

Cover



Proposed CDER Office Seeks to Change Quality Paradigm in Industry

Many industries set high standards for quality and base their branding on achieving high quality goals. This is most notable in the automobile industry, where carmakers such as Toyota (the Toyota Way) and Ford (Quality is Job 1) made it their corporate missions to promote the quality of their vehicles. And when quality defects impact their products (failing tires for Ford; unintended acceleration/brake problems for Toyota), the companies' sales take a big hit.

Cover Art Illustrated by Katja Yount

Departments

News & Notes

- 6 PDA Survey: Business Case for Pharmaceutical Quality

People

- 8 **PDA Volunteer Spotlight:** Anil Sawant
9 NE Chapter Celebrates 2012 Aboard *Spirit of Boston*
10 **Faces & Places:** PDA's 7th Annual Global Conference on Pharmaceutical Microbiology
14 **Tools for Success:** Micromanaging vs. Coaching

Science

- 16 **Science Snapshot:** PDA Publishing Activities up in 2012; TR Portal Introduced; **Interest Group:** Cold Chain IG Explores Use of Thermal Blankets; **Tech Trends:** Options Abound for Shipping Cold Chain Product
19 PDA Recognized By *BioProcess International*

Regulation

- 36 FDA Remembers Kefauver-Harris Amendments
38 Regulatory Briefs

Programs & Meetings

- 40 Zoom Off to the Future at the 2013 Annual Meeting
41 Follow Up on the Latest Process Validation Trends

TRI — Education

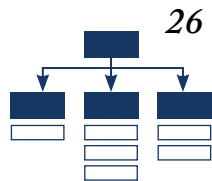
- 42 TRI to Offer Five-Day Cold Chain Training Course Series

Voices of PDA

- 44 **Voices of the Board:** The Vetting of Technical Report No. 60, *Process Validation : A Lifecycle Approach*
46 Editor's Message

Contents

Features



26

New CDER Office Seeks Improved Pharma Supply Chain

It has been 18 months since the U.S. FDA reorganized CDER's Office of Compliance, designating it as a "Super Office" and creating a number of new "Offices" within it: Office of Drug Security, Integrity, and Recalls (ODSIR), Office of Manufacturing and Product Quality (originally the Division of Manufacturing and Product Quality), Office of Scientific Investigations, and the Office of Unapproved Drugs and Labeling Compliance.



30

Microbiologists Key in Preventing Contamination

"If you see something, say something" has been the mantra of numerous homeland security agencies across the country and worldwide for over a decade. While aimed mostly at commuters, this message can also be applied to the microbiologists diligently working to identify microbial contaminants in the pharmaceutical industry.

PDA's MISSION

To develop scientifically sound, practical technical information and resources to advance science and regulation for the pharmaceutical and biopharmaceutical industry through the expertise of our global membership

PDA's VISION

To be the foremost global provider of science, technology, and regulatory information and education for the pharmaceutical and biopharmaceutical community



Connecting People, Science and Regulation®

EXECUTIVE STAFF

Richard Johnson
President

Robert Dana
Sr. VP, Regulatory Affairs & TRI

David Hall
VP, Sales

Wanda Neal
VP, Programs & Registration Services

Craig Elliott
CFO

Adrienne Fierro
VP, Marketing Services

Rich Levy, PhD
Sr. VP, Scientific & Regulatory Affairs

Georg Roessling, PhD
Sr. VP, PDA Europe

PDA BOARD OF DIRECTORS

OFFICERS

Chair: Anders Vinther, PhD
Genentech

Chair-Elect: Harold Baseman
ValSource

Treasurer: Rebecca Devine, PhD
Regulatory Consultant

Secretary: Steven Mendivil
Amgen

Imm. Past Chair: Maik Jornitz
Sartorius Stedim Biotech

DIRECTORS

Ursula Busse, PhD
Novartis

Ian Elvins
Lonza AG

Gabriele Gori
Novartis

Michael Sadowski
Baxter Healthcare

Sue Schniepp
Allergy Laboratories

Christopher Smalley, PhD
Merck

Jette Christensen
Novo Nordisk

John Finkbohner, PhD
MedImmune

Stephen Rönninger
F. Hoffmann-La Roche

Junko Sasaki, *Dainippon*
Sumitomo Pharmaceuticals

Lisa Skeens, PhD
Baxter Healthcare

Glenn Wright
Eli Lilly

Cover



Cover Art Illustrated by Katja Yount

20 Making the Case for QbD in Vaccine Development

Is it time for vaccine manufacturers to consider utilizing QbD principles in vaccine development? Leading experts from both industry and regulatory think so, and cite the A-VAX case study as proof.

