January 2018 PDA Letter

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Collaboration Through Mutual Reliance Brings FDA and EMA to the Table

Rebecca Stauffer, PDA

In the past ten years, the number of U.S. FDA-regulated shipments at 300 U.S. ports have doubled. These products originate from more than 150 countries, 130,000 importers and 300,000 foreign facilities. These numbers illustrate the level to which foreign production of FDA-regulated goods and materials has exploded over the last decade.

Cover Art Illustrated by Kagenmi

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Regulators Tackle Tough Micro Questions on Panel

The *12th Annual PDA Global Conference on Pharmaceutical Microbiology* concluded with an "Ask the Regulators" panel. Find out what some of the interesting questions that arose during this panel in a transcript of a portion of the session.

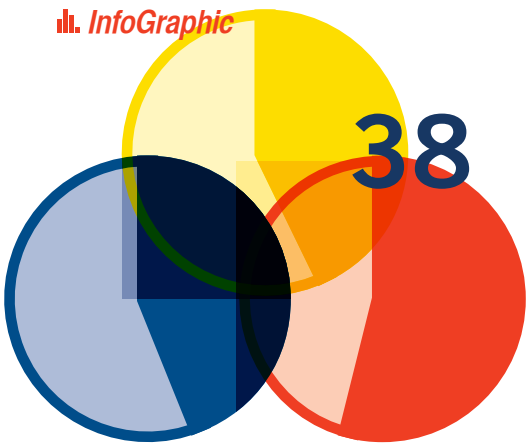
AIDC is a Sign of Things to Come: Part II

Napoleon Monroe, New Directions Consulting

34

In order to save overall payer costs, ensure access to products when needed and improve compliance with protocols, combination products are often designed to be administered by patients or nonprofessional caregivers.

InfoGraphic



38

Mad for RABS

PDA recently conducted a survey of both members and nonmembers regarding current aseptic processing trends within the industry. Over 300 responded, providing insights into the current state of aseptic processing. Some of these insights pertain to the state of restricted access barrier systems (RABS).

PDA Letter

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Departments

Digital Exclusives

> **On the Issue** | Contamination Recovery Rates in Low-bioburden Facilities
Bristol-Myers Squibb's **Paula Peacos** discusses how to use contamination recovery rates for environmental monitoring trending in the latest On the Issue video.

> Cracking the Challenges of Glass Packaging
In the early 2010s there was a spike in drug recalls related to glass packaging. What has changed since then?

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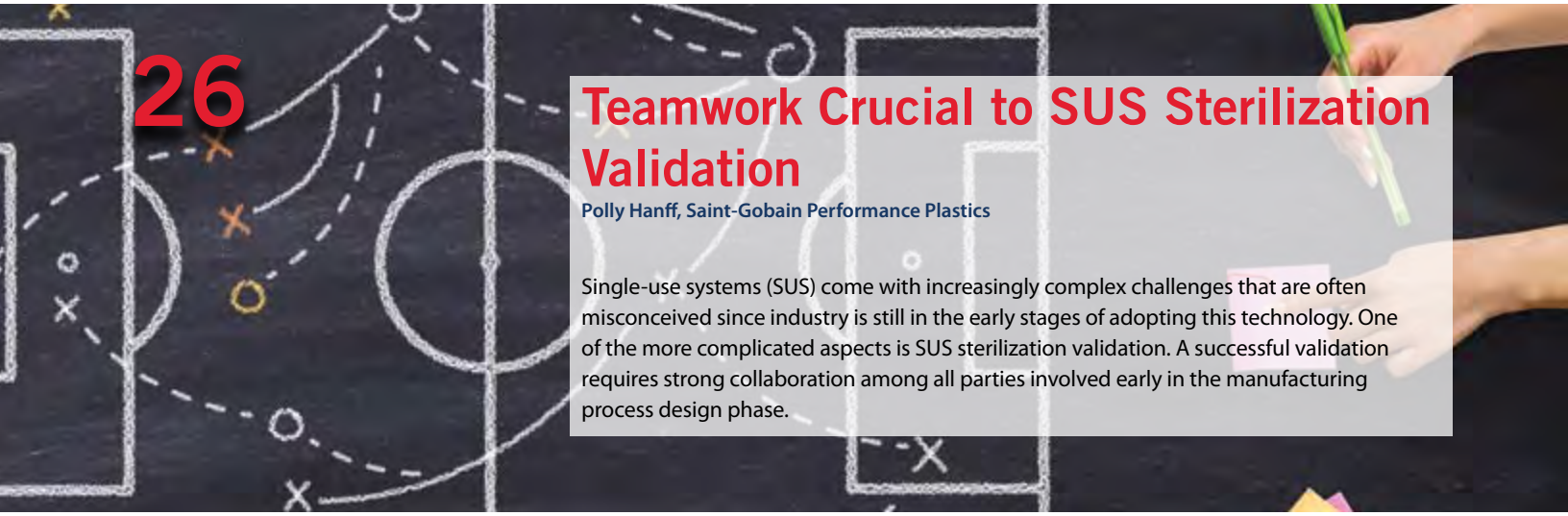
February 2018 PDA Letter

