Regulatory Concerns Drive New Developments in Glass Packaging
Rebecca Stauffer, PDA

Find out what some of the speakers and program planning committee members behind the upcoming PDA Parenteral Packaging conference think is spurring development of new types of glass packaging.

An Overview of Container Closure Integrity
Qingyu Zeng, PhD, West Pharmaceutical Services, Inc.

A typical container closure system has three major components: a rubber stopper, vial and aluminum seal. In order to satisfy mandatory patient safety requirements, container closure integrity must be ensured through a holistic consideration of many critical aspects.

United States and Europe Align on Glass

Find out how the U.S. Pharmacopeia has aligned with the European Pharmacopoeia around glass packaging.
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> On the Issue | Big Data
Roche’s Aaron Goerke talks about what big data means for pharma manufacturing.

> Holistic Verification Requires a New Mindset
CSL Behring’s David Hubmayer explains why holistic verification is key to manufacturing drug products in an increasingly patient-centric world.

> Amsterdam Move Reflects Larger Trend
EMA is not the only thing moving to Amsterdam!

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Discover the latest advancements in parenteral manufacturing at the 2019 PDA Annual Meeting by reading through our special Annual Meeting supplement!

PUPSIT & the Proposed Annex 1 Revision

Hal Baseman, ValSource

Since its publication in December 2017, the proposed Annex 1 revision has been much discussed. As coleader of the team that prepared PDA’s comments on the revision, I am intimately familiar with the intricacies of the document. As such, I want to share some thoughts on the revision, culminating in four pieces of advice concerning one of the most debated points of contention within Annex 1.

Annex 1 Ready of Not?

The PDA Letter conducted an informal survey last year to ascertain how prepared PDA members are for the proposed Annex 1 revision.
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> Alternative to LAL Gains Ground
As alternatives to the traditional LAL assay enter the market, what does this mean for the industry?

> Growth Promotion Testing for EM
Why are reference materials critical for environmental monitoring?

pda.org/letter
Industry Eyes Future of Visual Inspection
Five Critical Areas of Concern Draw Attention of Pharma Industry

John Shabushnig, PhD, Insight Pharma Consulting; Markus Lankers, PhD, MIBIC; John Ayres, MD, Pharma Safety Solutions; Roy Cherris, Bridge Associates; Robert Miller, Pfizer; Romain Veillon, GSK Vaccines; and Rick Watson, Merck

It goes without saying that visual inspection is critical to parenteral manufacturing. All units produced must be inspected to ensure a high level of quality assurance. Visual inspection can be performed with the human eye by a trained inspector under controlled conditions or via automation using advanced camera and computer technology.

The Challenges of Visually Inspecting IV Bags

Florian Krickl, Vitronic

Is there a common technical standard for automated visual inspection in difficult-to-inspect parenteral products? Talk with any quality manager or project engineer in the pharma manufacturing sector and they will tell you that there are a number of processes where inspection results often do not meet the expectations. As long as there is no independent standard defining the quality of automated visual inspection, however, inspection results can vary significantly case by case. This is a particular concern for IV bags.

Can We Achieve “0” Defects for Visible Particles?

Find out what can be done to accomplish this challenging goal in the latest PDA Letter InfoGraphic!

Big Data is Here to Stay

2018 PDA Manufacturing Intelligence Workshop
Commands a Crowd

Aaron Goerke, PhD, F. Hoffmann-La Roche AG, and Michele D’Alessandro, Merck & Company, Inc.

Implementing big data within pharmaceutical manufacturing will require extensive collaboration. Fortunately, a 2018 PDA workshop suggests this is possible.
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Merck’s Kenneth Boone covers recovery of anaerobic microorganisms from an aerobic aseptic process simulation.

> Change is in the Air for Packaging Components
West’s Cathy Zhao offers her perspective on the latest packaging trends.
pda.org/letter
The Pharmacopeia in the 21st Century
Pharmacopeias Move to Modernize in Changing Times
Susanne Keitel, EDQM

Maintaining a comfortable state of health has always been a major human preoccupation. By the dawn of the first millennium, this was manifested in De Materia Medica, generally considered to be the earliest example of a pharmacopoeia. This treatise compiled contemporary tried and tested herbal and other remedies, methods for their preparation and their effects on patients. Fast forward two thousand years and the world has changed entirely and, with it, attitudes about health and well-being.

