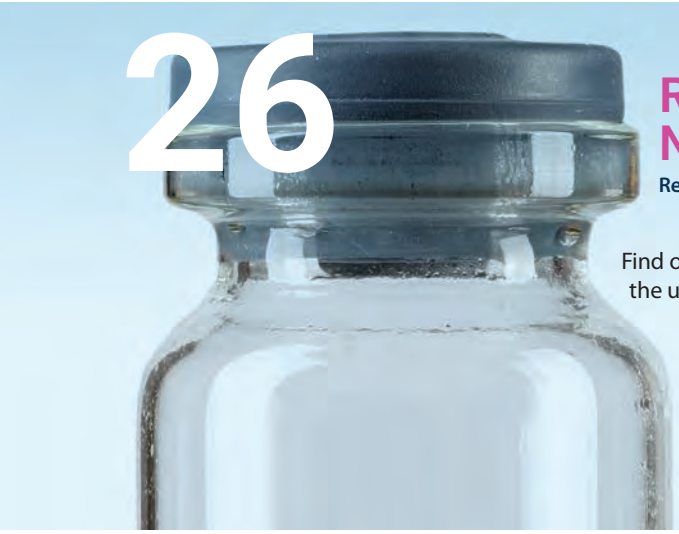
January 2019 PDA Letter

Parenteral Packaging conference

This year's *Parenteral Packaging conference* is scheduled for March 19–20 in Venice, Italy. Articles with this banner at the top of the page relate to this important meeting.

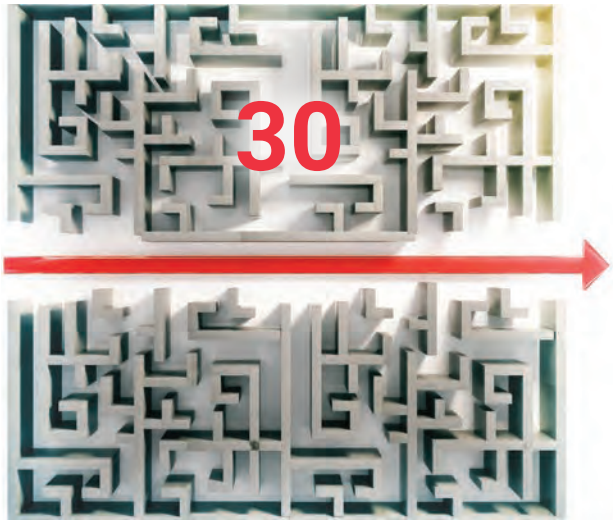


Regulatory Concerns Drive New Developments in Glass Packaging

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.

Cover Art Illustrated by Katja Yount



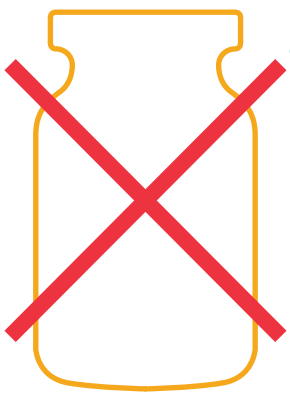
An Overview of Container Closure Integrity

Considerations for Achieving an Optimal Performance Window for Container Closure Systems

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.

InfoGraphic



United States and Europe Align on Glass

Find out how the U.S. Pharmacopeia has aligned with the European Pharmacopoeia around glass packaging.

PDA Letter

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Departments

Digital Exclusives

> **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 Hubmayr** 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!

pda.org/letter

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February 2019 PDA Letter

2019 PDA Annual Meeting

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

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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.

Cover Art Illustrated by Katja Yount

InfoGraphic

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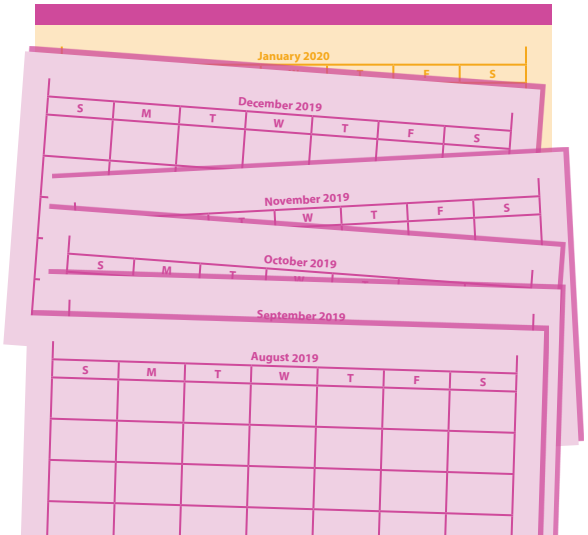
Annex 1
Ready of Not?