2018 PDA Annual Meeting

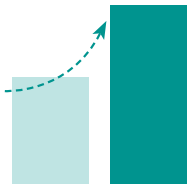
Show Issue

This year's Annual Meeting takes place in Orlando, Fla. and will feature a new format and schedule. Thoughout this issue are a number of articles highlighting talks and other events at this signature PDA meeting.



Cover Art Illustrated by Creative-Touch

InfoGraphic



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Departments

News & Notes

People

Science

Regulatory

Voices of PDA

Digital Exclusives

> Quality: One Question, Many Answers
How can industry and the U.S. FDA adapt current quality standards to innovative therapies? Find out from DPS Engineering's **Stephanie Gaulding** who attended the *2017 PDA/FDA Joint Regulatory Conference.*

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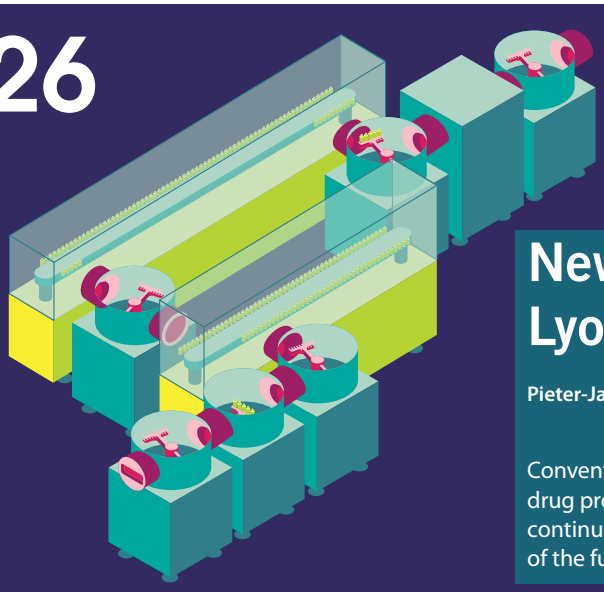
March 2018 PDA Letter

26



New Approach Suggests Continuous Lyophilization is Possible

Pieter-Jan Van Bockstal, Ghent University, Jos Corver, RheaVita, Thomas De Beer, Ghent University

Conventional batch freeze-drying has long been the mainstay for stabilizing biologic drug products in storage and distribution, but it presents many challenges. An innovative continuous process for freeze-drying has been developed, however, that may offer a view of the future of freeze-drying for biologics.

Cover Art Illustrated by Katja Yount

InfoGraphic

32

A Model for Downstream Continuous Biomanufacturing

Many biologics manufacturers wonder if continuous manufacturing is achievable for downstream processing. A model approach indicates it is.

35

Smoke Signals

One Plant's Secret for Assuring Aseptic Control

Tony Pavell, Fresenius Kabi

Airflow visualization testing, conducted as part of a routine review program, can help assure that aseptic filling areas remain under a state of proper control.

PDA Letter

Volume LIV • Issue 3 www.pda.org/pdaletter

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Departments

Digital Exclusive

> Adapt Your Nest-and-Tub System as the Industry Evolves
How can ready-to-use components such as nests and tubs support flexible manufacturing?

> New Tech Disrupts Traditional Aseptic Processing
Two speakers from the 2018 PDA Annual Meeting discuss recent advancements in isolator technology.

