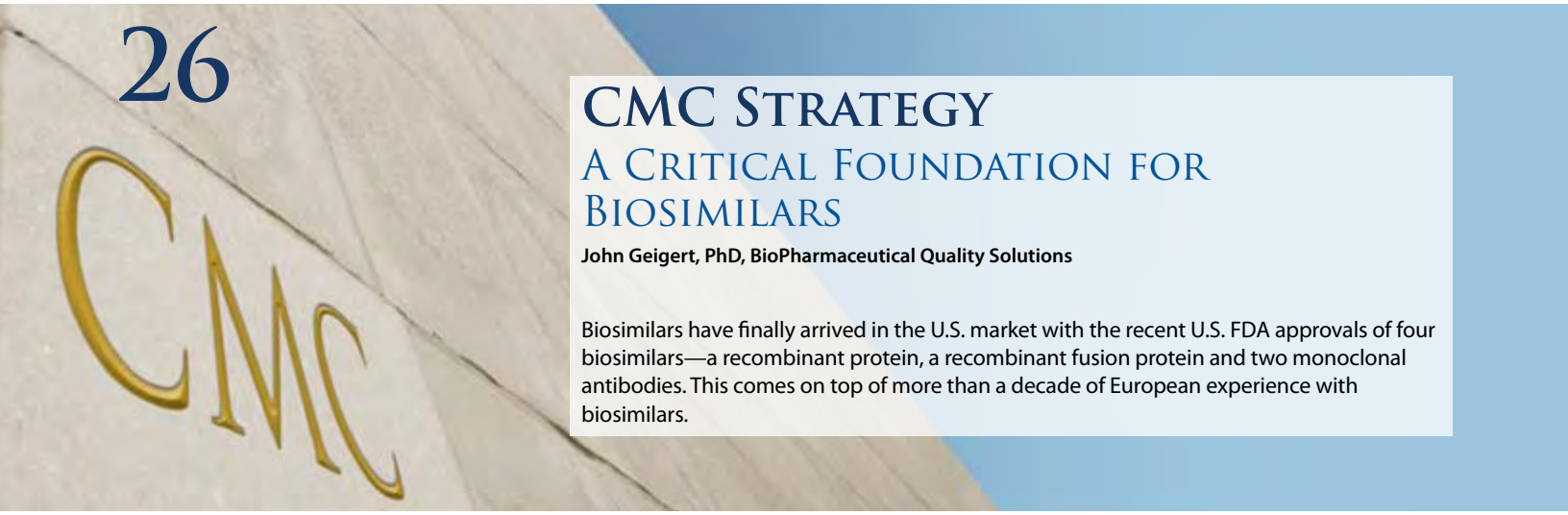
January 2017 PDA Letter



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CMC Strategy
A Critical Foundation for Biosimilars

John Geigert, PhD, BioPharmaceutical Quality Solutions

Biosimilars have finally arrived in the U.S. market with the recent U.S. FDA approvals of four biosimilars—a recombinant protein, a recombinant fusion protein and two monoclonal antibodies. This comes on top of more than a decade of European experience with biosimilars.

Cover Art Illustrated by Lorim Ipsum

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Challenges for Biosimilar Sponsors
Proving Comparability of Products Affected by Manufacturing Change

Michael VanDerWerf, Teva

Once a biosimilar sponsor has successfully presented their product to regulators and it has been approved as similar enough to the innovator product to enjoy the same labeling, how should that sponsor approach supporting post-approval manufacturing changes? Is the sponsor obligated to demonstrate biosimilarity to the innovator's reference product again? Or does the approved biosimilar undertake its own lifecycle, only needing to prove comparability to itself?

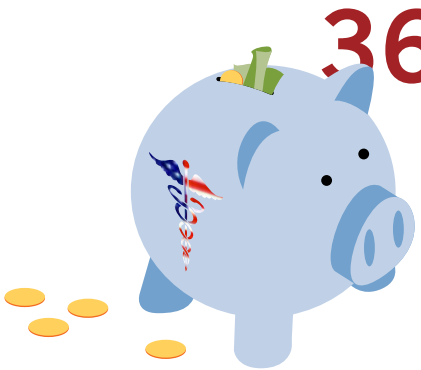
Notes from the First PDA Biosimilar Conference

33

Stephan Krause, PhD, AstraZeneca Biologics, and Emanuela Lacana, PhD, CDER, FDA

The development of biosimilar products is complex, and regulatory approval remains challenging. In response to the industry's need for current and reliable information on this rapidly growing area of pharmaceutical manufacturing, PDA offered the *2016 PDA Biosimilars Conference* last June. Cosponsored with the Product Quality Research Institute (PQRI), the conference drew a sizable crowd of attendees interested in advancing their knowledge of biosimilar development.

