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### 26 For Combo Products, the Human Factor is Key

Human factors engineering has become an integral component of product development for medical devices, and consequently, combination products. By executing user tests in simulated environments, manufacturers try to determine how consumers will use and interact with the product. If problems arise during testing and manufacturers determine the problems represent moderate to high risk of error, mitigation strategies might be necessary.

Cover Art Illustrated by Katja Yount

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The U.S. FDA Center for Devices and Radiological Health (CDRH) is currently taking steps to finalize a draft guidance on human factors testing, issued in draft form on June 22, 2011.



### 36 RMM Sessions Catch Blogger's Attention

Michael Miller shares his blog posts about the RMM sessions at the 6th Annual PDA Pharmaceutical Microbiology Conference.

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### 26 Lack of Compendia Harmony for Visible Particles Causing Confusion

The major compendia have harmonized the testing methodology and acceptance criteria for subvisible particles; however, the absence of a harmonized guidance for visible particles has led to confusion in the global industry.

### 30 The Importance of Commenting on Public Standards

To ensure items being introduced by USP are appropriate, industry must take the time to participate in the USP commenting process.

### 34 USP Updates Given at PDA's 2011 Micro. Conference

During last year's PDA Micro meeting, the USP stated that they were going to update/revise the existing USP 1223 informational chapter and provide additional guidance with respect to the use of alternative micro methods.

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It is anticipated that further discussions among the constituencies, with focus on control strategy, should lead to the final version of ICH Q 11(Step 4) before the end of the 2nd quarter in 2012.



### 38 Audit Program Part of FDA Pathway for Global Product Safety

The Center for Devices and Radiological Health (CDRH) and the Center for Biologics Evaluation and Research (CBER) are testing a Pilot Multi-Purpose Audit Program in 2012 and 2013 that will allow medical device companies under their jurisdiction to voluntarily submit certain audits and receive Agency inspection relief for one year.

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The Annual Meeting “Career Development Strategies” breakfast session will feature some interesting insights on how to get a job, be promoted and move to a different department.

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### 28 Interview with James Akers On Revised USP <1116>

When the PDA Letter learned that USP Chapter <1116> was updated and about to publish, we went right to the top—the top of the USP Committee of Experts of Microbiology and Sterility Assurance—to find out what is new.



### 32 **2012 PDA ANNUAL MEETING** A Look at New Sterilization Methods

New sterilization methods are always in demand as many products cannot withstand traditional dry and wet heat sterilization. Recent developments in terminal sterilization technologies have allowed biological, combination and sensitive small molecule products to undergo sterilization treatments.

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Determining a drug manufacturer's state licensing obligations is not always straightforward, because states do not have uniform requirements.

Cover Art Illustrated by Katja Yount

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In reaction to an alarming increase of falsified medicines and in order to prevent falsified medicines entering the legal supply chain of medicinal products, the EU Falsified Medicines Directive 2001/62/EC was released in 2011.



### 32 The Benefits and Challenges of Targeted Drug Delivery

Targeted drug delivery that allows precise release of the desired drug to the exact location where it is needed is rapidly progressing.

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### 22 Considerations for Successful Design, Operation and Maintenance of an Ultrapure Water System

Water is undoubtedly the most fundamental requirement in the pharmaceutical manufacturing environment, but it is often an overlooked commodity in terms of maintenance and assurance of low bioburden levels. While multiple preventive measures are implemented into most water purification systems, contamination of the water by microorganisms remains a cause for concern.

### 29 Biofilm Myths

The following was adapted from the presentation, "Design and Control Strategies to Minimize Biofilm Risk," given on April 17, 2012 at the 2012 PDA Annual Meeting.

Cover Art Illustrated by Katja Yount

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The scope of *PDA Technical Report, No. 55, Detection and Mitigation of 2,4,6-Tribromoanisole and 2,4,6-Trichloroanisole Taints and Odors in the Pharmaceutical and Consumer Healthcare Industries* provides guidance on how to detect and mitigate 2,4,6-tribromoanisole and 2,4,6-trichloroanisole taints and odors from tribromophenol-treated wood pallets.



### 36 Tracking (and Tracing) Counterfeits in the Supply Chain

The U.S. FDA is pushing harder for the implementation of track and trace methods for drug products to protect patients from dangerous, low-quality fakes. Recent findings of counterfeit Avastin, a Roche anticancer drug, only heighten FDA's concern over the growing threat to patient safety in the United States.

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## 32 RMM Implementation Case Study Reveals Challenges

Rapid screening ostensibly offers huge advantages over traditional testing methods when it comes to microbial testing in the pharmaceutical industry.

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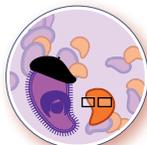
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### 40 A Condensed History of Rapid Screening in Selected Industries

This article highlights the use of rapid screening in other industries and offers a small glimpse of how modern analytical technologies can solve real-world challenges and improve processes.



### 41 Rapid Microbiological Method Myths

The following is part of **Michael Miller's**, PhD, presentation on rapid microbiological methods that he gave at *PDA's 6th Annual Global Conference on Pharmaceutical Microbiology* in 2011.

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### 28 Industry Comes Clean at PDA Annual Meeting

Cleaning: It happens in every manufacturing plant, storage facility and anywhere else a drug product is processed, stored, etc., and it is a vital part of the manufacture of quality, safe products. Whether for a facility, equipment or instruments, cleaning seems like a rather straightforward proposition; yet, there is a lot of science associated with a high-quality cleaning program.