Departments

News & Notes

- 6 PDA TRI CPE Credits Go Electronic, Will No Longer Be Mailed

People

- 7 **PDA Volunteer Spotlight:** Marsha Hardiman
9 New Keck Student Chapter Hosts First Event
10 **PDA Photostream:** 2012 Cold Chain Management & Good Distribution Practice Conference; 2012 PDA/FDA Pharmaceutical Supply Chain Conference; 2012 Parenterals & Rapid Microbiological Methods Training Seminar

Science

- 14 **Science Snapshot:** Experts Explore QRM in Upcoming Technical Reports; Tech **Trends:** Plant-Based Production Grows Up; Insect Cell Production Offers Less Bugs; Interest Group **Corner:** Vaccines IG Seeks to Expand Regulatory Discussion; Journal **Preview:** Jan/Feb Issue Covers Hot Topics

Regulation

- 36 Regulatory Briefs

Programs & Meetings

- 38 Workshop to Showcase Analytical Method Lifecycle Steps
39 Human Factors Affect the Manufacturing Environment
40 Next PDA/FDA Glass Quality Conference is on the Horizon

TRI — Education

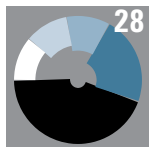
- 42 TRI Combines Viral Filtration and Viral Spikes Courses

Voices of PDA

- 44 **Voices of the Board:** Board of Directors Includes Two New Members; PDA Bids Farewell to Two Board Members
46 Editor's Message

Contents

Features



QbD and Vaccines: PDA IG Members' View

The PDA Letter worked with the Vaccines Interest Group to conduct this survey on QbD in vaccines manufacturing to get a sense for the uptake of QbD principles within their operations, and if not, why. We also wanted to ascertain what QbD means to their companies.



Networking, PDA Involvement Keys to Success for Lisa Skeens

Are you looking to make a career change in the coming year? Do you want to move up to a management position? Are you curious what skills hiring managers are looking for in potential hires? The beginning of a new year marks a time when many people evaluate their careers and make plans look for a new role or explore options outside of their current employer. With this in mind, the *PDA Letter* reached out to Lisa Skeens, PhD, Vice President of Global Regulatory Affairs at Hospira, and PDA Board Member.



Parenterals Conference Draws 200 to Spain

Almost 200 professionals from the pharmaceutical industry, from technology and equipment suppliers to government agencies convened in Barcelona, Spain Nov. 6-7 for the *2012 PDA Parenterals: Contribution of Biologics to Public Health*. This symposium focused on the manufacture of biopharmaceutical products. Presentations covered numerous areas impacting the manufacturing of biopharmaceuticals, including: new guidelines on manufacturing and validation, manufacturing environment, manufacturing technologies, components (such as elastomers, containers, devices and efficiency), and cost and compliance.

PDA's MISSION

To develop scientifically sound, practical technical information and resources to advance science and regulation for the pharmaceutical and biopharmaceutical industry through the expertise of our global membership

PDA's VISION

To be the foremost global provider of science, technology, and regulatory information and education for the pharmaceutical and biopharmaceutical community



Connecting People, Science and Regulation®

EXECUTIVE STAFF

Richard Johnson
President

Robert Dana
Sr. VP, Regulatory Affairs & TRI

David Hall
VP, Sales

Wanda Neal
VP, Programs & Registration Services

Craig Elliott
CFO

Adrienne Fierro
VP, Marketing Services

Rich Levy, PhD
Sr. VP, Scientific & Regulatory Affairs

Georg Roessling, PhD
Sr. VP, PDA Europe

PDA BOARD OF DIRECTORS

OFFICERS

Chair: Anders Vinther, PhD
Genentech

Chair-Elect: Harold Baseman
ValSource

Treasurer: Rebecca Devine, PhD
Regulatory Consultant

Secretary: Steven Mendivil
Amgen

Imm. Past Chair: Maik Jornitz
G-Con

DIRECTORS

Ursula Busse, PhD
Novartis

Ian Elvins
Lonza AG

Gabriele Gori
Novartis

Michael Sadowski
Baxter Healthcare

Sue Schniepp
Allergy Laboratories

Christopher Smalley, PhD
Merck

Jette Christensen
Novo Nordisk

John Finkbohner, PhD
MedImmune

Stephan Rönninger
F. Hoffmann-La Roche

Junko Sasaki, *Dainippon*
Sumitomo Pharmaceuticals

Lisa Skeens, PhD
Hospira

Glenn Wright
Eli Lilly

Cover



18 Global Regulators Address Role of Quality in Shortages, Seek Solutions

Health authorities worldwide are grappling with the surge in drug product shortages that has been exacerbated by recent plant closures at a few large generic injectable manufacturers. The U.S. FDA, the EMA and other regulatory authorities are seeking solutions that ensure an ample supply of medication without sacrificing quality and endangering patients.


