

June 2007

Here is the latest information about upcoming educational opportunities in Europe and other ISPE news you should not miss!

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MEMBER SPOTLIGHT



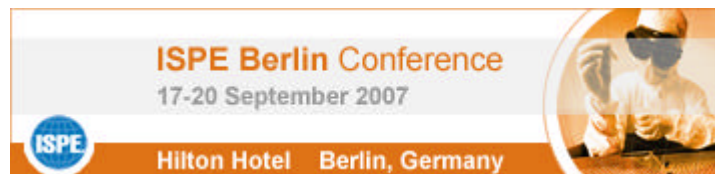
Carlo Bestetti
GAMP Italiano

Q: As the main driver of GAMP Italiano, can you tell us about the achievements you have made so far, and how these relate to the initial reasons why you decided to create this local GAMP COP two years ago?

A: The GAMP Italia has progressively increased to 50 members, including manufacturers, suppliers, consultants, academia and students. Equipment Validation has been a major focus of our work: a working group has been created, an article was written

GET THE KNOWLEDGE YOU NEED TODAY TO MAKE A DIFFERENCE TOMORROW

Regardless of where you are in your career, ISPE provides critically important opportunities for you to gain skills, acquire knowledge, and collaborate with industry leaders. We give you the resources and know-how you need to get your job done today, and to help you impact your company's goals to lower production costs, improve process efficiency, increase production quality, and meet regulatory requirements.



Berlin Conference,
17-20 September 2007, Berlin, Germany

Friday, 3 August is the deadline for special pre-registration rates to the ISPE Berlin Conference. This event is designed to give practical solutions to the daily problems you face, as well as details on current and future industry trends.

- ✎ **Product Quality Lifecycle Implementation (PQLI): Practical Approach to Quality by Design**
ISPE's unique leadership in the facilitation of global solutions for a globally-based industry will be demonstrated during this session. Take part in the debate with regulatory agencies to turn Q8 and Q9 into a cross-functional and

LOCAL AFFILIATE EVENTS

JULY

Date TBD
UK Affiliate Central Region
Seminar: *Packaging*
Location TBD

Date TBD
UK Affiliate Southern Region
Full day seminar: *Continuous processing*
Location TBD

5 July
Italy Affiliate
ISPE Night
Milan, Italy

5 July
Italy Affiliate
Seminar: *Meet Between Pharmaceutical Industry,*

illustrating the approach and a seminar was held in May at the University of Parma. Cooperation with other Special Interest Groups is in progress. We are especially interested in being included in the review process of GAMP5. We also set up a discussion website that facilitates communication amongst the members. The aim of enhancing local and international cooperation is therefore reached. Future plans include the development of a second working group on IT and the GAMP EU Steering Committee meeting to be held in Milan.

NEW MEMBERS

Last month, ISPE welcomed 120 new Members in Europe. Find out who joined!
[New Members' List](#)

- practical reality and define areas where industry will be able to provide the technical framework for the implementation of QbD in regulatory submissions.
- ✎ **Good Engineering Practice – Implication of the New ASTM Standard on Commissioning and Qualification**
This seminar will provide information on the recently approved *ASTM Standard Guide* for Specification, Design, and Verification of Pharmaceutical and Biopharmaceutical Manufacturing Systems and Equipment and its application and impact on the revision of the *ISPE Commissioning and Qualification Baseline® Guide*.
 - ✎ **Barrier Isolation Technology: Innovation Updates and New Case Studies**
Get a global perspective on the topic presented by speakers from Asia, Europe and the US and discuss state-of-the-art advancements in developing and manufacturing pharmaceuticals using RABS and isolators.
 - ✎ **Moving Towards GAMP® 5: “Benefit not Bureaucracy”**
Gain insight into the thinking behind *GAMP 5* directly from its authors and discuss the impact of regulatory trends particularly in the areas of PAT and risk-based qualification for the 21st century.
 - ✎ **21st Century Laboratories: Quality, Efficiency, Flexibility**
Explore current and future trends in the instrumentation and technology, including the impact of PAT on future laboratory design.
 - ✎ **Biotechnology: Global Biopharm Facility Strategies**
Discover the factors to consider when deciding whether to expand or build a new biopharmaceutical facility or whether to optimise and streamline existing biopharmaceutical processes. Hear strategies for site selection, construction, start-up and approval of new biopharmaceutical facilities, as well as technology updates on optimisation strategies and novel approaches in technology transfer to new or existing facilities.
 - ✎ **Investigational Products: Meet the Challenges of Today and Tomorrow**
During this highly-interactive seminar, enhance your knowledge on ways of working to meet current and future challenges in the manufacturing, packaging and supply of IPs and hear the view of big pharma, regulators and representatives of the emerging markets.