The *PDA Letter* conducted an informal survey last year to ascertain how prepared PDA members are for the proposed Annex 1 revision.

PDA Letter

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Departments

Digital Exclusives

> 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

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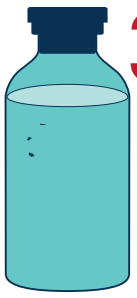
March 2019 PDA Letter

Cover photo courtesy of Antares Vision. This photo depicts the company's Visual Rotating Inspector machine

InfoGraphic



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Departments

Digital Exclusives

> **On the Issue** | P. Acnes in an Aerobic Process
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.

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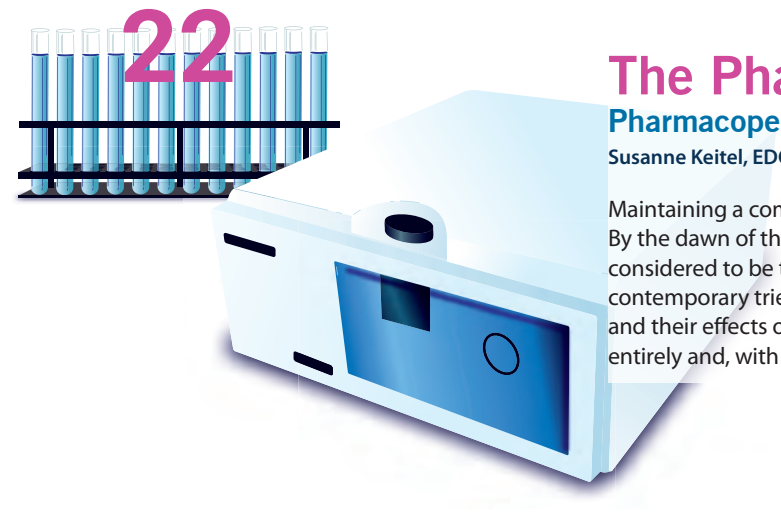
April 2019 PDA Letter



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.

Cover Art Illustrated by Katja Yount

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.

InfoGraphic

Avoid These 5 SOP Pitfalls

Learn what mistakes to avoid in order to ensure an effective SOP for your GMP operations.

PDA Letter

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Digital Exclusives

> 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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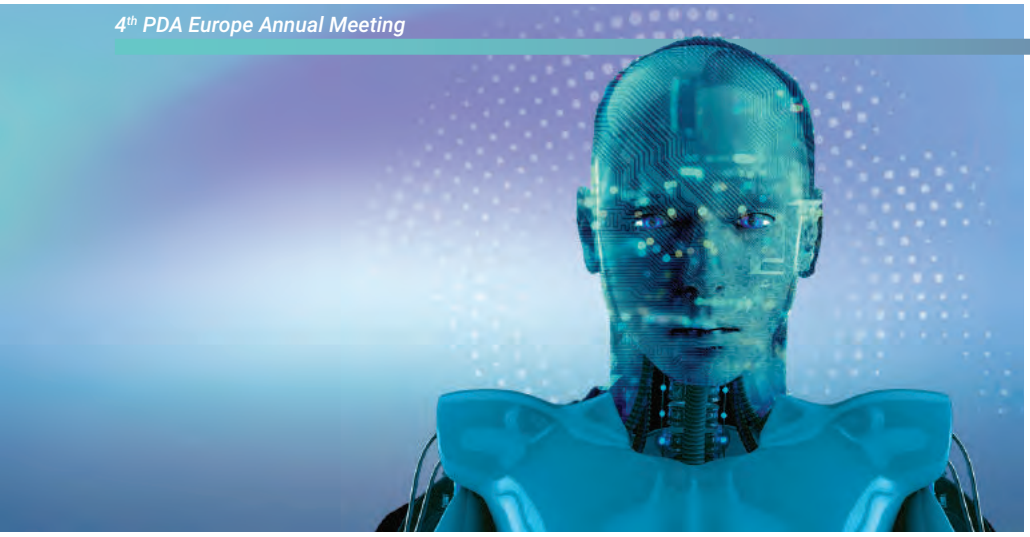
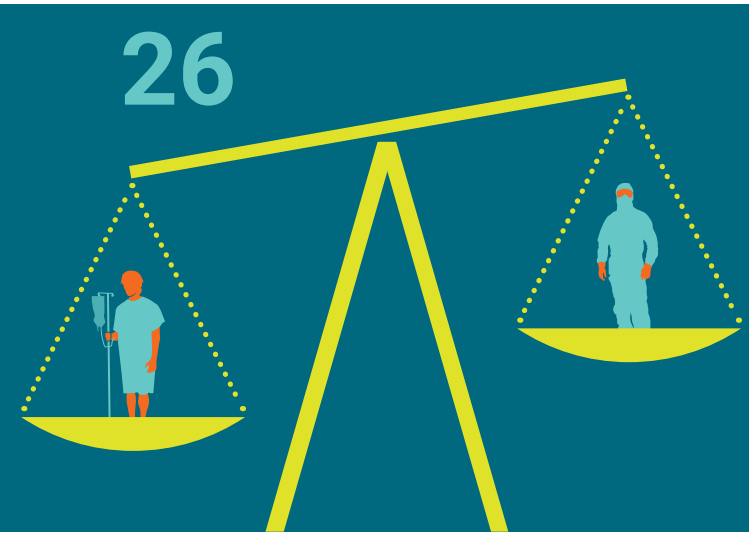
May 2019 PDA Letter