Future Lies in Continuous Manufacturing Technology
What do the Global Regulators and Pharmacopeias Have to Say?
Bei Ma, Pinea Group

In recent years, the pharmaceutical manufacturing leaders have been exploring innovative and new technical solutions to achieve better quality, improve productivity and operational efficiency, increase process throughput and yields.

Advancements in technologies such as, digitalization, artificial intelligence and machine learning, 3D printing, precision medicine, automation, augmented and virtual reality, will shape the pharmaceutical industry over the next five to ten years.

Growth Promotion Testing For EM
Reference Materials Critical for Ensuring Effective Environmental Monitoring Tests
Brendan Tindall, biomerieux, and Graham Vesey, Regeneus

Growth promotion testing of culture media is an important part of microbiological testing in support of pharmaceutical quality. The growth promotion test is a quality control requirement that confirms the ability of a new batch of media to support growth of a predetermined selection of representative microorganisms.

Avoid These 5 SOP Pitfalls
Learn what mistakes to avoid in order to ensure an effective SOP for your GMP operations.
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> Industry and Regulators Convene to Address Vaccines Challenges
Read a summary of last year’s Vaccines conference in this longform article!

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What does the future hold for parenteral manufacturing in Europe? Find out by reading through our special section highlighting the 4th PDA Europe Annual Meeting!

Highly Potent APIs
Balancing Patient and Operator Safety
Rebecca Stauffer, PDA

When contamination control comes up as a topic of discussion at a PDA conference the conversation usually concerns how to protect product from potential contamination. But what about the operator?

Technology Transfer
Failure to Communicate?

Earlier this year, PDA conducted a survey on tech transfer. The results were showcased at the 2019 PDA Annual Meeting. Check out some highlights from the survey.
The PDA Letter is published 10 times per year, exclusively for PDA members. Articles published in the PDA Letter do not represent the official positions of PDA, Inc., but are the opinions of the authors submitting the articles.

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SKANS: Richard Denk discusses EU requirements to prevent cross-contamination at the 2019 PDA Annual Meeting

> On the Issue | Implementing a Completely Closed, Robotic Isolator for Flexible Filling
Emergent: Kevin Gadient provides insights on implementation of a gloveless, robotic isolator

> Air Bubbles versus Transparent Particles
Find out how to differentiate between the two during automated visual inspection

pda.org/letter
Gloveless Isolators Offer Speedy Throughput
Jim Akers, PhD, Akers Kennedy and Associates

If the reader thought this was going to be another commentary on the impact of humans on contamination and the elimination of direct interventions, they are going to be surprised. Automated, gloveless aseptic technologies are a logical progression as our field moves into the 21st century.

Aseptic Technology Advances to the Next Level
A Review of Four Technologies Used to Reduce Operator Interventions in Aseptic Manufacturing
Subrata Chakraborty, Cipla

The pharmaceutical industry has never been a rapid pioneer in adopting new technologies, preferring instead to evolve slowly and consciously.

Isolators Trending for Manufacturers
Check out results from PDA’s 2017 aseptic processing survey specific to isolators.
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> On the Issue | USP <1207> and the Future of CCI Testing
Diane Paszkiet of West Pharmaceutical Services discusses the impact of <1207> on container closure integrity testing.
pda.org/letter

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Handling post-approval changes (PAC) can feel like an unending game of varying regulatory requirements. But following the ICH quality guidelines and ensuring robust quality systems can help achieve PAC goals.
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West Pharma’s Amy Kim and Biogen’s Maria Bednar discuss their Young Professionals presentations at the 2019 PDA Annual Meeting.

Excipients’ Attributes Crucial for Parenteral Preparations
Learn why quality attributes are important for the excipients used in our industry.

