

Meet Your New Board

The following Members were elected to positions on the 2012-2013 ISPE International Board of Directors.

Officers

Chair

Charlotte Enghave Fruergaard is Director of Technology/Process for NNE Pharmaplan Denmark where she has 18 years of experience with projects focused on pharmaceutical production, isolator and barrier technology and sterilization techniques. She has led or participated in projects throughout the Nordic region, the European continent, in the US, and in Brazil. Fruergaard has been an ISPE Member for 17 years; she is a founding member of the Nordic Affiliate and served on the Affiliate Board of Directors in a variety of roles including Chair. She has been an ISPE conference leader and has participated on the Sterile Products Processing Community of Practice Steering Committee. She was elected to the ISPE International Board of Directors in 2007. Fruergaard holds an MSc and a PhD in Mechanical Engineering from

Danmarks Tekniske Universitet, as well as an EBA in Engineering Business Administration from Copenhagen University College of Engineering.

Vice Chair


Damian J. Greene is Global Network Strategy Lead for Pfizer Animal Health where he is responsible for the company's manufacturing and supply network strategy, product sourcing, and long-range capacity planning. Throughout his 29 year career at Pfizer he has held leadership roles in Pfizer's Global Supply, Manufacturing, Food Sciences and Chemical Divisions where he has been responsible for API operations, product launch, and network evaluation/restructuring. Damian Greene has been a Member of ISPE for nearly 8 years where he has been involved in the API Community of Practice and has chaired the Community of Practice Council. He was elected to the ISPE International Board of Directors in 2007. Damian Greene holds a BE in Chemical Engineering from University College Dublin, an MSc in Chemical Engineering from the University of Missouri-Rolla, and a Certified Diploma in Accounting and Finance from the Chartered Association of Certified Accountants.

2013 Critical Utilities Conference

ISPE will hold a two-day education intensive conference (25-26 February 2013, Tampa, Florida, USA) that will offer relevant case studies to illustrate alternatives for cost-effective, risk-based approaches to design, construction, and maintenance for critical utilities. Attendees will gain a better understanding of US FDA and international regulatory requirements during panel discussions and understand how to optimize lifecycle costs through interactive workshops. Plenty of networking opportunities will be available.

Featured tracks include:

- Alternatives for Pharmaceutical Water and Ozone
- Alternatives for HVAC and Process Gases

In addition, delegates will receive one complimentary guide from the following choices: Pharmaceutical Water Systems, Ozone Sanitization of Pharmaceutical Water, HVAC or Process Gases. 

Treasurer

Brian H. Lange, PE is Operations Director/PMO, North American Operations and Merck Consumer Care for Merck & Co, Inc. He has been with Merck for more than 24 years and held leadership roles in Manufacturing, Engineering and Quality. Prior to his current role, he spent 12 years in various leadership roles within Vaccine and Sterile Operations, as well as Director of Quality Engineering supporting the Global Vaccine Operations network. Lange has been a Member of ISPE for 21 years and is a past Chairman of the ISPE International Board of Directors. He served on numerous International Committees over the years, chairing the Education and Technical Documents Committees, as well as the Chapter Council. He is currently a judge for the FOYA program. In 2012 he was the co-leader of the Future Visioning Team and he was also a conference leader for the cGMP Conference held in June. Lange holds a BS in Mechanical Engineering from Villanova University and he is a registered Professional Engineer in the Commonwealth of Pennsylvania, USA.

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Pharmaceutical Engineering Announces Winner of the Article of the Year Award

Pharmaceutical Engineering is pleased to announce that the winner of the 2012 Roger F. Sherwood Article of the Year is:

January/February 2012
Volume 32, Number 1

Risk Analysis and Mitigation Matrix (RAMM) – A Risk Tool for Quality Management

by Alex Brindle, Steve Davy, David Tiffany, and Chris Watts

This article presented a new type of risk tool. Risk Analysis and Mitigation Matrix (RAMM) was developed to be incorporated into a modern risk management system and align with latest FDA guidances.