*Cover Art Photographed by Katja Yount, courtesy of Training and Research Institute's Facility*

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Bioburden and ongoing regulatory problems in the manufacture of sterile products are just two of the major issues discussed at the *2012 PDA Innovation & Best Practices on Sterile Technology Conference*. For those who missed it, the cochairs have highlighted the top 10 lessons they learned during the event.



### 38 Current Sterile and Lyo Issues Discussed at Joint IG Session

Interest in the unique requirements for aseptic processing of lyophilized products is heightening with the number of new therapeutics increasing on the market, including many new biopharmaceuticals such as monoclonal antibodies.



### 44 Ensuring a Quality Culture

Pharmaceutical companies can boast about their ability to manufacture products of the highest quality; yet, pressure is mounting on firms to improve their quality culture.

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### 30 Job Aids Slowly Evolve from Paper to Electronic, Move From Shop Floor to Office Suites

For ICU doctors and nurses, the simple and elegant checklist is a valuable, though not common job aid—and not always a welcomed one. Over the last decade, however, checklists for routine ICU procedures have improved medical practitioner performance, saved lives and reduced costs.

Cover Art Illustrated by Katja Yount

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### 24 **Advanced Delivery Systems are Popular, but Pose Challenges for Biotech Injectables**

Momentum behind the use of Prefilled Syringes as a delivery device for injectable drug products has gained so much steam, it is no longer accurate to describe them as “emerging” delivery systems. For sure, they have arrived.

### 28 **Vegas Offers Answers to Your Burning Questions**

Time is flying and the 9<sup>th</sup> *PDA Universe of Pre-filled Syringes and Injection Devices* is just around the corner. This year’s conference, in Las Vegas, brings together the drug delivery marketplace under the theme: “*Integrating the Unmet Market Needs: Bringing it All together for Tomorrow’s Success*”.



### 36 **A Year Later, FDA Issues Updated Endotoxin Testing Guidance**

The U.S. FDA’s new recommendations for pyrogen and endotoxin testing do not replace a more comprehensive 1987 Agency guideline, but they include useful guidance not found elsewhere.



### 40 **Reports from the 2012 PDA/FDA Glass Quality Conference**

More than 500 people participated in the scientific sessions of the conference and discussed market trends in glass quality improvement over the whole drug product lifecycle, June 4-5 in Washington, D.C. The on-site exhibition offered an excellent platform for attendees to further exchange opinions about required improvements in glass quality and to see the latest technologies.

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### 24 Industry Asks FDA to Look to EU for Biosimilar Regulations

On May 11, the U.S. FDA held a public hearing at its White Oak Campus in Silver Spring, Md., to obtain input on three recently issued draft guidances relating to the development of biosimilar products. FDA released the draft documents on Feb. 9 as part of its efforts to implement the Biologics Price Competition and Innovation Act (BPCIA) of 2009.

Cover Art Illustrated by Katja Yount

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### 32 Next Gen Microbiologists Need to Broaden Their Knowledge of Pharma Business

Preparing the workforce of the future for the pharmaceutical industry is an ongoing challenge industry-wide, but is particularly challenging with respect to specialized experts like microbiologists due to the dominance of other areas of expertise, particularly chemistry. Today, there are close to 4,000 microbiologists working in manufacturing in the pharmaceutical industry, compared to over 13,000 chemists. Ultimately, microbiologists make up just over 8% of the scientific staff employed within the industry.



### 38 Audit-Sharing Can Lead to Fewer Supply Chain Headaches

Drug and device companies are often resource-constrained, which can lead to limited resources for auditing contractors and suppliers. While auditing of drug substance and drug product contract manufacturing organizations is a heavy focus, less attention is often given to other materials, such as excipients and chromatography resins, especially during early clinical development. There are, however, safety risks with some commodity excipients and materials (e.g., glycerin and gelatin capsules, to name some recently adulterated materials that made headlines), and there is no way of knowing what material may be adulterated next. It makes sense to use shared resources that are available from independent organizations to help qualify material suppliers and to monitor supply chain issues.

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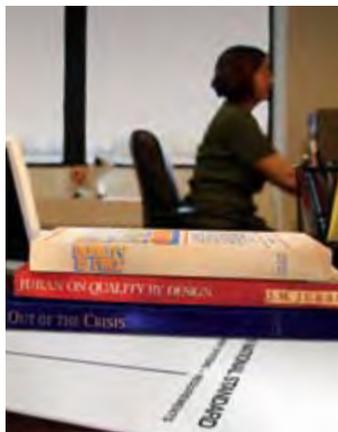
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## 22 QbD Offers Opportunities, Challenges for Vaccine Makers

Can both quality improvements and reductions in regulatory burden be realized by vaccine manufacturers who use the Quality by Design approach? Three FDA representatives shared their views on this very topic at PDA's *Applying QbD Principles in Vaccine Development* workshop in May to address this question and other questions regarding QbD and its viability to a cohort of manufacturers that has not readily adopted QbD.

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Are pharmaceutical quality systems too complex to be effective? According to an industry expert and a regulator, they are, and an injection of simplicity will help manufacturers improve quality performance.



### 32 **Make a Lasting Impression During Preapproval Inspection**

Everyone knows how important first impressions are. From a first date to a job interview, being prepared is always critical, and the lack of preparation can have lasting negative effects. This is especially true for preapproval/prelicensing inspections. Preparation for this event is key, even for companies with products already on the market, for the preapproval inspection is *the* moment to demonstrate to the regulatory authorities that your firm is able to produce a quality drug product.

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