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### 28 Compounding in the United States: A Retrospective

Compounding is the art and science of preparing medications for an individual patient either by a pharmacist or under the supervision of a pharmacist, pursuant to an order from a licensed prescriber. The compounding pharmacist can combine individual ingredients in the exact strength and dosage form to meet a patient's specific needs. This can be necessary if commercially available medication is inappropriate for a specific patient due to clinical reasons, such as allergies to dyes or other ingredients, or due to population factors, including newborns, children and the elderly. Sometimes the medication may be compounded due to a shortage of manufactured product.

Cover photo courtesy of Mierlo-Hout, [www.mierlohout.nl](http://www.mierlohout.nl)

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### 32 PDA Members Discuss Compounding Events' Impact on Industry

The following is a discussion among PDA members about the impact of the pharmaceutical compounding problems that surfaced in 2012/2013 and the impact on industry. The discussion occurred during the Q&A following the opening plenary presentations at the *2013 PDA Aseptic Processing-Sterilization Conference* in Chicago, Ill., June 20–21. This discussion is abridged for space considerations. The full transcript of the proceedings, including slides, is available at the PDA Bookstore, [www.pda.org/bookstore](http://www.pda.org/bookstore).

### 33 Quality Metrics Conference Shapes PDA Agenda

Over 300 industry experts on drug product quality and manufacturing assembled to participate in breakout discussions and select the most important and useful quality metrics. The interactive sessions were set up to assist a PDA task force draft a points to consider report on pharmaceutical quality metrics, which PDA intends to submit to the U.S. FDA in December.



### 34 Solutions Available for Compounders

This issue's infographic showcases PDA services that offer solutions for issues faced by those involved in sterile compounding.

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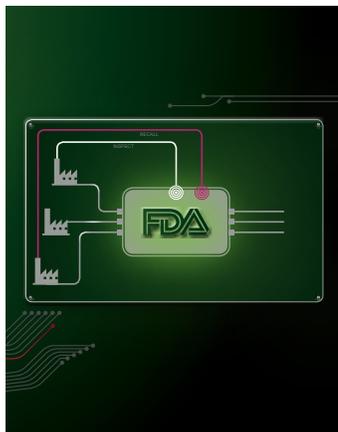
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## 22 PDA Responds to FDA's Call for Quality Metrics Recommendations

PDA answered the U.S. FDA's Center for Drug Evaluation and Research (CDER) call for help in identifying quality metrics that can be used for the Center's new drug quality enforcement initiative by connecting people, science, and regulation.

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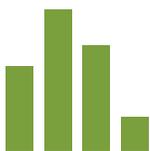
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### 28 Metric Session Readout Reports Highlight Industry Views

We are presenting a modified transcript from the breakout session readouts during the closing plenary session of the *2013 PDA Pharmaceutical Quality Metrics Conference* held Dec. 9–10 in Bethesda, Md. Here, **Anil Sawant, PhD, Joyce Bloomfield, Glenn Wright and Sue Schniepp**, who all served as facilitators for the conference's breakout sessions, discuss participants' selections of particular metrics and the reasons behind them.



### 34 PDA PtC ID's Range of Useful Metrics

This issue's infographic showcases recommended metrics developed and discussed during the *2013 PDA Pharmaceutical Quality Metrics Conference*.

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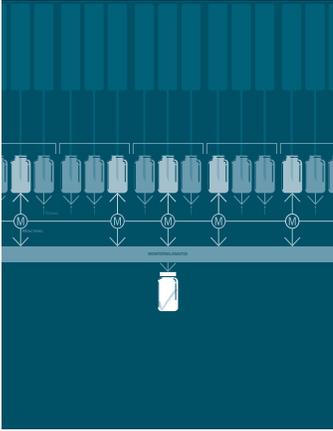
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## 22 **2014 PDA ANNUAL MEETING** The Changing Landscape of Release Testing for Sterile Drug Products

Has the time finally arrived when parametric release and real-time release can be implemented for sterile drug products, even those manufactured in aseptic processes without a sterilization phase, perhaps ultimately leading to a parametric release-like program for aseptically processed products?