InfoGraphic



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Biosimilars: A New Market for Biologics Firms

In 2010, the Patient Protection and Affordable Care Act went into effect. This law created a pathway for biosimilars in the United States. Now, innovator biologics manufacturers are testing the biosimilar waters. Some are even developing biosimilars of their own products.

PDA Letter

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Departments

Digital Exclusives

> **On the Issue** | PAC iAM Packs PAC Punch
Find out what PDA's Post Approval Change: Innovation for Availability of Medicines (PAC iAM) Task Force is doing to tackle the challenges companies face when trying to implement post-approval changes.

> **On the Issue** | Change is Coming to USP Micro Chapters
Expert Committee Member David Hussong discusses recent changes to USP's general chapters relating to pharmaceutical microbiology.

> How Should Annex 1's Requirements be Interpreted?
As industry nears the Annex 1 revision, take a look at which areas of the regulation may have been interpreted in ways the original authors never considered.

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February 2017 PDA Letter

Changing Currents
What Water Treatment Advancements Mean for Pharma

Mike Henley, Ultrapure

Pharmaceutical water is key to the production of pharmaceutical drug products, many of which require high-purity water. This is water purified according to guidelines as defined by the USP or other pharmacopeias.

Cover Art Illustrated by Katja Yount

The New Annex 16 – Eight Questions for Rainer Gnibl

Sabine Paris, PhD, Maas & Peither AG

Maas & Peither editor **Sabine Paris,** PhD, interviews German GMP Inspector **Rainer Gnibl**, PhD, on the Annex 16 revision, "Certification by a Qualified Person and Batch Release," that became effective last year. Excerpted from the April 21, 2016 issue of the Maas & Peither cGMP newsletter.

InfoGraphic

Know Your High-Purity Water System

There are many types of high-purity water systems used within the pharma industry. This issue's *PDA Letter* InfoGraphic offers a primer for some of the most commonly seen or referenced.

PDA Letter

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> China FDA Taking Closer Look at Clinical Trial Data
In November, the Chinese FDA announced plans to inspect clinical trial sites for 30 products. What does this mean for data integrity in the country?

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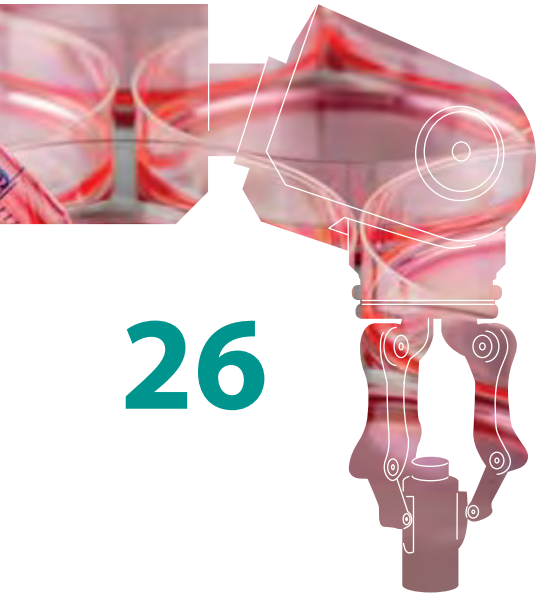
March 2017 PDA Letter

Show Issue

This year's Annual Meeting takes place in Anaheim, Calif. and will offer in-depth presentations on the next wave of manufacturing innovation. Throughout this issue are a number of articles highlighting talks, courses, and other events at this signature PDA meeting.



Reaching for Next Gen Biopharma Manufacturing

Rebecca Stauffer, PDA

Robotic arms. Gloveless isolators. Manufacturing pods. Process modeling. Big data. Automation. Welcome to the future—or "next generation"—of pharmaceutical manufacturing, "Industry 4.0." Pharmaceutical manufacturing is on the precipice of a paradigm change, particularly when it comes to biologic products.