SoCal Student Chapter Keeps Busy
Find out what the PDA Southern California’s student chapter has been up to!
Lifecycle Approach Wipes Away Cleaning Validation Concerns
Raji Vathyam

Cleaning validation is a perpetual undertaking for multiproduct drug manufacturing companies, particularly those with dynamic product profiles and frequently changing commercial needs. With rising demands for complex molecules or highly potent drugs, manufacturers now must continuously invest in new technologies such as containment systems, which offer protection to both operators and finished products.

Human Error Causes OOS Investigation
One Company’s Experience with Determining Root Cause for an Endotoxin Testing Failure
Rebecca Stauffer and Madeline Cusick, PDA

Testing failures are not unheard of in the industry. Routine samples that normally pass specification can, out of the blue, suddenly fail.

Endotoxin Control in Another Industry
Find Out How an Operating Room Improved Their Endotoxin Control

Endotoxin control is a major concern for pharmaceutical microbiologists. Did you know it is also an issue in operating theaters? A ten-year study of endotoxin-retainive ultrafilters used for reverse osmosis (RO) plants in an operating theater was highlighted last year in the PDA Journal of Pharmaceutical Science and Technology.
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> Another Perspective on rFC
Lonza’s Allen Burgenson comments on recent coverage of alternative endotoxin testing technologies.

> SE Chapter Helps Students Build Bridge to Future
Learn more about the new student chapter affiliated with the Southeast Chapter!

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Can We Reprogram the Human Computer?

CEO Jeff Galvin Believes We Can
Rebecca Stauffer, PDA

What if developers of cell and gene therapies treated their products like software releases? What if the human body could be manipulated like a highly complex computer?

**Jeff Galvin**, CEO of American Gene Technologies, certainly has that mindset, frequently referring to cell and gene therapies as “reprogramming the human computer.”

Conference Puts Human Face on Cell and Gene Therapies
Rebecca Stauffer, PDA

Cell and gene therapies will unquestionably comprise a large part of biotech companies’ portfolios in the upcoming decades. Unlike traditional large molecules, these products have different manufacturing and supply chain needs, requiring a fresh look at existing regulations. Yet these challenges will need to be addressed due to the promise of these products to cure a variety of diseases and disorders.

Process Approach Goes Global

Earlier this year, the European arm of PDA’s Quality Systems Interest Group surveyed members of its process owner subgroup about how they have implemented the process approach at their companies.
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> On the Issue | Here They Come: Pharma Students | Keck Graduate Institute Student Lyanna Jauregui discusses her poster at the 2019 PDA Annual Meeting with the Southern California Chapter’s Jason Kerr.
> Are Your RMM Organisms Reflective of Your Process? | Find out how you validate your rapid method.

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FDA Takes Close Look at Innovation
Rebecca Stauffer, PDA

Industry 4.0. Artificial intelligence. Big data. Even continuous manufacturing. All of these new technologies will drive the future of pharmaceutical and biopharmaceutical manufacturing. Yet questions persist as to how the U.S. FDA and other global regulatory agencies will address these new technologies, leaving some companies reluctant to fully embrace these advances as early adopters.

Robotics and Big Data Key to Lab of the Future
Peter Crane, Synthace

I had the good fortune to attend the Digital Robot Pharma Fab workshop and the 4th PDA Europe Annual Meeting in Amsterdam this past June.

Add Sherlock Holmes to Your Investigation Team
The Role of a Microbiologist in Teams Investigating Product Failures Due to Manufacturing Issues
Tony Cundell, PhD, Microbiological Consulting, LLC

You have reported a microbial test failure to your site’s management following confirmation by a laboratory investigation. You then assemble a cross-functional team to investigate the most likely cause of the failure during manufacturing.

Data Integrity: Remediation and Quality Culture

The 2019 Data Integrity Workshop opened with a real-time survey of attendees, the majority representing pharma/biopharma manufacturing. Here are some highlights that pertain to remediation and quality culture.
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> Strategic Application of Advanced Analytics for CGT Development

Advanced analytical data can help ensure a stable pipeline of cell and gene therapy products and even address CMC issues.

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