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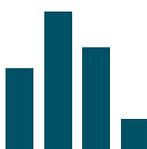
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### 26 **2014 PDA ANNUAL MEETING** Innovations Offer Solutions for Vaccine Supply Limitations

A variety of factors have caused shortages in the marketplace for vaccines, but outdated manufacturing processes and lack of characterization stand out as some of the most prevalent, if not correctable, factors. Regulators across the globe and manufacturers are searching for ways to stabilize vaccine supplies.



### 32 **2014 PDA ANNUAL MEETING** The 2014 PDA Annual Meeting by the Numbers

This issue's infographic breaks down the 2014 PDA Annual Meeting, showing the percentage of topics addressed for attendees.

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### 24 USP Looks at Future of Microbiology With New Standards

From a microbiological perspective, pharmaceutical products fall into two categories, nonsterile and sterile. For either category, manufacturers must eliminate or minimize potential health risks to patients related to microorganisms and the toxins they produce, while also maintaining product quality. Many contributing factors may affect the quality of a medicine or its ingredients, but microbial bioburden control and proper sterilization methods are critical considerations for the manufacturer throughout the product's lifecycle.

Cover Art Illustrated by Katja Yount

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### 30 Industry, Regulators Meet to Drive QbD Implementation

Since the first QbD workshop held in 2009, industry and regulators have continued working together to advance implementation of QbD principles. In January, PDA Europe organized a workshop to address continued progress in this area at the EMA's London headquarters. This workshop was co-chaired by **Jean-Louis Robert**, National Health Laboratory EP (Luxembourg) and Chair of the EMA Quality Working Party, and **Georges France**, Novartis, for the European Federation of Pharmaceutical Industry and Associations (EFPIA).



### 33 Pharmacopoeias: The European System

This infographic spotlights the European Pharmacopoeia and its governance structure.

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### 22 **Adapting Development Guidelines for Advanced Therapies**

Traditional pharmaceutical manufacturing is very familiar to all of us. It is easy to picture the conventional setup whereby a company maintains a facility involving large batch manufacturing in an assembly line fashion, manages extensive supply chains and creates product with lengthy shelf lives.

Cover Art Illustrated by Katja Yount

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### Developing an Effective Manufacturing Control Strategy for Cellular Therapy Products

Successful commercialization of a cellular therapy product requires the development of the best quality product to suit patient needs.



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### The State of Advanced Therapies

This issue's infographic shows the number of approved advanced therapy products in Europe and the United States broken down by category.

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### 28 Drug Manufacturers Face More “How to Do” CMC/GMP Requirements in Europe

Pharmaceutical manufacturers increasingly are facing more detailed “how to do” requirements focusing on a widening scope of activities (e.g., distribution) in Europe as the European Union continues to upgrade CMC and GMP requirements.

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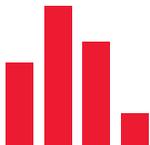
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The rate of ongoing changes to European pharmaceutical legislation and guidance are at an unprecedented level. Many are likely to have a profound impact on the industry over the next five years and some will require significant investment.



### 37 PDA Letter InfoGraphic: U.S. vs EU Process Val Guidances

This issue's infographic details some of the similarities and differences between European and U.S. process validation regulations.

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### 32 Industry, FDA Still Wary of Supply Chain Security

Public confidence in pharmaceutical products has waned in recent years based on patient harm caused by adulteration, drug shortages and poor quality resulting in recalls. Along with concern for patient safety, pharmaceutical professionals at all levels within their organizations have become keenly aware of the potential for damage to the company brand by such incidents.

*Cover photo courtesy of Jim Greipp of Pau Hana Productions for Custom Processing Services (www.customprocessingservices.com). This photo depicts the GMP blending suite with two all-stainless double-ribbon blenders at Custom Processing Services' dedicated GMP facility in Reading, PA. As a CMO, CPS follows ICH Q7A and their API processing conforms to part 210/211 of CFR 21 from the U.S. FDA.*

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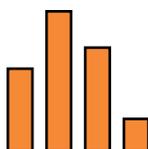
### 36 Outsourcing Management: Key Component of a QMS

Regulatory agencies hold firms responsible for delivering high quality products that meet all established requirements and specifications. Suppliers and vendors (most recently referred to as “outsourced materials and services”) play a key role in meeting GMP mandates, and it is a firm’s responsibility to make sure vendors/suppliers are meeting specifications for the supplied materials, components, equipment and/or services.