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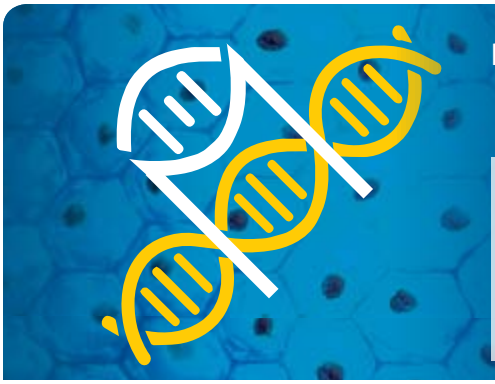
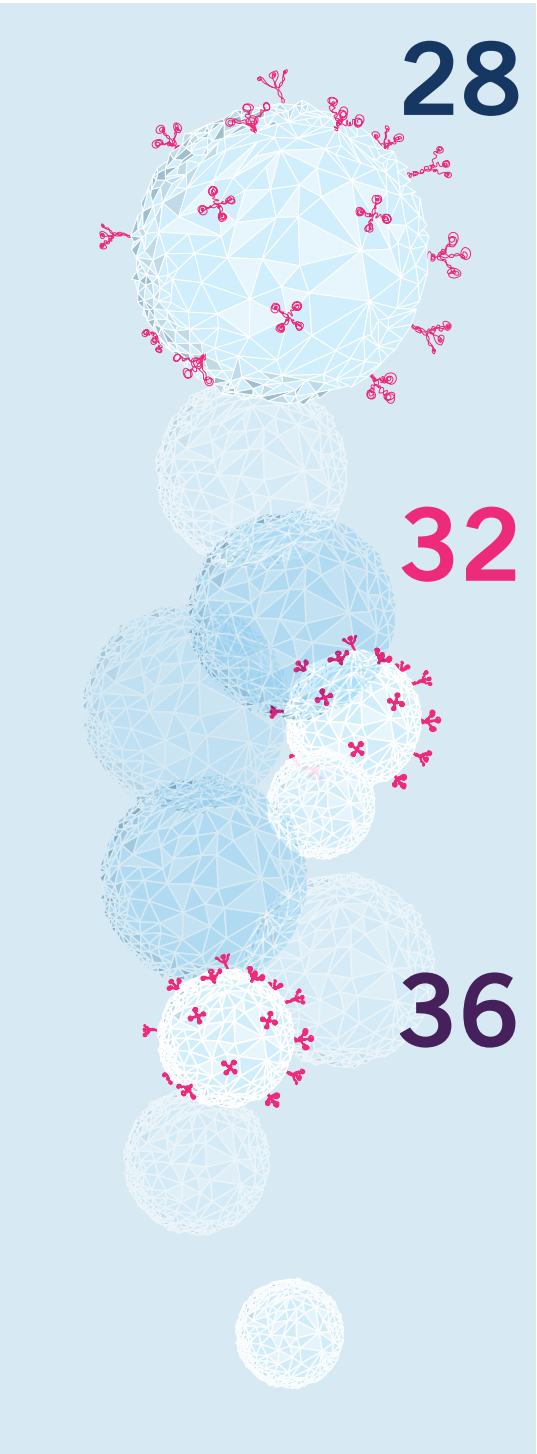
April 2018 PDA Letter



PDA Europe Conference on Advanced Therapy Medicinal Products

Show Issue

This year's *Advanced Therapy Medicinal Products* conference takes place in the city of Amsterdam, June 5–6. Articles with this banner at the top of the page include information relevant to this meeting and these innovative new therapies.



Cover Art Illustrated by Kaija Yount

Speaking the Language of GMP

An interview with Dr. Lutz Uharek

Rebecca Stauffer, PDA

How can clinicians involved with cell therapies learn the language of GMP? This year's Chair of the *Advanced Therapy Medicinal Products* conference, **Lutz Uharek,** speaks to the *PDA Letter* about his experience moving from the clinic to a GMP environment.

Cell and Gene Therapies Present Challenges, Promise

Joshua Eaton, PDA

Did you miss last year's PDA *Cell and Gene Therapy Conference*? This summary offers a look at the main topics of discussion at the conference,including, talks from regulators.

InfoGraphic

Cell and Gene Therapies By the Numbers

A look at the current and future state of cell and gene therapies.

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Digital Exclusives

> **On the Issue | USP <660> Containers-Glass**
Corning's Timothy Hunt discusses planned revisions the USP chapter <660> Containers-Glass.