The winner was recognized at ISPE's 2012 Annual Meeting, 11-14 November in San Francisco, California, USA, and selected from the following group of finalists:

September/October 2011
Volume 31, Number 5

Cleaning Validation for the 21st Century: Acceptance Limits for Active Pharmaceutical Ingredients (API's): Part II

by Andrew Walsh

This article discussed how to establish true science-based limits using data from clinical and toxicological studies, a risk-based approach to evaluating cleaning validation data, and guidance on setting statistical process control limits from that data.

November/December 2011
Volume 31, Number 6

Online Rouge Monitoring: A Science-Based Technology to Measure Rouge Rates

by Nissan Cohen and Allan Perkins

This article presented the implementation and installation of an online rouge monitor which measures in near real-time the rouge rate and rouge accumulation (metal loss) over time helping to determine derouging and passivation frequency based on empirical data.

March/April 2012
Volume 32, Number 2

Application of Pre-Owned Equipment in Pharmaceutical Manufacturing Operations

by Stephan Sirabian, Bob Matje, Jeff Biskup, and Witold Lehmann

This article presented considerations to be made prior to making a capital investment in pre-owned equipment for new or refurbished pharmaceutical facilities.

May/June 2012
Volume 32, Number 3

Pressure Pulse Approach for Optimized Tank Cooling after Steaming

by Magnus Stering, Olivier Chancel, and Luc Pisarik

This article presented an approach for faster cooling after steaming or after hot cleaning in place without the risk of generating vacuum inside the vessel and without the need for any large sized vent filter.

July/August 2012
Volume 32, Number 4


The Use of Acceptable Daily Exposure (ADE's) for Managing the Risk of Cross Contamination in Pharmaceutical Manufacturing

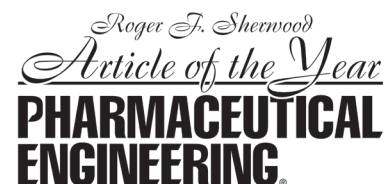
by Stephanie Wilkins and Julian Wilkins

This article presented a convincing justification for the use of Acceptable Daily Exposures (ADEs) to scientifically manage the risk of cross contamination in all types of bio/pharmaceutical facilities.

The Roger F. Sherwood Article of the Year Award recognizes the contribution of authors. Articles are evaluated by a panel of volunteer reviewers according to a number of criteria, concentrating on the importance and timeliness of the subject matter and the quality of the presentation. The criteria for judging includes:

- Is it directly useful to the readers in their efforts to improve the industry and themselves?
- Does it improve knowledge/understanding of key topics?
- Is it clear, easy to read? (Low jargon usage)

The finalists for the Article of the Year are chosen from the September/October issue of the previous year, through the July/August issue of the current year. The award program was established to express appreciation to all of the authors who submit their work for publication in *Pharmaceutical Engineering*. 



Meet Your New Board

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Secretary

Andrew D. Skibo is Executive Vice President, Operations for MedImmune where he affects changes in manufacturing operations, quality oversight, and cross-functional relations throughout the company. Previously he has worked in other senior leadership roles at Amgen, Genentech, and Foster Wheeler, among others. In these roles he has been responsible for significant aspects of the companies' operations including engineering, construction, and validation for large-scale capital projects related to bio-pharmaceutical manufacturing. He is a member of the International Leadership Forum (ILF), and a member of the Materials Technical Advisory Committee of the US Department of Commerce, specializing in non-proliferation issues associated with biological and chemical weapons. As an ISPE Member for more than 23 years, Skibo has served on the judging panel for the FOYA program, he has been a conference leader, and he participates on several committees. He was elected to the ISPE International Board of Directors in 2011. Skibo holds a BS in Organic Chemistry and an MS in Chemical Engineering, both from MIT.

Past Chairman

Arthur "Randy" Perez currently holds the position of Director, IT Risk Management and Compliance for Novartis Pharmaceuticals. His responsibilities at Novartis include a wide range of IT Compliance issues, such as GxP, Sarbanes-Oxley, and data privacy. During his 29-year tenure at Novartis, he has worked as a chemistry group leader in process research, managed a chemical manufacturing process validation initiative, and ran both a GMP training program and a QA validation group for pharmaceutical operations. Perez has been an ISPE Member for 10 years. He was instrumental in the formation of GAMP Americas and from 2002-2008 he was Chairman of that group. He has been a member of the global GAMP® Council since 2002. He initiated and led the Global Information Systems SIG, who wrote a GAMP® Good Practice Guide that was published in 2005, and was part of the core team that led the development of GAMP® 5, published in 2008. He was elected to the ISPE International Board of Directors in 2005, and he served as Chairman in 2012. Perez earned a BS in Chemistry at MIT and a PhD in Organic Chemistry at University of Michigan.