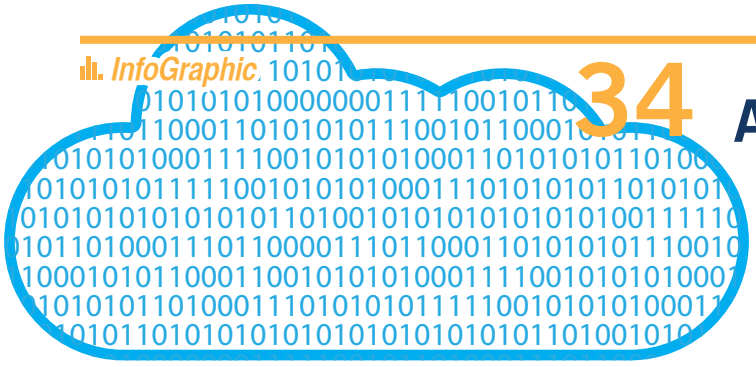
Cover Art Illustrated by Katja Yount

Leveraging Video to Improve Operations

If a Picture is Worth a Thousand Words, What is a Video Worth?

Colleen Walson-Billin, Amgen

According to YouTube, they have over a billion users, almost one-third of all people on the Internet, and, every day, people watch hundreds of millions of hours of YouTube videos, generating billions of views. It's also been reported that videos increase people's understanding by 74%. If a video is worth a thousand words, a video is worth 1.8 million words per minute.



An Inside Look at Industry 4.0

The terms "Industry 4.0" and "Industrial Internet of Things" keep getting bandied around. But what do they mean?

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Digital Exclusives

> **On the Issue** | Keeping it Clean
PDA Education instructor **Mary Carver** discusses cleaning and disinfection for aseptic processing

> New Approach to Validation for New Manufacturing Technologies
Learn about a next generation approach for validation of automation, facilities, utilities and equipment

pda.org/letter

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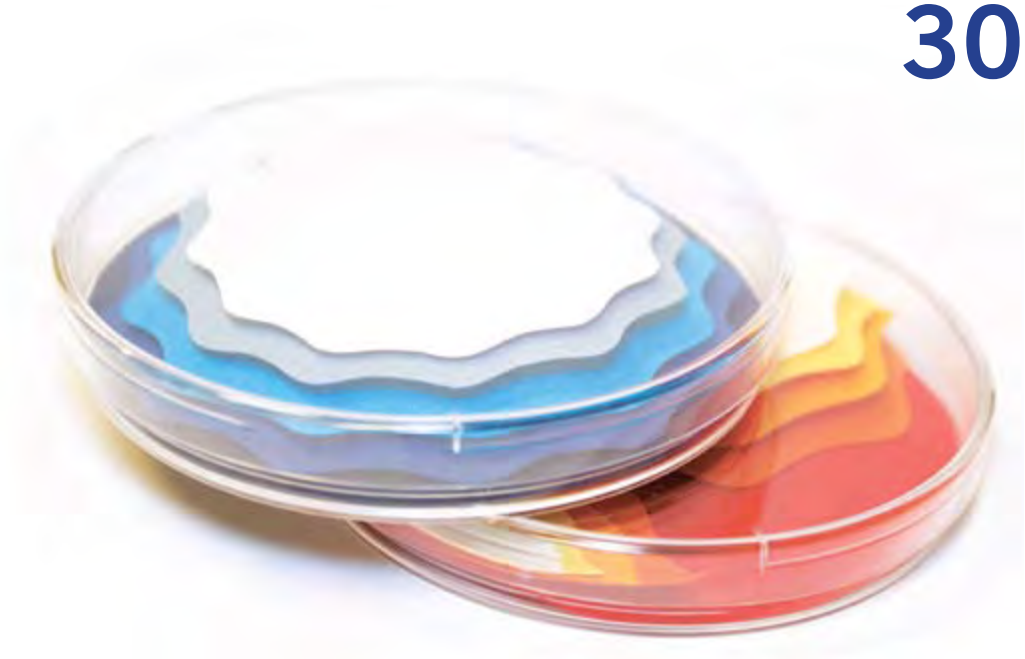
April 2017 PDA Letter

Cover Art Illustrated by Katja Yount



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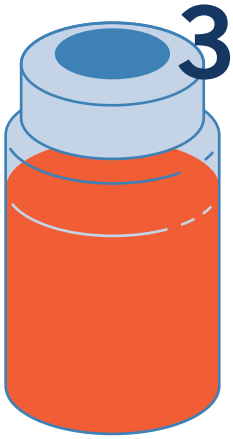

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> **On the Issue** | Defining the Quality Culture
Cylia Chen-Ooi, one of the members of PDA's quality culture subgroup of its quality metrics task force, talks about why quality culture is critical within the industry.