> **Novel Manufacturing Tech Drives Novel Product Development**
Read a summary of some of the manufacturing sessions at last year's *Universe of Pre-filled Syringes and Injection Devices.*

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May 2018 PDA Letter

3rd PDA Europe Annual Meeting

Show Issue

Annex 1. Big data. Industry 4.0. ICH Q12. Data integrity. These are the current topics of interest across our industry. And these topics will be addressed in sessions at the *3rd PDA Europe Annual Meeting* in Berlin, June 26–27. For articles in support of this meeting, look for this banner at the top of the page.

Cover Art Illustrated by PhonlamaiPhoto

InfoGraphic

3-D Printing Leading Medical Advancements

3-D printing offers clear advantages for biopharmaceutical manufacturing. Yet it also has implications for other parts of healthcare.

PDA Letter

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Digital Exclusives

> **On the Issue** | Strategies for Reducing Human Error Nonconformances
PDA Education instructor **Elaine Lehecka Pratt** discusses the role of quality culture in preventing human error.

> New Drugs Need Agile Biomanufacturing
NNE's **Jeffery Odum** discusses the need to adjust manufacturing practices for new therapies.

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June 2018 PDA Letter

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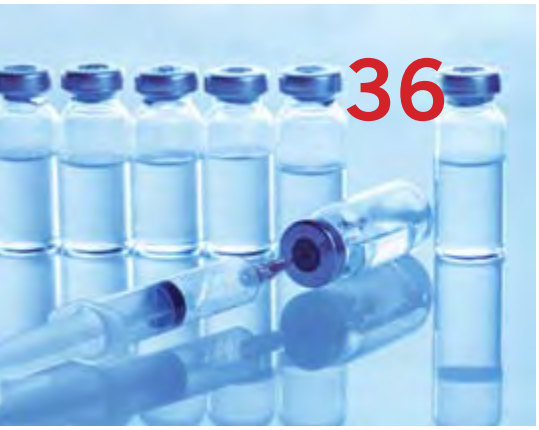
Can ICH Q12 Unlock Manufacturing Innovation?

Ursula Busse, PhD, Novartis, and Melissa Seymour, Biogen

Human medicine has come a long way in the last 100 years. Paradigm-changing therapies have made their way into the clinic since the end of the last century, nurtured by better understanding of the underlying causes of various diseases.

Cover Art Illustrated by Katja Yount

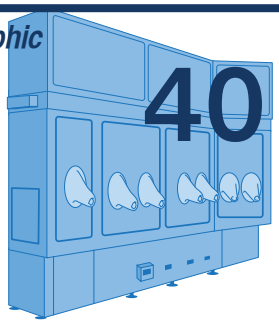


Prospects for Post-Approval Change Management

Naheed Sayeed-Desta, Apotex, Ajay Babu Pazhayattil, and Ivy Louis, Vienni Training and Consulting LLP

As new types of biologic products enter the market, the need for innovative processes continues to grow. This requires improvements in post-approval change management. *ICH Q12: Technical and Regulatory Considerations for Pharmaceutical Product Lifecycle Management* offers a solution to post-approval change challenges in the form of a post-approval change management protocol (PACMP).

InfoGraphic



A Post-Approval Change for an Aseptic Filling Isolator

When a manufacturer implements a new isolator as part of a post-approval change, a Process Design and Characterization Study is required.

A Wealth of New Tech Possibilities

Annual Meeting Showcases the Latest in New Drugs, Manufacturing Technology

Scott Bozzone, PhD, Pharm Lifecycle Validation LLC

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Healthy patients are always the end goal for PDA members. This means it is now more important than ever for industry to modernize existing processes. This year's Annual Meeting in Orlando, Fla., provided no shortage of sessions highlighting the importance of producing quality parenteral medicines for patients while also maintaining top-notch manufacturing systems.

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> **On the Issue | 3 Questions on a New RABS/Isolator Combination**
Annual Meeting speaker **Ute Schleyer** from Vetter discusses the company's new isolator/RABS technology

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July/August 2018 PDA Letter

2018 PDA/FDA Joint Regulatory Conference

Show Issue

The *2018 PDA/FDA Joint Regulatory Conference* will feature numerous sessions and panels that bring together regulators and industry representatives. Much of the discussion will focus on the state of the supply chain in recognition of the ten-year anniversary of the heparin incident. Look for this banner at the top of the page for articles previewing this meeting.