### 40 CMO Vet of 40+ FDA Inspections Discusses Reg Landscape

**Robert Darius**, VP, Regional Quality Unit, GSK Biologicals, interviewed **Joachim del Boca** for his thoughts on FDA’s aseptic processing guidance, harmonization, regulatory inspections and the role of Quality Agreements. Joachim del Boca, VP of Regulatory Affairs and Quality Compliance at Vetter, a contract development and manufacturing organization, has 31 years in the industry and is a veteran of over 40 U.S. FDA regulatory inspections.



### 44 Five Typical Mistakes Found in Quality Agreements

This issue’s infographic highlights some typical mistakes found in Quality Agreements with CMOs.

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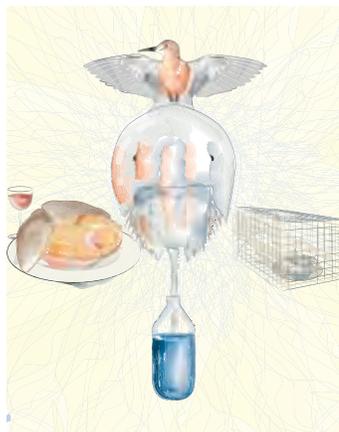
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### 26 Will a Shorebird Knot Up Bacterial Endotoxin Assay Supplies?

The remarkable red knot shorebird has one of the longest migrations of any bird—over 9,000 miles from the southern tip of South America to the Arctic. That's 18,000 miles round trip. A long annual journey made possible by its many stops on South American and North American Atlantic shores.

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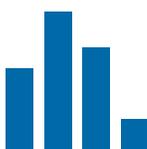
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### 30 Proposed USP Chapter on Nonsterile Bioburden Long Overdue But Clarification Still Needed

USP's microbiology-related chapters continue to evolve and a new one is wending its way through the pharmacopoeial pathway. The new chapter, with a focus on nonsterile products, is unique and much needed.



### 34 Common Areas of Cleanroom Contamination

This issue's infographic details areas of a typical cleanroom that often face contamination risks.

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### 26 Career Advancement Strategies Without the Noise

What hot skills are pharmaceutical and biopharmaceutical companies looking for today? What jobs are most in demand? What do companies want in their quality and regulatory or their manufacturing and process science professionals including those at the Director and Vice President levels? Can you give me some advice on my resume?

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### 31 Reduce Human Error in a GMP Facility

Pharmaceutical companies often cite human error as the sole cause of a manufacturing deviation or noncompliance issue. For medical device manufacturers, identifying and reducing the occurrence of human error is commonly part of the regulatory and overall risk management process, but for pharmaceutical facilities, the assessment of human error in the workplace is not always so rigorously assessed during deviation investigations.



### 34 Skillsets and Training: Aseptic vs. Solid Dosage Operators

This issue's infographic shows some of the different training and on-the-job requirements for aseptic vs. sterile dosage operators.

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### 32 Keeping the Signals Clear: Industry and FDA Collaborate on Innovation

The *PDA/FDA Joint Regulatory Conference* offers a chance for regulators and members of industry to share information and discuss the pressing issues of the day. This year, two attendees—one with the U.S. FDA and the other with a pharmaceutical company—took the time to share their insights of the conference. Not surprisingly, both noted the spirit of collaboration that marked this year's joint regulatory conference.

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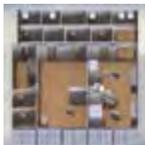
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### 36 **Amgen's Next Gen Manufacturing: A Conversation with Madhu Balachandran**

On September 2, the *PDA Letter's* **Walter Morris** interviewed **Madhu Balachandran**, Executive Vice President, Amgen, Inc. on manufacturing of the future in advance of his presentation at the *PDA/FDA Joint Regulatory Conference* on September 8. Balachandran answered questions about Amgen's "Next Generation Manufacturing" facility opening soon in Singapore.



### 40 **Key Takeaways From the 2014 PDA Drug Shortage Workshop**

Learn about the latest data on drug shortages in this issue's infographic which utilizes information presented at this year's drug shortages workshop.

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