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May 2017 PDA Letter

2nd PDA Europe Annual Meeting

Show Issue

This year's *PDA Europe Annual Meeting* once again takes place in the city of Berlin, June 13–14. Throughout this issue are a number of articles highlighting talks, courses, and other events at this new signature PDA meeting. For a preview of the exciting sessions offered at this meeting, look for articles with this banner at the top of the page.

Lower the H_2O_2 Concentrations in Your Isolator with One Easy Upgrade

Stefan Kleinmann, PhD, and Matthias Scheu, METALL+PLASTIC, Roland Schuhwerk, and Volker Baur, Cilag AG

In recent years, the number of protein-based biologic drug products has grown. Parallel to this, the use of filling line isolators in biopharmaceutical manufacturing plants has increased. Some of these products are extremely sensitive to oxidation. The majority of aseptic manufacturing isolators are decontaminated with H_2O_2, so potential oxidation of these sensitive products has become a concern.

Cover Art by Karol Keane, photo courtesy of Metall + Plastic

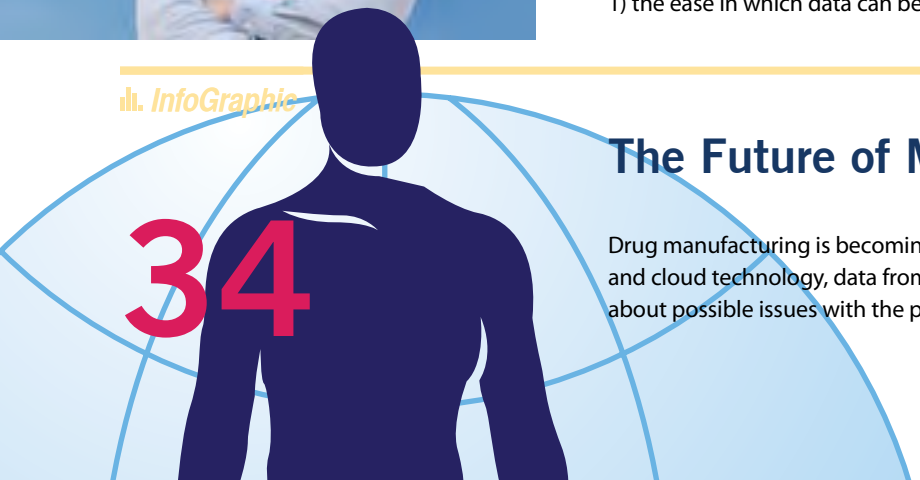
Pharma Has its Head in the Cloud

Big Data is Leading Pharma Manufacturing to Greater Maturity

Toni Manzano, bigfinite

Today, huge amounts of information are continuously being generated and stored in many different systems: external and internal hard drives, virtual disks, network storage systems, pen drives, e-drives, etc. In addition, social networks, multimedia platforms, and Internet of Things (IoT) technology contribute increasingly greater bytes of data. In fact, 2016 saw about 2.5 trillion (2.5×10^{18}) bytes of data created each month. This enormous amount of electronic information, commonly referred to as "big data," is directly related to two factors: 1) the ease in which data can be stored, and 2) the ability to connect to the internet.

InfoGraphic



The Future of Medicine

Drug manufacturing is becoming increasingly patient-centric. Thanks to wearable devices and cloud technology, data from the drug/device provides more accurate information about possible issues with the product.

PDA Letter

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> **Editor's Hot Seat** | *2017 PDA Annual Meeting* Poster Presenters
Four poster presenters discuss their presenations, which will also be written about in the Letter.