4th PDA Europe Annual Meeting



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?

Cover Art Illustrated by Katja Yount

InfoGraphic

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.

PDA Letter

Volume LV • Issue 5 www.pda.org/pdaletter

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Departments

Digital Exclusives

> **On the Issue | Controlling Contamination and Cross-Contamination**
> SKAN's **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's **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

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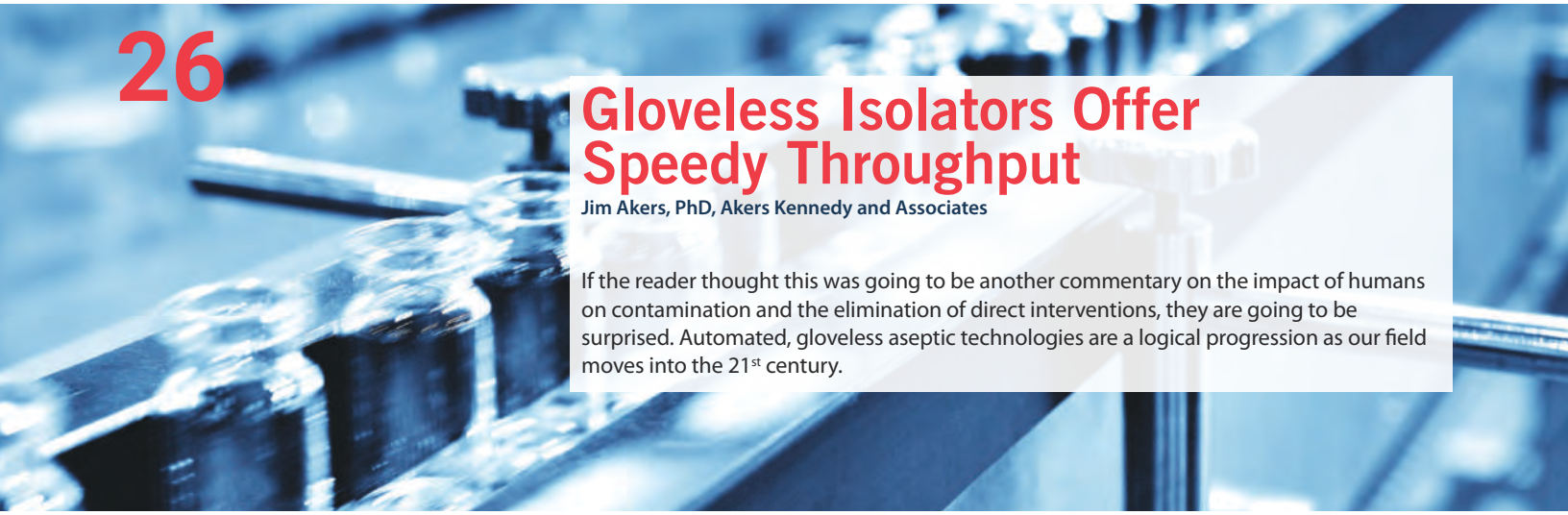
June 2019 PDA Letter



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.

