnlineLearning for a complete listing of ISPE recorded webinars available anytime, anywhere.

Online Courses

- ✓ Fundamental Industry Knowledge Courses
- ✓ CPIP™ Online Courses
- ✓ US FDA GMP Inspection Approach Online Courses

For a full list of education session recordings, please refer to:
http://www.ispe.org/cs/education_and_training_section/online_learning

Payment Method:

You could pay online directly with credit card, or you could register through ISPE China Office:
Tel: +86 21-5116 0265
Fax: +86 21-5116 0260
Email: china@ispe.org

GAMP Good Practice Guide Released



A Risk-Based Approach to Operation of GxP Computerized Systems GAMP Good Practice Guide, A Companion Volume to GAMP 5 – released January 2010

During the operational life of a GxP system regulators usually focus on the integrity, consistency, and completeness of controls required to maintain compliance. This Guide highlights the importance of the operation phase of the system lifecycle, when the return on investment for the significant time and resource expended in implementing new computerized systems can be achieved. The Guide will help regulated organizations achieve regulated computerized systems that are fit for intended use and compliant with applicable regulations and provides comprehensive

guidance for maintaining control of regulated systems throughout their operational life.

ISPE Launches Electronic Document Delivery System ---TAMPA, FLORIDA, USA, 16 FEBRUARY 2010

ISPE has announced the launch of its electronic document delivery initiative with its first three technical documents. They are available for sale as individual PDF downloads from the ISPE Web site. ISPE will release one to three technical documents per month in this new format throughout 2010.

The first three documents already released are:

- ✓ Sterile Baseline Guide (original)
- ✓ ISPE Good Practice Guide: HVAC
- ✓ ISPE Good Practice Guide: Maintenance

The next five documents slated for electronic download will be:

- GAMP® 5
- Oral Solid Dosage Forms Baseline Guide (2nd Edition)
- GAMP® Good Practice Guide: A Risk-Based Approach to Operation of GxP Computerized Systems
- GAMP® Good Practice Guide: Manufacturing Execution Systems (MES)
- GAMP® Good Practice Guide: Validation of Process Control Systems (VPCS).

For more information, please refer to:

http://www.ispe.org/cs/technical_documents_section/technical_documents_overview

New Knowledge Brief released!

Applied Risk Management in Commissioning and Qualification

by David D. Dolgin and Jörg Block

Level: Intermediate

This Knowledge Brief describes the general concepts of an ISPE Good Practice Guide under development intended to “bridge” the differences between traditional C&Q, as discussed in the ISPE Baseline Guide: Volume 5 – Commissioning and Qualification, and the risk-based ASTM verification practices.

For more information, please visit refer to:

http://www.ispe.org/cs/resource_library_section/knowledge_briefs

Membership News

ISPE Kicks Off New Year with New Web Features

—TAMPA, FLORIDA, USA, 28 JANUARY 2009

ISPE has lately announced the implementation of a new Content Management System (CMS) that has provided increased functionality and power to many of the ISPE Web site features!

Some of the new features at www.ISPE.org include increased search functionality and new views and filters that allow users to zero in on events of interest on the ISPE Event Calendar. In particular, the more robust search feature and broader tagging of content are designed to add even greater value to Members in search of solutions and information from ISPE.

In addition, ISPE Members will experience a new, individualized landing page tailored to their Member type, Affiliate/Chapter, and selected Areas of Interest. Each Member can easily update their contact information; renew their Membership online; view ISPE education, purchase, and activity history; set their email preferences; access news directly from their Affiliate or Chapter; view all upcoming international events for which they are registered; find content tagged for their chosen Area(s) of Interest, and save specific ISPE Web pages for future reference. Improvements to the web site navigation are expected to be implemented later this year.

ISPE provides support to layoff members

With the Society’s focus to provide outreach and ongoing communication with current Members who may be in transition due to layoffs or company restructuring, please keep us apprised if you hear of any upcoming company layoffs or restructuring that may affect a significant amount of our Members. Email communication will be routinely deployed to these Members to let them know that ISPE is Here to Help and remind them of all the important resources available to them as they face these challenges.

Call to ISPE Global Volunteers:

Volunteers are vital to the success of ISPE. There are many ways to volunteer your time and expertise to ISPE. Volunteering for a committee, council, task team, or COP steering committee is one of the most common ways to get involved. Other ways to volunteer include:

- Presenting at an international conference or local event
- Developing and/or presenting a Webinar
- Writing or reviewing a technical article
- Serving in a leadership position or being active on an Affiliate or Chapter Board or Committee

This year, ISPE has **new Volunteer opportunities** for ad hoc volunteers located anywhere in the world who are willing to participate in short-term assignments.

Please take a moment to learn more about volunteering at ISPE and the existing volunteer opportunities that currently exist by visiting www.ispe.org/volunteers and completing the [Volunteer Profile](#).

We look forward to hearing from you and to benefitting from your commitment and dedication to the enhancement of our industry. Please email ISPE Volunteer Services at volunteerservices@ISPE.org if you have questions or suggestions.

Community of Practice (COP)

Active Pharmaceutical Ingredients Community of Practice Presents Process Technology Training in Milan

Under the expert lead of European and North American Active Pharmaceutical Ingredients (API) subject matter experts, the API Community of Practice (COP) will present the seminar *Advances in API Process Technology* during the next ISPE *Milan Congress on Science and Risk Assessment for Business Success* from the 22 to the 25 of March 2010 in Milan, Italy. This seminar focuses on competitive manufacturing through process intensification and continuous processing. For more information on the Milan Conference activities, access the following link: http://www.ispe.org/cs/2010_milan_congress/congress_programme. For more information about other API COP discussions and activities, go to www.ispe.org/cops and click the button to the right labeled "**Login to COPs**".

The Process Analytical Technology Community of Practices Sponsors The Fourth EuPAT Conference Series

The Process Analytical Technology (PAT) Community of Practice (COP) invites its membership in Europe to join the activities of the *Fourth EuPAT*, a unique forum for scientists and engineers meeting in Finland on 5-6 May 2010. The fourth pan-European Science Conference on PAT, organized through ISPE's Nordic Affiliate, encourages and promotes progress in the sciences behind PAT, and strengthens the interdisciplinary scientific discussion that bridges between the various fields underpinning PAT. For more information on PAT COP discussions and activities, go to www.ispe.org/cops and click the button to the right labeled "**Login to COPs**". Then, scroll down, place a check mark on the PAT COP, and click the join button at the very end of the page to confirm your membership.

For more information, please refer to:

http://www.ispe.org/cs/communities_of_practice_section/communities_of_practice_overview

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Advertisement opportunities at ISPE main website, ISPE Chinese website, and even on one of the most famous magazine in pharmaceutical industry - PE (Pharmaceutical Engineering) to broadcast your company to the world and establish your authority brand! For more details, please contact [Jackie Liu](#), ISPE China membership & Affiliate Relations Manager.

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