University and Regulating Corporations
Polytechnic Auditorium, Milan, Italy

6 July
Italy Affiliate
Facility Tour
Location TBD

18 July
UK Affiliate NW Region
Evening site visit: *Sterile Inspection Technology, Wockhardt Pharmaceuticals*
Wrexham, UK

AUGUST

29 August
Nordic Affiliate
Seminar: *Science Based Manufacturing – Packaging*
Stockholm, Sweden

[ISPE Global Events Calendar](#)

For more information and registration, please go to www.ispe.org/berlinconference.

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Dublin Training Courses
8-11 October 2007, Dublin, Ireland

Now is the time to register for Dublin Training Courses. Get the edge you need to succeed in the following topics:

- ✎ **Biotechnology Basics**
Gain an understanding of fundamental concepts of the biotechnology industry, as well as the science and how it forms the foundation of the industry. Review fundamental engineering principles; basic terminology and how it is applied in the industry; unit operations; regulatory requirements; emerging technologies and validation issues that are shaping the industry.
- ✎ **Practical Approach to Calibration**
Learn how to set up a calibration management system, based on a criticality assessment, in order to ensure effectiveness and regulatory compliance.
- ✎ **Facility Project Management in the Regulated Pharmaceutical Industry**
Get to know the facility project lifecycle; hear about project delivery methodologies; compliance to regulatory, environmental, health and safety legislation; and product speed to market expectations and how they impact a pharmaceutical facility project.
- ✎ **Pharmaceutical Water Systems**
Understand and apply regulatory requirements, purification, distribution and validation for European water systems.
- ✎ **Application of Commissioning and Qualification**
Develop a test plan to implement the integration of C&Q including installation, operation and performance qualifications and protocols.
- ✎ **Application of GAMP[®]4 – Computer Systems Validation**
Apply practical techniques and solutions to solve computer systems validation challenges; get an overview of performing and documenting risk assessments; develop a validation strategy and write a validation plan; and plan and perform a supplier audit.

For more information and registration, please go to www.ispe.org/dublintraining.

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Amsterdam Conference
26-29 November 2007, Amsterdam, The Netherlands

Mark your calendar and don't miss the opportunity to meet face-to-face with industry experts and worldwide regulators at the Amsterdam Conference. Keep abreast of current trends and challenges on topics such as:

- ✎ **Containment Technology Forum**
Discuss and hear case studies on recent developments in containment, including RISK-MAPP.
- ✎ **Efficient Packaging for 2010**
Understand emerging packaging technologies and the latest regulatory requirements.
- ✎ **Lean, Green and Sustainable Manufacturing**
Learn how to be "lean yet green" under current regulatory, commercial and environmental pressures.
- ✎ **API (Bulk) Baseline[®] Guide – New Guide Review and Workshop**

Grasp the philosophy behind the Guide and apply its concepts in a hands-on workshop.

✎ **Heating, Ventilation and Air Conditioning: the Best Current Practice in the Industry**

Find out about the best current practices towards building robust HVAC systems.

✎ **Sterile Regulations, Practices and Case Studies**

Get the latest information on cleanroom regulations, including an update on the EU Annex 1 revision.

For more information and registration, please go to

www.ispe.org/amsterdamconference.

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2007 ISPE Annual Meeting

4-7 November, Caesars Palace, Las Vegas, Nevada, USA

The ISPE 2007 Annual Meeting is this November. Look for the Programme Brochure in the mail and visit www.ISPE.org/annualmeeting for registration and current information on this international gathering of pharmaceutical manufacturing professionals. You can also call ISPE customer service at tel: +1-813-960-2105 for details and to register.

Exhibit and sponsorship opportunities available. Please contact Dave Hall, ISPE Director of Sales, by tel: +1-813-960-2105, Ext. 208, or e-mail: dhall@ISPE.org for details. Thanks to current 2007 ISPE Annual Meeting sponsors: IPS (Platinum Sponsor), Stantec Consulting (Platinum Sponsor), Parsons (Platinum Sponsor), Commissioning Agents, Inc. (Platinum Sponsor), Eaton (Gold Sponsor), PharmaConsult US, Inc. (Gold Sponsor), Pharmadule (Gold Sponsor), Pharmaserv (Gold Sponsor), ProPharma Group (Gold Sponsor), Structure Tone (Silver Sponsor), Johnson Controls (Bronze Sponsor), Austin AECOM (Cyber Café Sponsor), and Turner Construction (Lanyard Sponsor).

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ISPE BODY OF KNOWLEDGE NEEDS YOUR BRAINPOWER

The Society's Body of Knowledge Committee (BOKC) is looking for committee liaisons to join the BOKC to ensure all fields of the industry are represented. The following groups need liaison representation: NAEC, DLC, API COP, GAMP DACH, GAMP EU, GAMP Nordic, GAMP Francophone, and GAMP Italia. If interested, please contact one of the following: Mark Stefko, Vice President of Sales and Marketing, 1-813-739-2287, mstefko@ispe.org; or Carol Winfield,

Knowledge Management Manager, 1-813-960-2105 ,
cwinfield@ISPE.org.