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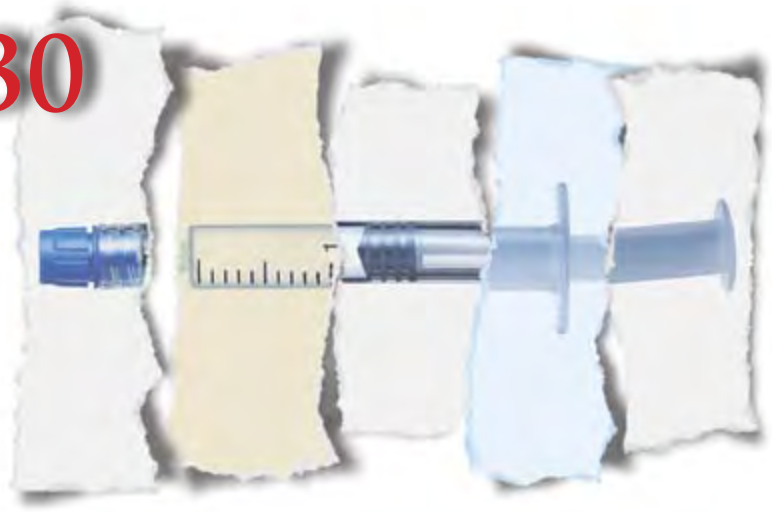
June 2017 PDA Letter

Putting the Pieces Together

Are the Components in Your Prefilled Syringes Compatible?

Wendy Saffell-Clemmer, Baxter Healthcare



Prefilled syringes offer potential cost savings for high-value, complex, biologic products because minimal overfill volume is needed in the primary container as compared to vials. While a prefilled syringe offers many advantages for biologic products, manufacturers must carefully evaluate the potential impact of a prefilled syringe on product quality by conducting laboratory studies prior to selecting the final components. In particular, assessing the impact of silicone oil and tungsten residues is crucial.

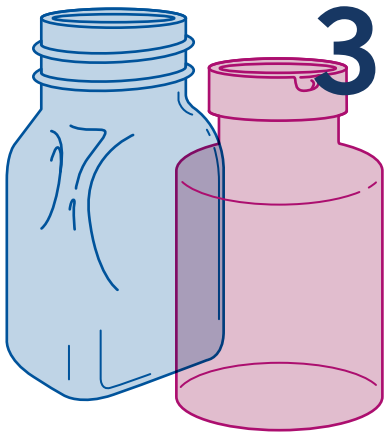
Cover Art Illustrated by Katja Yount

How to Use QbD to Select Packaging Components

Nrupa Patel, Teligent Pharma Inc., and Sandip Patel, Navinta LLC

The development of a safe and effective drug product requires not only high quality ingredients but also careful selection of appropriate primary packaging components as these come directly into contact with the drug product. Interaction between primary packaging components and the drug product may result in failure to meet the quality target product profile (QTPP). This can be avoided by relying on a Quality by Design (QbD) approach.

InfoGraphic



A Sampling of Glass Defects

Glass is the predominant container used within our industry. That's why it's important to identify glass defects. This infographic illustrates a sampling of defects pulled from *PDA Technical Report No. 43 (Revised 2013): Identification and Classification of Nonconformities in Molded and Tubular Glass Containers for Pharmaceutical Manufacturing: Covering Ampoules, Bottles, Cartridges, Syringes, and Vials.*

PDA Letter

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Digital Exclusives

> **On the Issue | Straight-Through Processing: Strategies for Implementation**
Merck's Director of Vaccine Operations **Lisa Sykes** discusses flexible manufacturing.

> A Conversation with Packaging Suppliers
In this Q&A article, representatives from two packaging suppliers discuss the industry's reluctance to embrace new technologies in this area.

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July/August 2017 PDA Letter

2017 PDA/FDA Joint Regulatory Conference

PDA/FDA JRC Show Issue

This year's *PDA/FDA Joint Regulatory Conference* in Washington, D.C., features a slate of sessions covering product quality in an era of innovation. For a preview of these sessions, look for articles with this banner at the top of the page.

PDA's 4th Metrics Conference: Measuring the State of Quality Metrics

32

Stephanie Gaulding, DPS Engineering

The *2017 PDA Quality Metrics and Quality Culture Conference* offered an overview of FDA's recently revised quality metrics guidance and discussion. This summary of the two-day meeting showcases some of the highlights.

Cover Photo by DNY59

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U.S., UK Regulators Share Passion for Quality Culture

Rebecca Stauffer, PDA

Find out what the FDA's **Jeffrey Baker** and MHRA's **David Churchward** had to say about quality culture at PDA's February metrics conference.

