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PDA Connector

Scientific and Regulatory Affairs

- On Jan. 1, 2016, the Pharmacy and Poisons Board of Hong Kong and the Agency for Medicinal Products and Medical Devices of Croatia [became the 47th and 48th PIC/S Participating Authorities](#).
- The U.S. FDA recently issued a draft guidance that clarifies the mission and scope of the Emerging Technology Team (ETT), which was established to work directly with industry to help identify and resolve scientific issues for new technologies, and provides recommendations to companies on effective ways to work with the ETT. [Read more](#).
- The ICH has welcomed the Therapeutic Goods Administration (TGA) of Australia as [its newest Observer](#). ICH Observer status enables TGA to have representatives attend ICH assembly meetings and participate in ICH activities.

European Events

March 2016

- Mar. 1: [Join](#) other visual inspection professionals at the [Interest Group Meeting Visual Inspection](#) for discussions about difficult-to-inspect containers and particle load on stoppers and elastomers.
- Mar. 2-3: [Register](#) for the popular hands-on training course, [An Introduction to Visual Inspection](#) before it's sold out! The skills developed through this course may be applied to both manual human inspection and automated machine inspection.

April 2016

- Apr. 11: Are you involved in developing or manufacturing pre-filled syringes? Then the [Interest Group Meeting on Pre-filled Syringes](#) has something for you! Take advantage of an open forum format to discuss and share your professional experience with colleagues and get first-hand information on current activities of the Pre-filled Syringes Interest Group. [Register today](#).

U.S. Conferences & Session Recordings

March 2016

- Mar. 14-16: Celebrating its 65th anniversary this year, the PDA Annual Meeting continues to be the ideal forum for knowledge sharing and networking, navigating development and manufacturing sciences, and

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Publications

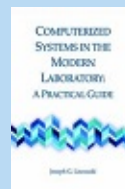


Visual Inspection and Particulate Control

Pre-order your copy **by Feb. 19** and **save 15%**. Enter campaign code **VIPC** to apply discount during checkout.



Global Sterile Manufacturing Regulatory Guidance Comparison – with Link to Comparison Spreadsheet



Digital Copy

Computerized Systems in the Modern Laboratory: A Practical Guide

Hard Copy
Digital Copy

Career Resources

[Mid-Level Manufacturing Scientist Indianapolis, IN](#)
Eli Lilly & Company

[Director Sterile Quality Assurance West Point, PA](#)

exploring compliance and regulatory considerations. At the [2016 PDA Annual Meeting](#), plenary sessions and a series of parallel tracks will feature more than 30 presentations and case studies that will address the evolving manufacturing environment. Concurrent session tracks will specifically address upstream and downstream process technology innovations, monitoring and optimization. Breakfast sessions will focus on such topics as facilities of the future, QRM in engineering design, data integrity and defining the project specification, and more. [Register today](#)

- Mar. 16-17: Learn how to prepare your company for its next regulatory inspection, how to incorporate process variability tools into your operation and how to make the business case for pursuing process improvements at the [Preparing for the Next Generation of Regulatory Inspections: A 2016 Manufacturing Science Workshop!](#) Join industry and regulatory experts as they discuss new regulatory inspection models, process variability, data integrity issues, and the barriers to improving processes and methods. [Register today!](#)

There's still time to register and save for the Conference and Workshop!

April 2016

- Apr. 19-20: The [San Diego – 2016 PDA Workshop: Current Challenges in Aseptic Processing, Potential Changes in EMA/PIC/S Annex 1 Revision](#) will help you can better understand aseptic processes, the associated risk of contamination, and how to develop optimal process control strategies. Industry and regulatory experts from around the world will also explore the critical topics within the scope of the new revision of the EU GMP Annex 1. [Register before Mar. 6](#) and save up to \$200.

Session Recordings



On-Demand Recordings: [2015 PDA/FDA Joint Regulatory Conference](#)

Session Recordings



On-Demand Recordings: [2015 PDA Pharmaceutical Quality Metrics](#)

Conference Session Recordings

Education Courses

April 2016

- Apr. 12-14: At the [Validation of Moist Heat Sterilization Processes](#) course, you'll learn the science of sterilization (microbiology and thermal science) using a validated steam autoclave and thermal validation equipment. Bring your challenges to this lecture and hands-on training course and brainstorm possible solutions with the class and instructor while running actual loads! [Register now.](#)

June 2016

- June 15-16: Discover new ways to formulate in-house environmental control concepts to reduce bioburden in operations and analyze current regulations as they relate to contamination control with PDA's [Fundamentals of Cleaning and Disinfectant Programs for Aseptic Manufacturing Facilities](#) course. Learn to identify and describe systematic elements essential to assuring an appropriate and compliant contamination control program when you attend this course - [register today!](#)
- June 22: The [2016 Biosimilars Course Series](#) will help you better understand the challenges that must be considered before entering the field of biosimilar manufacturing. [Register now.](#)

Membership and Chapters

- **New online content just added to the PDA Letter:** Read **Markus Lankers's** article on [USP Chapter <790>](#) and how it will impact the visual

Merck & Company, Inc.

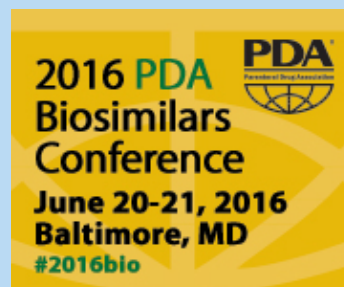


Exhibit at the 2016 Annual Meeting!

Time is running out to reserve your booth at the [2016 PDA Annual Meeting!](#) Increase your company's visibility, strengthen its brand image *and* connect with hundreds of decision makers in the bio/pharmaceutical manufacturing industry by contacting **David Hall** today!

inspection field.

February 2016

- Feb. 23: At the **PDA Delaware Valley Chapter's Breakfast Symposium on Aseptic Processing**, you'll have access to five panelists with more than 170 years of combined aseptic processing knowledge and experience! [Don't miss this opportunity](#) to ask for advice, guidance or opinions on any and all topics related to aseptic processing.
- Feb. 24: The **PDA Ireland Chapter** invites you to attend the [Medicinal Products Quality Defects and Recalls Research Report Launch](#) event, which will launch the report resulting from an innovative study conducted by DIT's Pharmaceutical Regulatory Science Team and the Health Products Regulatory Authority on medicinal product quality defects and recalls in Ireland from 2010-2014. [Register to hear a presentation on research results.](#)

March 2016

- Mar. 9: [Register today](#) for the **PDA New England Chapter Contract Manufacturing and Risk Analysis of Nonconformities** event. Hear presentations on contract manufacturing for biotech products and special requirements for gene and cell therapy. Risk analysis of non-conformances in research model production will also be discussed.

[Forward to a Colleague](#)