Cover Photo by Zora Zhuang

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.

InfoGraphic

Isolators Trending for Manufacturers

Check out results from PDA's 2017 aseptic processing survey specific to isolators.

PDA Letter

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Digital Exclusives

> **On the Issue** | USP <1207> and the Future of CCI Testing
Diane Paskiet of West Pharmaceutical Services discusses the impact of <1207> on container closure integrity testing.

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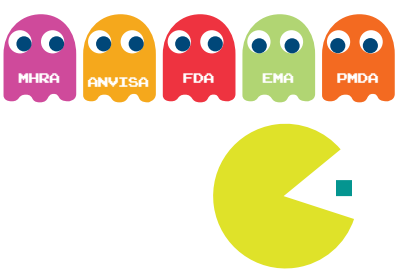
July/August 2019 PDA Letter

PDA/FDA Joint Regulatory Conference

Learn what to expect at the *2019 PDA/FDA Joint Regulatory Conference* in our special section.

DATA INTEGRITY

InfoGraphic



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Departments

Digital Exclusives

> **On the Issue** | Here They Come: Pharma Young Professionals
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!

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September 2019 PDA Letter

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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.

Cover Photo by Katja Yount

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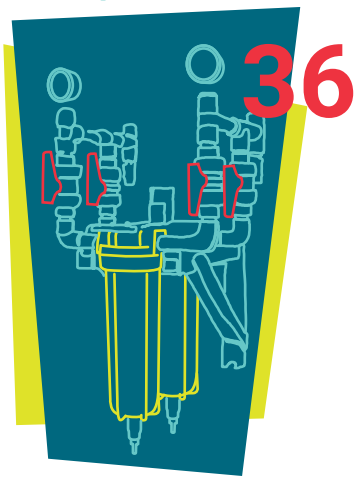
Human Error Causes OOS Investigation

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.

InfoGraphic



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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-retentive ultrafilters used for reverse osmosis (RO) plants in an operating theater was highlighted last year in the *PDA Journal of Pharmaceutical Science and Technology.*

PDA Letter

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> **On the Issue** | Here They Come: Pharma Young Professionals
West Pharma's **Amy Kim** and Biogen's **Maria Bednar** discuss their Young Professionals presentations at the *2019 PDA Annual Meeting.*

> 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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October 2019 PDA Letter

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."

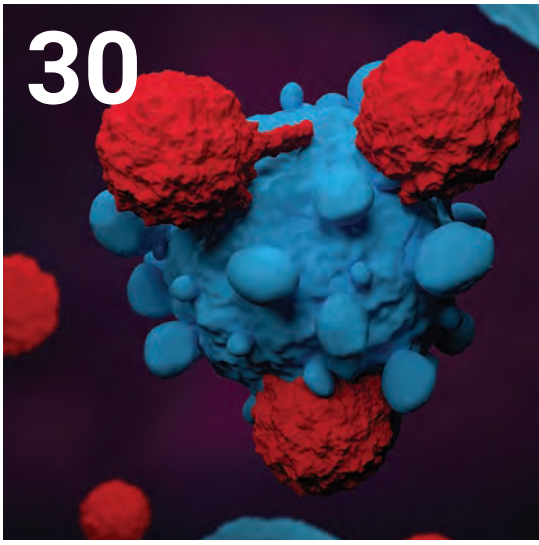
26

Kevin Allen Photography

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.



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InfoGraphic

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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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Digital Exclusives

> **On the Issue** | A Particulate Matter Lifecycle Approach in Harmony with <1790>
Gateway Analytical's **Antonio Scatena** discusses USP <1790> at the *2019 PDA Visual Inspection Forum.*

> **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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November/December 2019 PDA Letter

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.

Cover Photo by Christopher Ames

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.

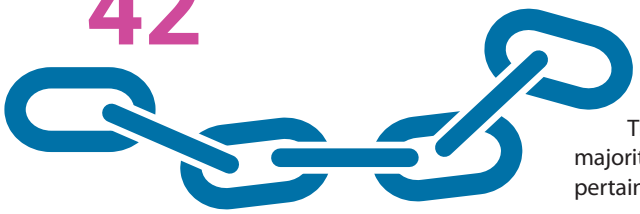
Add Sherlock Holmes to Your Investigation Team

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.

InfoGraphic



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.

PDA Letter

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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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