The BOKC serves as the "Proactive Librarian" representing all content creating Committees and COPs. The goal is for each Committee and COP to have a member on the BOKC to ensure overall global collaboration for all published content including technical documents, articles in our publications, and educational curricula.

The overall mission of the BOKC is to deliver a fully-integrated Body of Knowledge that helps industry to understand the science behind each aspect of the manufacturing process, promoting product, process, and technological innovation. The BOKC helps Committees and COP members disseminate and share information, as well as aid in the integration of all ISPE products.

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API GUIDE NOW AVAILABLE FOR PURCHASE

Get your copy of Active Pharmaceutical Ingredients, a revision of *Bulk Pharmaceutical Chemicals*, on-line at www.ispe.org/publications. The revised Guide builds on the original principles from ISPE's first *Baseline® Guide BPC* and expands on current regulations, technology and topics including: ICH Q7; ICH Q9; GAMP® 4; 21 CFR Part 11; Guidance for Industry; Sterile Drug Products Produced by Aseptic Processing – Current Good Manufacturing Practice (cGMP); and FDA Draft Guidance for Industry PAT – A Framework for Innovative Pharmaceutical Manufacturing and Quality Assurance.

New Guide features include: critical unit operation; contamination review; design qualification; intended patient use; direct, indirect, and no impact systems; critical and non-critical components; facility designation; process analytical technologies; process review; risk to patient; and understanding of process.

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CALL FOR PAPERS

The *Journal of Pharmaceutical Innovation (JPI)* is issuing an international call for papers and invites you to submit your high-quality original research for consideration and possible publication within the journal. JPI invites **perspectives, case studies, research letters, research articles, and reviews** of the following topic areas: solid dosage form design; pharmaceutical product development; design space; controlled substance dispensing; nanotechnology; coating uniformity; multivariate calibration; and process analytical technology. The December 2007 issue manuscript **deadline is 15 August 2007**. For submission instructions, contact: Gloria N. Hall, Managing Editor, JPI, ISPE, 3109 W Dr Martin Luther King, Jr Blvd, Suite 250, Tampa, FL 33607, USA; ghall@ispe.org.

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ON-LINE KNOWLEDGE

ISPE is developing **18 on-line seminars** to help individuals who want to supplement their knowledge for Certified Pharmaceutical Industry ProfessionalSM (CPIPSM) certification, or gain diverse pharmaceutical industry knowledge.* Topics include: **Product Development, Facilities and Equipment, Information Systems, Supply Chain Management, Production Systems, Regulatory Compliance** (Includes drugs, environmental, health, and safety), and **Quality Systems**. E-mail training@ispe.org for more information.

* Completion of any of these seminars does not guarantee successful completion of the CPIP certification exam, and these seminars do not include every subject to the depth of what will be covered on the CPIP exam.

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NOW ACCEPTING CPIPSM ELIGIBILITY APPLICATIONS

Following the official launch of the **NEW Certified Pharmaceutical Industry ProfessionalSM (CPIPSM)** credential programme at ISPE's 2006 Annual Meeting in November, the ISPE Professional Certification Commission (PCC) is now receiving eligibility applications.

The computer-based examination dates for 2007 are: **9 July - 4 August** and **5 November - 8 December**. Eligibility applications **should be submitted at least 60 days prior to exam dates**. Those CPIP candidates deemed eligible by the PCC will be authorised to register for and take the exam.

The examination will be available in Thomson Prometric Professional Testing Centers located in major cities around the world. Eligible candidates will be able to make a reservation on-line at a local testing center close to their work or home. To obtain a CPIP eligibility application (free download) or to purchase the CPIP Study Guide, visit www.ispe-pcc.org.

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BOOK OF THE MONTH DISCOUNTED FOR MEMBERS

ISPE Members are entitled to a 20% discount off any Informa Healthcare publication. The featured book for June is ***Pharmaceutical Isothermal Calorimetry***, Simon Gaisford and Michael A. A. O'Neill, The School of Pharmacy, University of London, UK (October 2006/363 pp./ISBN-10: 0849331552/ISBN-13: 9780849331558). Nonmember Price: \$199.95 / ISPE Member Price: \$159.95.

Pharmaceutical Isothermal Calorimetry discusses the application of isothermal calorimetric techniques to challenges encountered during the rational design and development of novel drugs and drug delivery systems. Providing a comprehensive review of recent research and trends, this book contains an expert discussion of research and applications to pharmaceutical characterisation and formulation.

Exercise one of your membership benefits and order a copy today. To place an order, please visit <http://www.crcpress.com> and refer to code ADF83 to receive your Member discount.

Plus, [click here](#) to receive a 20% discount off Informa Healthcare's Premier Titles for

the pharmaceutical manufacturing professional.

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To better serve ISPE Members in Europe, we are always looking for ideas, article topics and possible new features. Let us know if you have a suggestion about what you want to see in your *Informer*. Contact the [ISPE European Office](#).

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