Come hear from the new ISPE Baseline Guide®, Risk-Based Manufacturing of Pharmaceutical Products (Risk-MaPP) authors on how to implement the guide into your quality systems to manage the risk of cross contamination. Your opportunity to learn from leaders across the globe.

### Attendee Benefits

- **Learn** from Guide authors how to apply the principles of the Guide
- **Hear** about companies that have employed the Risk-MaPP principles and their interactions with regulatory bodies
- **See** presentation by French regulatory authority (AFSSAPS) and pre-recorded FDA presentation on Risk-MaPP
- A recorded webinar presentation: “Risk-MaPP: What Is It and Why You Need It” will be presented prior to the Seminar to give participants an opportunity to maximise their understanding of the Seminar.

#### Where

**Novotel, Clarke Quay**  
**Singapore**

**When**  
**25 - 26 October 2010 (Mon & Tues)**

**Pre-Seminar Presentation**  
**20 (Wed) October 2010**  
**Jurong Country Club**  
**5.30-7.30pm**
**DESCRIPTION**

As manufacturers are looking to reduce cost and increase efficiency, more multi-product facilities are being utilized either directly by the manufacturers or through partnerships with contract manufacturing organizations (CMO’s). With the use of multi-product facilities, the risk of cross contamination increases. By properly managing the risk of cross contamination manufacturers can reap the benefit of lower cost and higher efficiency while maintaining product quality and patient safety.

The much anticipated release of ISPE’s New Baseline Guide® Risk-MaPP, provides a scientific risk-based methodology based on ICH Q9 to manage the risk of cross contamination.

The seminar will focus on use of the logic diagram, how health based limits are developed, setting cleaning validation limits, risk assessments for cross contamination, and formulating a Quality Risk Management Plan as part of a Quality System. Attendees will hear about companies that have implemented Risk-MaPP principals in several case studies and participate in work-shops.

**TAKE BACK TO YOUR JOB**

At the conclusion of this seminar, participants will be able to:

- Determine when multi-product facilities can be used
- Use the logic diagram to guide a team through the process of determining how to manage the risk of cross contamination.
- Understand where to get health-based data for use in risk assessments
- Develop scientific risk-based cleaning validation limits
- Understand how others have implemented Risk-MaPP principles into their operations
- Prepare a Quality Risk Management Plan for Cross Contamination

**WHO SHOULD ATTEND**

Anyone dealing with multi-product facilities especially QA, Toxicologists, EH&S Professionals, Engineers, Operations, Cleaning Validation, Project Managers, Regulators/Inspectors.

**Seminar Leader**

**Stephanie Wilkins**

Stephanie Wilkins, PE, Lean Six Sigma Green Belt, is president of PharmaConsult US, Inc., which provides potent compounds containment consulting to the Pharmaceutical industry.

Wilkins has over 25 years of professional experience in project management, engineering and validation solutions for the pharmaceutical/biotech industry including research, development, pilot plant and manufacturing facilities.

She is co-Chair of ISPE Risk-MaPP Baseline Guide Task Team and is a member of the ISPE International Board of Directors.

**Speakers:**

- Paul Wreglesworth
  Independent Consultant, formerly AstraZeneca, UK
- Bruce Naumann
  Merck – USA
- Richard Forsyth
  Senior Consultant, Hyde Engineering and Consulting
- Julian Wilkins
  Vice President, PharmaConsult US Inc., USA
- Catherine LeFebvre
  AFSSAPS (French Health Products Safety Agency)

**RECEIVE FREE GUIDE!**

After registration, a link to download an electronic copy of the Guide (available mid-Sept) will be sent to you so you can get familiar with the document prior to the Seminar. Please remember to print out and bring your Guide to the Seminar.
General Information

Registration

Course Fee Includes:

• Course materials
• Morning and afternoon tea/coffee
• Lunch
• Electronic version of Guide
• Webinar session (including tea/coffee)

Hotel accommodation is not included.

Registration Fees (in Singapore Dollars)

By September 24, 2010
ISPE Members: $ 950
Nonmembers: $ 1,350
Academia Member: $ 500
Emerging Market Member: $ 500
Government Member: $ 500

After Sept 24, 2010
ISPE Members: $ 1,200
Nonmembers: $ 1,600
Academia Member: $ 650
Emerging Market Member: $ 650
Government Member: $ 650

See below for Payment and Registration information.

