From: PDA

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Membership and Chapters

Members Only: On Mar. 22, members of the Technology Transfer
 Interest Group (TTIG) will hold a webinar to plan the group's activities for
 2016. Any PDA members who are interested in participating in the
 webinar, but who are not currently members of the TTIG, should contact
 volunteer@pda.org.

April 2016

- Apr. 11: When you attend the PDA Missouri Valley Chapter Spring 2016 Event, you'll hear from two U.S. FDA speakers and an industry speaker regarding how you should prepare, manage and respond to an FDA inspection. Don't wait until it is too late, register now!
- Apr. 12: Register for a seminar on data integrity hosted by PDA's Metro Chapter.
- Apr. 19: PDA's Delaware Valley Chapter Regulatory Affairs Event will
 cover current U.S. FDA inspection trends, behaviors and data integrity
 concerns that the industry is currently encountering. Register today.

Scientific and Regulatory Affairs

- The U.S. FDA's Office of Regulatory Affairs (ORA) has created a new resource, an ORA ombudsman, who can help find solutions to problems that arise with external partners, including industry, other governmental agencies and consumers, and improve communications between ORA and stakeholders through outreach and education.
- The U.S. FDA's Center for Devices and Radiological Health has released its list of proposed guidance documents for 2016.
- The European Medicines Agency has established a task force of experts with specialized knowledge in vaccines, infectious diseases and other relevant expertise to help with the global response to the Zika virus. Read more.

European Events

April 2016

 Apr. 14-15: At the *Drug Delivery Combination Products* Workshop, you will learn how to identify appropriate testing schemes and requirements specific to your products. Register now.

June 2016

Follow us:





PDA Membership

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Publications

ASSURING DIVIAINTEGRITY FOR LIFE SOENCES Assuring Data Integrity for Life Sciences

GOOOO

Save 15% through **Apr. 30** when you pre-order now! Enter campaign code **DILS** to apply discount during checkout.



Trend and Out-of-Trend Analysis for Pharmaceutical Quality and Manufacturing Using Minitab®

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Career Resources

GMP Facility Manager

- June 6: The Viral Safety of ATMPs Conference will offer plenty of opportunities for learning and discussion between representatives of industry, academia and international regulatory authorities. Don't wait, register today.
- June 7-8: Sign up for the Advanced Therapy Medicinal Products (ATMPs)
 Conference! This event will focus on regulatory and technical aspects of
 the development and manufacturing of ATMPs and what has to be
 considered when choosing raw material components.

U.S. Conferences and Session Recordings

Call for Abstracts

 Share your expertise and take your place among the industry's most influential presenters by submitting an abstract for a one-day poster presentation at the 2016 PDA Universe of Pre-filled Syringes and Injection Devices by Apr. 1. Topic areas of interest include but are not limited to advances in primary containers, technology, application systems/devices, and development and manufacturing.

April 2016

 Apr. 19-20: Join us at the 2016 PDA Workshop: Current Challenges in Aseptic Processing, Potential Changes in EMA/PIC/S Annex 1 Revision – San Diego to learn more about aseptic processing. This Workshop will address the most difficult issues companies are currently facing, based on recent inspections and process performance history.

Can't make this event? PDA will hold three additional Workshops in three global locations throughout 2016!

Find out more.

September 2016

Sept. 14-15: The 2016 PDA Data Integrity Workshop in Washington, DC will explore important aspects of data integrity, such as quality culture, human behavior, training needs and technology requirements. Register today.

Can't make this event? PDA will hold three additional Data Integrity Workshops in three global locations throughout 2016!

Session Recordings

On-Demand Recordings: 2015 PDA/FDA Joint Regulatory Conference Session Recordings

On-Demand Recordings: 2014 PDA Drug Shortage Workshop Session Recordings

Education Courses

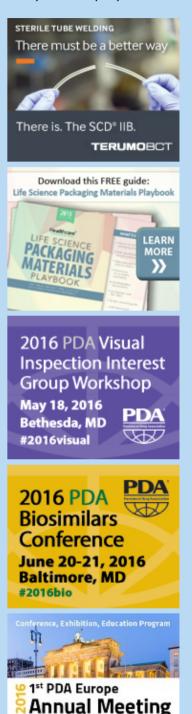
April 2016

Apr. 12-14: PDA Education's Validation of Moist Heat Sterilization Process
course will provide a foundational understanding of sterilization science,
which can be applied to selection of cycle design approach, sterilization
process development and performance qualification. Register today.

August 2016

 Aug. 8-12: Register today for PDA's Quality Systems for Aseptic Processing course and receive the tools needed to optimize your quality systems Burnaby, Canada Northern Lipids

Research Scientist-Pharmaceutical Sciences Cambridge, MA *Eli Lilly and Company*



Advertise/Exhibit

28 June – 1 July 2016 Berlin | Germany

Advertise on the PDA website, which attracts more than 32,000 unique visitors each month. Contact **David Hall** for more information.

- associated with aseptic processing.
- Aug. 22-26 & Sept. 19-23: PDA's Aseptic Processing Training Program
 blends lectures with hands-on activities to equip you with the information
 and experience necessary to properly evaluate and improve your aseptic
 processes and ensure sterile products. The first three sessions have sold
 out, and this fourth session is quickly filling up, so secure your spot at this
 very popular course today!

Forward to a Colleague