Industry Expert Weighs in on Quality Metrics

40

Rebecca Stauffer, PDA

The *PDA Letter* talks to Regulatory Compliance Associates' **Susan Schniepp** about the FDA's quality metrics initiative.

InfoGraphic

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Grounded by Post-Approval Changes

Post-approval changes (PAC) present one of the biggest challenges for our industry. Long approval timelines and lack of collaboration hinder innovation. But how does this impact the industry?

PDA Letter

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> **On the Issue** | Cell & Gene Therapies: Five Keys to Industrialization
Seattle Genetics' Karen Walker discusses how a CAR-T cell therapy was realized

> PQRI Establishes Thresholds for Leachables & Extractables Identification
Find out what PQRI is doing to establish threshold limits for identifying leachables and extractables

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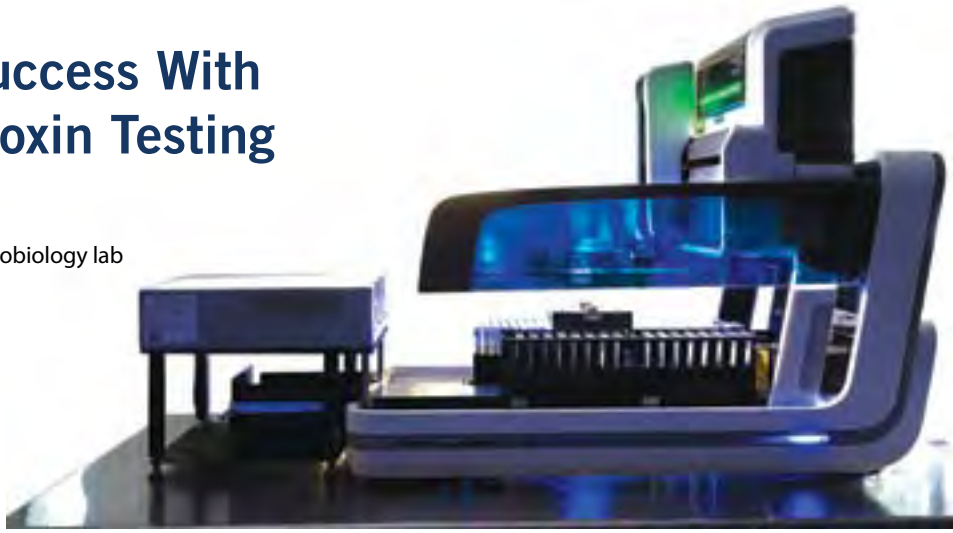
September 2017 PDA Letter

12th Annual PDA Global Conference on Pharmaceutical Microbiology

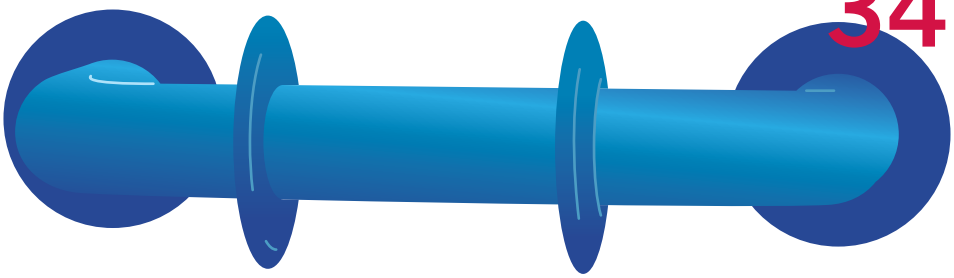
Show Issue

How can today's microbiologists solve the latest pressing challenges in microbial control? By achieving a culture of collaboration. In this spirit, look for articles previewing sessions of this year's microbiology conference with this banner at the top of the page.



Cover Photo Courtesy of Charles River Laboratories

InfoGraphic



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Digital Exclusives

> A Stepwise Approach to Effective Data Management and Analysis
PDA Education Instructor **Gilberto Dalmaso** discusses how to develop a data management plan for environmental monitoring. This is a preview of his course that follows the *12th Annual PDA Global Conference on Pharmaceutical Microbiology.*

> The Future of Cell and Gene Therapies is Here
Both industry and regulators are working together to resolve the challenges of manufacturing new therapies.