Re-elected Directors

Joseph C. Famulare, Senior Director, Global Quality Compliance and External Collaboration, Genentech, USA

Gordon Leichter, PhD, Eastern Regional Sales Manager, Belimed, USA

New Directors

Michael A. Arnold, Senior Director, Strategic Partnerships, Pfizer Inc., USA

Jennifer Lauria Clark, CPIP, Technical Services Project Manager, Commissioning Agents, Inc., USA

James A. Durkin, Project Manager, United Kingdom National Health Service, United Kingdom


Directors elected in 2011 to serve a two-year term:

James A. Breen, Jr., PE, LEED AP, Vice President, Worldwide Engineering and Technical Operations, Johnson & Johnson's Supply chain, USA

Timothy P. Howard, CPIP, PE, Vice President and Company Officer at Commissioning Agents, Inc., USA

Doyle R. Johnson, New England Operations Leader, Hargrove Life Sciences LLC, USA

Morten Stenkilde, Director of QA, Novo Nordisk, Denmark

Udo J. Vetter, Chairman of the Control Board, Vetter Group, Germany 

Complete biographical information on all of ISPE's Directors can be found at www.ispe.org/meet-your-new-board.

Revised ISPE Guide Focuses on Risk-Based Approach to Testing of GxP Systems

The first edition of the ISPE GAMP Good Practice Guide (GPG) – Testing was released in 2005. During the years since the document was written, there has been recent regulatory and industry developments focusing attention on patient safety, product quality, and data integrity. In an effort to address these developments, ISPE is expected to publish in December the ISPE GAMP GPG: A Risk-Based Approach to Testing of GxP Systems, a revision of the first edition on this topic.

The revised Guide also has been updated to align with the concepts and terminology of GAMP® 5 and associated GAMP guidance. GAMP 5 and associated GPGs aim to provide guidance to achieve computerized systems that are fit for intended use and meet current GxP regulatory requirements, by building upon existing industry good practice in an efficient and effective manner. The revised Guide builds on the framework described in GAMP 5 and provides detailed guidance on testing GxP systems.

The approach and terminology used in this Guide are generally harmonized with the following industry guidance:

- International Conference on Harmonization (ICH) Guidance including Q8, Q9, and Q10
- ASTM Standard E2500-07, Standard Guide for Specification, Design, and Verification of Pharmaceutical and Biopharmaceutical Manufacturing Systems and Equipment
- EU GMP EudraLex Volume 4 Annex 11 and Chapter 4 revisions

This edition of the Guide has also been aligned with advances in industry best practice, including:

- Increased adoption and implementation of Process Analytical Technology (PAT) and Quality by Design (QbD)
- Increased industry focus on risk-based approaches
- Increased use of non-linear development life cycles
- Increased use of automated test tools

This Guide has been written to provide regulated organizations and suppliers with pragmatic guidance on the testing of computerized and software based systems that impact patient safety, product quality, and data integrity. The key objective of this Guide is to encourage regulated organizations and suppliers to work together to ensure sufficient test coverage to guarantee fitness for intended use, while minimizing any duplication of effort.


The Guide seeks to identify the testing that should be performed and the associated level of documentation. Where suppliers' systems do not

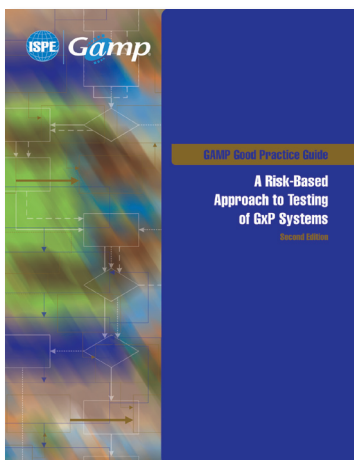
meet the expectations of a regulated organization, the Guide identifies suitable risk control strategies. These strategies can include the execution of additional testing, or the selection and use of alternative suppliers or products, by the regulated organization. This Guide intends to provide pragmatic answers to questions such as:

- Why should I test?
- What should I test?
- How much testing is enough?
- How should I conduct tests?
- How should I document my testing?

