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ISPE-CCPIE China Conference October 2010, Beijing

ISPE-CCPIE China Conference 2009 was successfully held in Shanghai in October 2009 with around 400 participants, 95% of whom are satisfied with the overall quality of this conference.

To further facilitate Internationalization of China Pharmaceutical Industry and understand more about WHO, 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.

Date: 26-29 October 2010

Venue: China National Convention Center (CNCC), Beijing

Topics	Date	Session Leaders
Cleaning Validation	26 Oct	Rob Walker-EU
Solid dosage forms	26 Oct	Jack Chu-NA
PQLI	PM 27 Oct	John Berridge-EU
Technology Transfer from R&D to Production	PM 27 Oct	Patrick Wong-NA and AP
Commissioning and Qualification	PM 27 Oct& 28 Oct	Tim Howard-NA
Sterile Drug Manufacture	28 Oct	Gordon Farquharson
GAMP	28 Oct	Tracy Clemmer- AP

For more information about the Conference, please [click here](#).

ISPE-CCPIE China Training 2010

ISPE China training 2010 had a very good beginning with the success of GAMP5: A Risk-based Approach to Compliant GxP Computerized Systems, which was held on 12-13Apr, 2010 in Tianjin. 57 delegates attended the course, most participants valued highly of the training course and the instructor

Tracy L Clemmer.

Besides, as one of the best trainer in ISPE, Gordon Farquharson provided around 200 participants both the principles & the hands-on experience on HVAC for Pharmaceutical Facilities & Sterile Drug Manufacturing Facilities from May 24 to Jun 4 in Tianjin, Shanghai & Shenzhen. The attendees had high praise for the training courses.



The Course of **GAMP 5** will be repeated on **5-6 July in Shanghai**. This basic level course provides an overview of international regulations pertaining to computerized systems and introduces participants to the key concepts and basic principles of GAMP[®] 5. Tracy L. Clemmer will still be the instructor.

For more information about this course, please visit [ISPE event website](#), which is also available for online registration.

ISPE launches offline COP event in China

ISPE's Communities of Practice (COPs) are industry specific, interactive on-line communities. COPs provide professionals forum to discuss, problem-solve, and benchmark best practices in numerous industry disciplines.

To better serve the members in China, ISPE plans to launch offline COP event in the near future. The offline COP will be composed of 1-2 presentations and followed by discussions and learnings from other ISPE people. The event is free of charge for ISPE members.

Now we are looking for volunteers to make small presentation about your daily work. If you would like to make 30 minutes presentation of a topic there are filling your daily work life, please contact [ISPE China Office](#).

ISPE Annual Meeting 2010

With the theme of "Discovering What's Next: Reality, Retooling, Growth", ISPE Annual Meeting 2010 will be held 7-10 November in Orlando, Florida, USA. It will help answer what is next in pharmaceutical industry and how to prepare for it. During the four days, there will be 11 different education tracks to meet your knowledge needs.

Stay connected with the 2010 ISPE Annual Meeting by regularly visiting <http://blog.ispe.org/> or contact [ISPE China office](#) if you want to know more information.

ISPE Baseline Guide on Risk MaPP

This two-day workshop is planning by ISPE Singapore Affiliate and soon to be published. The Guide provides a mechanism that allows manufacturers to ensure that multiple products of varying risk can be safely produced in the same facility. The Guide outlines a risk management approach to ensure that cross contamination is at or below acceptable limits for multiple product facilities. The guidance provides a toolkit so that both industry and regulators can use a common agreed basis to assess risk controls necessary including the need for segregation/dedication. The workshop is planned for October. The exact dates are to be confirmed and it will be 2 full days, 8:30 to 17:10.

For more information, you can contact Mr Martina Crosbie, the Affiliate Manager of ISPE Singapore, please send email to ispesingapore@yahoo.com.sg.

ISPE launches 19 new electronic technical documents

ISPE has launched 19 technical documents and they are available for sale as individual PDF downloads from the [ISPE website](#). They are: GAMP 5, Biopharmaceuticals Baseline Guide, C&Q Baseline Guide, Water and Steam Systems Baseline Guide, OSD Baseline Guide, API Baseline Guide, GAMP GPG:EDA and so on.