Blockchain

Will it Transform the Pharmaceutical Supply Chain?

Mark Crawford

The pharmaceutical supply chain is becoming an increasingly complex system, making it harder for drug manufacturers and their partners to ensure safe and timely delivery. Keeping track of products is not always a transparent process.

Cover Art Illustrated by Creative Edge Design Studio

New Serialization Regs Impact Global Pharma

Darryl Peterson, Antares Vision

Pharmaceutical companies must contend with challenges stemming from supply chain security lapses (resulting in theft, diversion and product recalls), counterfeiting and stringent regulations. These challenges also impair the health of the industry by adversely impacting profits, brand credibility and research initiatives.

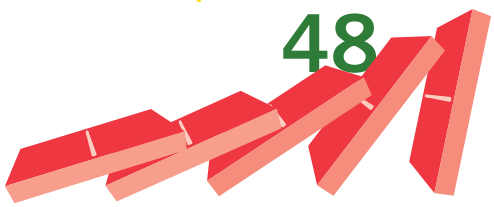
A Risk-Based Approach to Supplier Management

Roche/Genentech's Ralph Quadflieg Discusses the Company's Supplier Oversight

Rebecca Stauffer and Aneeta Mathur-Ashton, PDA

As the supply chain grows ever more complex, firms must closely monitor suppliers of raw materials, APIs and excipients. **Ralph Quadflieg,** PhD, Global Head of Lean Production System for Global Supplier Quality and External Quality, Roche/Genentech, discusses his company's approach to supplier management.

InfoGraphic



The Dominoes of Natural Disasters

Learn how a natural disasters can impact drug supply.

PDA Letter

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> **On the Issue** | Japanese Regulatory Considerations: Continuous Manufacturing
PDA board member **Masahiro Akimoto** interviews the Japan PMDA's **Issei Takayama** on Japanese regulations for continuous manufacturing at the *2018 PDA Annual Meeting*.

> **Editor's HotSeat** | Cell Viability After Cryopreservation
BioLife Solutions' **Brian Hawkins** discusses his *2018 PDA Annual Meeting* poster presentation.

> 3 Questions for Biogen's Amy Wilson
Biogen's **Amy Wilson** answers three questions about how the company's resilience approach has impacted manufacturing operations.

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September 2018 PDA Letter

Show Issue

The *2018 PDA Universe of Pre-Filled Syringes and Injection Devices* showcases the latest in drug delivery technology.

The *13th Annual PDA Global Conference on Pharmaceutical Microbiology* looks at the current state of pharmaceutical microbiology.

Revised USP Micro Chapters Address Changing Technologies

David Hussong, PhD, Eagle Analytical Services, Radhakrishna Tirumalai, PhD, USP, Edward Tidswell, PhD, Merck, and Don Singer, GSK

As technological advancements around microbiological testing continue to grow within the pharmaceutical industry, USP's Microbiology Expert Committee seeks to update some of its microbiology chapters. For each five-year cycle, the Expert Committee has an established workplan intended to help meet USP's standards-setting goals. Some of the workplan's major initiatives in the current USP cycle (2015–2020) include sterilization processes and sterility assurance, parametric release, depyrogenation, endotoxin testing, rapid sterility testing of short-life products and *Burkholderia cepacia* complex.

Cover Art Illustrated by Katja Yount with help from Rapid Micro Biosystems

Viewpoints on the EU Annex 1 Revision

Last December, the EU Annex 1 revision was released, drawing considerable industry attention. This issue features two authors' perspectives on different parts of the revision. **Walid El Azab** looks at proposed changes to the sections on sterilization and moist steam while **James Tucker** analyzes revisions to the section on cleaning and disinfection.

InfoGraphic

Common Issues Found in Nonsterile Drug Facilities

A look at eight years of U.S. FDA warning letters and EMA noncompliance reports.

PDA Letter

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Digital Exclusives

> Evaluating Cell Viability After Cryopreservation
How can companies address the challenges of using cryopreservation techniques on living cells used for regenerative medicines?

> Reclaiming Efficiency Amid Serialization Nightmares
Learn how the OEE equation may help with preventing serialization disasters.