Specifically, this Guide is intended to take a risk-based approach to compliance of GxP computerized systems and provide practical advice on the application of this approach in the planning and execution of testing.

The Guide is intended to assist:

- Regulated organizations (the pharmaceutical customer or regulated user organization contracting a supplier to provide a product)
- Suppliers (usually external third parties, but also including “in-house” providers of IT services) including:
 - suppliers of standard products
 - systems integrators responsible for configuration and coding of standard product to create a specific application
 - suppliers of control systems that are packaged with the process equipment
 - service providers
- regulatory agencies 



Anticipated release is December 2012. This Guide is available for pre-order at www.ISPE.org/Guidance-Documents.

World Class Directory Benefits Buyers, Suppliers, and Industry


Launched earlier this year, the international ISPE Buyers Guide is a free resource for both pharmaceutical professionals seeking technical products and services and for suppliers who want international exposure.

Currently, there are more than 500 listings of suppliers from 35 countries worldwide, allowing for an increased opportunity for a buyer to find the equipment or service they need on an international level. Listings include suppliers in emerging markets such as India, China, and Brazil, giving ISPE Buyers Guide users direct contacts in local markets where they are likely to be building facilities.

It is also an economical way for suppliers to reach potential customers on a global scale, according to John Phillips, ISPE Director of International Sales. "The supplier community represents 40% of ISPE's Membership. Marketers these days, more than ever, are looking for more economical ways to reach potential customers on a global scale. Our international Buyers Guide helps achieve this by offering detailed standard listings free of charge, as well as a variety of upgrades for enhanced exposure."

While the Buyers Guide reaches more than 20,000 ISPE Members from 90 countries worldwide, an individual does not have to be a Member of ISPE to have access to the directory and search for suppliers, nor does a supplier need to be a Member of ISPE to submit a listing.

“Ultimately, the directory contributes to industry by making it easier for suppliers and potential customers to connect to build innovative, cutting-edge facilities that improve regulatory compliance, product quality, and patient safety,” said Phillips.

The international ISPE Buyers Guide can be found online at www.ISPE.org. A printed copy of the Buyers Guide will be included in the next issue (January/February 2013) of *Pharmaceutical Engineering*. 

ISPE Releases New Knowledge Briefs

Knowledge Briefs are concise summary documents that provide easy-to-read overviews of issues, processes, and technologies impacting the contemporary pharmaceutical industry. Knowledge Briefs are intended to help industry professionals of all levels and disciplines get up-to-speed quickly on a particular topic and are categorized as Fundamental, Intermediate, or Advanced. Each brief includes links to additional ISPE resources, such as technical documents, Pharmaceutical Engineering articles, webinars, Communities of Practice, and educational seminars and training courses to provide more specific and detailed information on the subject. Knowledge Briefs are available for immediate download. They are free to ISPE Members, \$5 US / €3 to non-Members. The following are the latest additions to the ISPE Knowledge Briefs library:

Packaging Equipment: Blow/Fill/Seal (B/F/S) Technology

by Andrew W. Goll


Level: *Fundamental*

This Knowledge Brief provides a basic introduction to B/F/S technology and discusses how it may be suited for pharmaceutical liquid filling applications. It also provides a basic guidance for what is required to install a system and what complementing utilities, cleanrooms, environmental conditions, and inspection equipment may be considered.

Environmental and Financial Benefits of Single-Use Technology

by Wayne Flaherty and Pietro Perrone, PE

Level: *Intermediate*

This Knowledge Brief highlights the options available when considering single-use products and what financial advantages can result. Overall use of the products is covered, with a focus on the handling of the products after use. 

ISPE Publishes Concept Paper on Controlled Temperature Chamber Mapping

ISPE published a Concept Paper that describes good practices for the mapping of controlled temperature chambers, warehouses, and refrigerated storage areas used in the pharmaceutical and biopharmaceutical industries. The Concept Paper and relevant information can be found on the Packaging COP Resources page. 