Online Learning: webinars & courses

Live webinars:

- **22 Jun 2010: Manufacturing Execution Systems(MES) Good Practice Guide is Launched !**

Attend this webinar for a review of the guide and a discussion on how it can be used to successfully plan, design and manage a multiple-system manufacturing environment to address key challenges in life sciences manufacturing companies.

Page link: <http://www.ispe.org/mesgoodpracticeguide>

- 10 Aug 2010: How to Design and Manage a CAPA System
- 19 Aug 2010: The 800-pound Gorilla Hiding in your Bio-manufacturing Suite
- 09 Sep 2010: Development and Validation as an Integrity Test Method for Sterile

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.

Voting for the next ISPE technical guides translation

The Chinese version of GAMP[®] 5 was translated and published at the end of 2009. Thanks to all of you for your support and please do feel free to let us know your comments and suggestions.

ISPE now has the plan to translate more technical guides into Chinese within this year such as Sterile Manufacturing Facilities, Good Engineering Practice, etc. We appreciate your voting for the next translation. Please [click here](#) to vote for your favorite one!

CPIP

The Certified Pharmaceutical Industry Professional SM (CPIPSM), a competency-based international credential, was developed to recognize pharmaceutical industry professionals who meet the competency standards established by the PCC. The CPIP credential is part of an industry and government-wide initiative to drive innovation and improve drug product quality. The credential confirms your industry knowledge and experience and how you apply key competencies to achieve cost-effective and risk-based approaches, innovation, quality by design, and continuous improvement.

Exam Application Fee:

ISPE Members Yearly Fee: USD \$350 / EUROS €259
ISPE Nonmember Yearly Fee: US\$460 / EUROS €341

Examination Date:

6 September - 15 October 2010

8 March - 16 April 2010 (already past)

Test site: <http://www.prometric.com/ISPE/default.htm>

(We have examination site in both Shanghai and Beijing)

For more information, please visit our website: <http://www.ispe-pcc.org/> or contact [ISPE China Office](#).

Call for ISPE Volunteers

Volunteers are vital to the success of ISPE. There are many ways to volunteer your time and share your expertise with ISPE. Volunteering for a committee, task team, or COP 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 China has new volunteer opportunities for volunteers who are willing to participate in short-term or long-term assignments such as the translation of ISPE technical guides, technical presentation at offline COP events, sharing industry experience with students or young professionals. We look forward to hearing from you and to benefitting from your commitment and dedication to the development of our industry. Please feel free to contact [ISPE China Office](#).

New Executive Council Election for ISPE Sichuan University Student chapter

ISPE Student chapter of Sichuan University have finished the election of new Executive Council from Nominating Committee on 17th Apr, 2010. 69 members took part in the voting and 10 abstained the right. All sections met bylaws of the student chapter. The list of the Second Executive Council members is as follows:



President: Yiwen Zhang, 43 votes (serve for another term of office)

Vice president: Qinqin Li, 32 votes

Treasurer: Pengli Ma, 21 votes

Secretary: Xin Wang, 37 votes

Executive Council:

Shuang Xie, Hongjian Du, Yue Jia, Benhe Zhang, Pengwei Zhang, Daocai Wang.

After the election, the Executive Council held the meeting of ISPE student chapter in the first teaching building B403 on April 17th on Jiangan campus successfully. The Council's work handover will be accomplished at the end of the month. It is believed that the new Executive Council will lead the Chapter to a greater development.

Prof. Chu's Visit to Sichuan University

On May 25th, Jack Chu visited Sichuan University and talked with the student members about Risk management, V model in validation, URS, HVAC, etc. He also gave some valuable suggestions on the chapter's development. At the end, Wilson Zhang as the student representative sent Jack a special gift, one T-shirt designed for the Student Chapter of Sichuan University. Students highly valued Prof. Chu's visit as they got to know how to solve the problems and what the pharmaceutical industry would be like.

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Advertisement opportunities at ISPE main website ISPE Chinese websites, 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,
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