> **On the Issue | Continuous Microbial Monitoring: Four Points to Consider**
Pfizer's **Jeffrey Weber** discusses how biofluorescent particle counting can benefit a manufacturer's operations.

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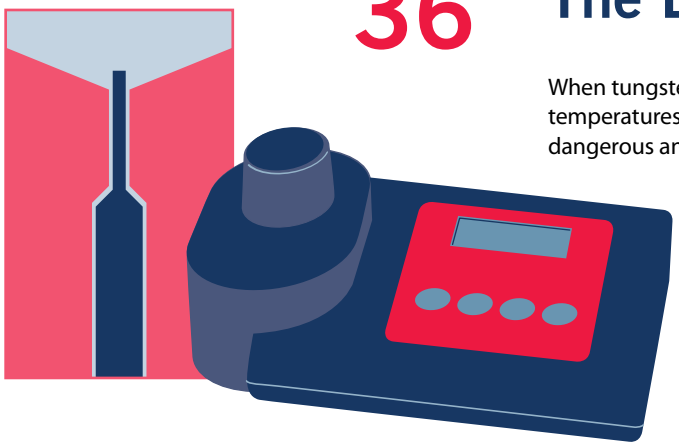
October 2017 PDA Letter

The Universe of Pre-filled Syringes and Injection Devices

Check out the latest advancements in prefilled syringes at the *Universe of Pre-filled Syringes and Injection Devices* in Vienna. For a preview of the sessions and exhibits at the meeting, look for articles with this banner at the top of the page.

Cover Photo Courtesy of Bosch GmbH

InfoGraphic



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Digital Exclusives

> **On the Issue** | Flexibility by Design
NNE's Alex Severin discusses how to design for flexible engineering at the 2nd PDA Europe Annual Meeting in Berlin

> The QC Lab of the Future
Find out what happened when a biologics manufacturer upgraded its laboratory asset management system

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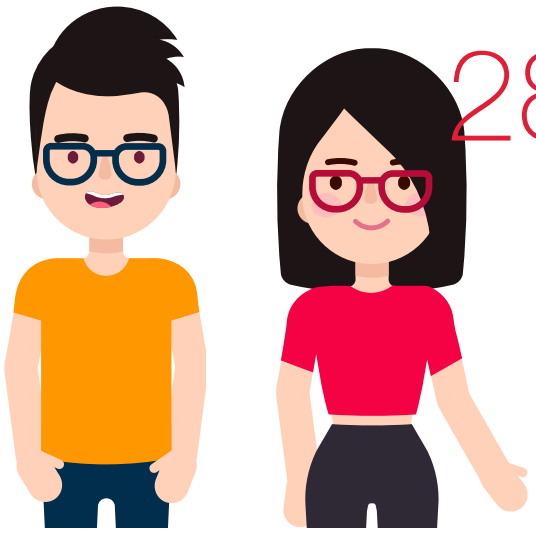
November/December 2017 PDA Letter



Millennials

How Manufacturers Are Training the New Generation of Workers

Rebecca Stauffer, PDA

Millennials recently surpassed Generation Xers as the largest generation in the U.S. labor force. Defined by the U.S. Census Bureau as those born between 1982 and 2000, millennials came of age in a time of great technological change and economic uncertainty. It is no surprise that workplace survey after workplace survey show this generation seeks specific requirements in order to stay fulfilled at their jobs.

Cover Art Illustrated by Karol Keane

InfoGraphic

Gen Xers versus Millennials

How do they differ when it comes to training and technology?

Isolator Surfaces and Contamination Risks to Personnel

GMP Cleaning Requirements for Nonproduct Contact Surfaces

Richard Denk, SKAN AG, et al.

When it comes to protection of cleanroom personnel and product, the possibility for contamination both within and on the exterior of an isolator exists.

AIDC is a Sign of Things to Come

Part I: What is AIDC and How Will it Impact Pharma Manufacturing?

Napoleon Monroe, New Directions Consulting

In 1974, a pack of Wrigley's chewing gum became the first retail item to be scanned with a Universal Product Code (UPC). IBM and the retail industry led the development and implementation of the UPC, but the healthcare industry did not embrace standardized bar coding.

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> **On the Issue** | Next Generation Manufacturing
Amgen's **Arleen Paulino** discusses next generation manufacturing at the company's facility in Singapore at the *2017 PDA/FDA Joint Regulatory Conference.*

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