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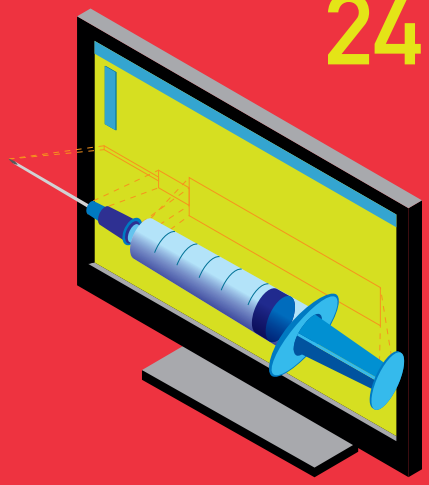
October 2018 PDA Letter



Big Data, Pharma 4.0 and Legacy Products

Jana Spes, Boston Biomedical, and Wayne Levin, Predictum

Big data offers companies a unique opportunity to close the knowledge gap that exists for legacy products and processes. Those companies that close this knowledge gap are better positioned to transform their manufacturing operations for Industry 4.0.

Cover Art Illustrated by Katja Yount

Big Data: The Panacea for Pharma's Ills?

Khan Lau, Promedica International

Two words are driving innovation within the pharmaceutical industry these days: "big data." Start-up companies like Datavant are receiving millions of dollars to harvest, organize, interpret and, hopefully, protect large amounts of data from a variety of stakeholders in the healthcare space.

InfoGraphic

Industry 4.0 in 3.0 Steps

Industry 4.0 has generated considerable buzz within pharmaceutical manufacturing but how can companies implement it?

PDA Letter

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Digital Exclusives

> **On the Issue** | Packaging Components: Extractable/Leachable Control
> The U.S. FDA's **Dan Mellon** provides the Agency's perspective on extractable and leachable control for packaging components.

> Industry Converges on Pharmacopeial Convergence
> Day 1 of the inaugural PDA Europe *Pharmacopoeia Conference* examined harmonization among the global pharmacopeias.

> A Deep Dive into Pharmacopeial Harmonization
> Presentations on Day 2 of the *Pharmacopoeia Conference* explored how industry can work together with the global pharmacopeias.

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November/December 2018 PDA Letter

FDA's ORA Realignment, MRA, NIPP, Concept of Operations:

How it All Fits Together

Rebecca Stauffer, PDA

Just over a year ago, the U.S. FDA released detailed information about the restructuring of the newly realigned Office of Regulatory Affairs (ORA). **Alonza Cruse,** Director, Office of Pharmaceutical Quality Operations, ORA, provided an update on this and other ORA initiatives on Sept. 24 in the second plenary of the *2018 PDA/FDA Joint Regulatory Conference.*

Cover Art Illustrated by Karol Keane

Process, Interrupted

The Effect of Gamma Irradiation Process Interruption on Microbial Resistance of *G. stearothermophilus*

Fatima Hasanain, Polymer Materials Specialist, Nordion (Canada) Inc.

Sterilization process monitoring and control is key to product safety in the pharma industry. ISO/AAMI 11137-1 addresses the importance of monitoring radiation process parameters to ensure products have been processed according to specification. Radiation sterilization standards generally state that any doses delivered to product are cumulative.

Hidden Contamination in Starting Materials

Are Your APIs Free of Dirt?

Annette Kirsch, PhD, Merck KGaA

Contamination by foreign particles has only been covered to a small extent in regulatory and compendial guidelines and, even then, mostly for parenteral products. The European Pharmacopoeia only covers particle contamination of oral herbal medicines. To cover this gap, the Active Pharmaceutical Ingredients Committee (APIC) and the International Pharmaceutical Excipients Council (IPEC) published position papers in 2015 explaining how pharmaceutical manufacturers should deal with particles in APIs and excipients.

InfoGraphic

Annex 1: Are You Prepared?

The EU Annex 1 revision is currently in draft form. Is your company ready for the final version?

Interactive

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> **On the Issue** | Audit Trails
Novartis' **Christian Scheidl** discusses the role of audit trails for ensuring data integrity at the 3rd PDA Europe Annual Meeting.

> Future Challenges in Visual Inspection Processes
Warning letters for visual inspection issues may have gone down but some issues remain.

> Standing Guard
A comparison of the standard LAL assay with alternative methods.

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