To become an ISPE Member: Simply log on to www.ispe.org to apply and pay online for immediate membership benefits, or contact Fiona Cronin, Affiliate Manager, at ispesingaffiliate@gmail.com to pay by cheque or electronic bank transfer.

To take advantage of ISPE member rates, application forms and payment must be received by 17 Sept to enable processing.

Venues

2 Day Seminar Venue
25 and 26 October 2010
Novotel Hotel
Clarke Quay
177A River Valley Road
179031 Singapore

Cinnamon Room
Registration: 9.00am – 9.30am

Pre-recorded Webinar:
20 October 2010
“Risk-MaPP: What Is It and Why You Need It”
This is a pre-recorded webinar which will be shown, followed by a moderated Q&A session (for those registrants who wish to maximise their understanding during the 2 day seminar).

Jurong Country Club
9 Science Centre Road
Singapore 609078
5.30pm – 7.30pm

Beverages provided.

Registration and Welcome: 5.30pm – 5.45pm

Special Requirements

If you have
- any special needs or dietary requirements
- are travelling from overseas and would like assistance with transport arrangements, directions, or accommodation,

please contact Fiona Cronin at ispesingaffiliate@gmail.com or telephone +65 6826 1105.

General Notice

The speakers engaged to present these programs are leading professionals in their fields. However, in rare circumstances, it may be necessary to make substitutions; in this event, every possible effort will be made to replace speakers with those of comparable qualifications. Agendas are subject to change without notice.

Every precaution is taken to ensure accuracy, but ISPE is not responsible for the accuracy of information distributed or contained in these programs or for any opinion expressed. ISPE is not responsible for lost airfare due to cancellations.

Cancellations

Cancellations must be made in writing. If cancellations are received two (2) weeks prior to the course, a full refund, minus a S$75 handling fee, will be issued. Should the registrant have received their electronic copy of the Guide prior to cancelling, (US) $200 will also be deducted from the refund.

Refunds will not be given except in the above circumstances. If the registrant is unable to attend, substitutions will be accepted.

Registrations strictly close by COB, 8 Oct 2010.
PLEASE PRINT OR TYPE CLEARLY

ISPE Member Number ____________________  Will you be attending the Pre-Seminar Presentation on 20 October?  Yes/No
Surname ___________________________________________  Given Name ___________________________________________
Nickname for Badge ___________________________________________  NRIC/FIN ___________________________________________
Job Title ___________________________________________
Company ___________________________________________
Business Address ___________________________________________
City ___________________________  State _______  Postcode _________  Country ________
Business Tel No: ___________________________  Personal H/phone No: ___________________________
E-mail Address ___________________________________________

☐ Cheque  ☐ Credit Card  ☐ Bank Transfer  Transaction Number _____________

Course Rates

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<th>COURSE DATE</th>
<th>*MEMBER FEES</th>
<th>NONMEMBER FEES</th>
<th>ACAD/EM/Gov MEMBER FEES</th>
</tr>
</thead>
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| 25 - 26 October 2010 (Seminar) and 20 October (2 hour webinar) | By 24 Sept $950  
After 24 Sept $1350 | By 24 Sept $1200  
After 24 Sept $1600 | By 24 Sept $500  
After 24 Sept $650 |

Payment and Registration Submission

Please return completed form and cheque/bank draft to:

**Fiona Cronin, Affiliate Manager**  
ISPE Singapore Affiliate  
C/o 73 Bukit Timah Road  
Rex House #04-01  
Singapore 229832  
Tel: +65 6826 1105

Completed forms may also be scanned and emailed to:  
Email: ispesingaffiliate@gmail.com

Please make cheques/bank drafts payable to:  
"International Society for Pharmaceutical Engineering (S)" and write your name and ‘RISK-MAPP’ on back and post, together with this completed form, to opposite address. Completed forms may also be scanned and sent to email address (opposite).

For credit card/TT payments/bank deposits:  
Please email or post completed form to opposite address.  
Credit Cards: Email ispesingaffiliate@gmail.com for how to pay. Check with your bank/credit card provider for rates/any additional charges.  
Bank Transfer/Deposits: DBS Bank, Shenton Way Branch  
International Society for Pharmaceutical Engineering Singapore (S)  
Acct#: 0010733680 (Current Account)  
Swift Id: #DBSSSGSG