Cover Art Illustrated by Katja Yount

Departments



News & Notes

- 6 Denyse Baker Joins PDA as Sr. Regulatory Advisor
- 7 Elizabeth Junker Joins PDA Journal Editorial Team
- 7 Members Raise Nearly 15K for Sandy Victims

People

- 8 **Volunteer Spotlight:** Mauro Giusti
- 9 PDA Taking the Initiative in India
- 10 **PDA Photostream:** PDA PIC/S Training: GMP for APIs
- 12  Join in the Fun with Fellow PDA Members at Annual


Science

- 14 **Science Snapshot:**  Single-Use Systems TR Coming Soon; Preview the Topic at Annual Meeting;  **Annual Meeting Preview:** Interest Group, Task Force and Advisory Board Meeting Schedule; **Task Force Corner:** Objectionable Microorganisms TF to Release Survey; **Tech Trends:** Companies Expanding LMS to Include Content


Regulation

- 34  Hot Regulatory Topics on Agenda
- 36 Regulatory Briefs

Programs & Meetings

- 38  Expand Your Expertise at Annual
- 40 Human Factors Impact Pharma Manufacturing
- 41 Experts to Discuss Glass Quality at May Conference
- 42 Lifecycle Approach Key to Process Validation

TRI — Education

- 43  TRI Offers One-of-a-Kind Courses Following Annual Meeting

Voices of PDA

- 44 Reflections — And Look Ahead
- 45 President's Message
- 46 Editor's Message

Contents

Features



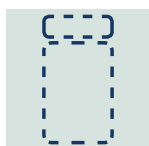
26 Industry Views on Quality-Related Shortages

Karen Ginsbury, PCI, and Tricia Griffiths, EMD Millipore, respond to the FDA's concerns



28 Drug Shortages in the United States: A Snapshot

Using information from the recent *Clinical Pharmacology & Therapeutics* article on drug shortages, plus information from other sources, the *PDA Letter* developed an infographic showcasing the various reasons behind the shortages.



30 **2013 PDA ANNUAL MEETING** Annual Meeting Plenary Talk to Address Shortages

The recent article by Janet Woodcock, MD, Director, CDER, U.S. FDA, and Marta Wosinska, PhD, Director, Economics Staff, CDER, FDA, explored the link between quality-related manufacturing issues and shortages of generic injectable drugs (see story on p. 18). So, what can manufacturers do to alleviate the issue of drug shortages? And how can quality serve as a guide throughout the entire manufacturing process?

PDA's MISSION

To develop scientifically sound, practical technical information and resources to advance science and regulation for the pharmaceutical and biopharmaceutical industry through the expertise of our global membership

PDA's VISION

To be the foremost global provider of science, technology, and regulatory information and education for the pharmaceutical and biopharmaceutical community



Connecting People, Science and Regulation®

EXECUTIVE STAFF

Richard Johnson
President

Robert Dana
Sr. VP, Education

David Hall
VP, Sales

Wanda Neal
VP, Programs & Registration Services

Craig Elliott
CFO

Adrienne Fierro
VP, Marketing Services

Rich Levy, PhD
Sr. VP, Scientific & Regulatory Affairs

Georg Roessling, PhD
Sr. VP, PDA Europe

PDA BOARD OF DIRECTORS

OFFICERS

Chair: Anders Vinther, PhD
Genentech

Chair-Elect: Harold Baseman
ValSource

Treasurer: Rebecca Devine, PhD
Regulatory Consultant

Secretary: Steven Mendivil
Amgen

Imm. Past Chair: Maik Jornitz
G-Con

DIRECTORS

Ursula Busse, PhD
Novartis

Ian Elvins
Lonza AG

Gabriele Gori
Novartis

Michael Sadowski
Baxter Healthcare

Sue Schniepp
Allergy Laboratories

Christopher Smalley, PhD
Merck

Jette Christensen
Novo Nordisk

John Finkbohner, PhD
MedImmune

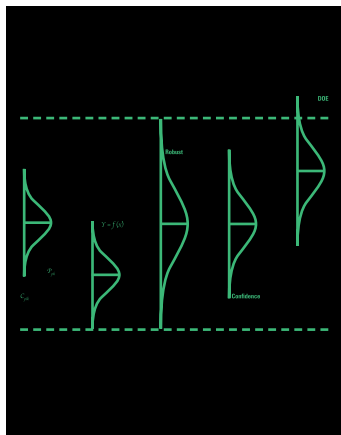
Stephan Rönninger
F. Hoffmann-La Roche

Junko Sasaki, *Dainippon*
Sumitomo Pharmaceuticals

Lisa Skeens, PhD
Hospira

Glenn Wright
Eli Lilly

Cover



18 Risk and Statistics Serve as Tools for Solving Variation Riddles and Creating Robust Processes

How much variation is acceptable in our products and processes? For such a simply stated question, the answer can be quite complex, especially when applied to drug product Stage 2 testing (Process Performance Qualification, or PPQ). It is a question industry needs to begin answering at the initiation of Stage 1 activities, with risk management as the key tool and driver in assisting to solve variation riddles and help drive knowledge management

Cover Art Illustrated by Katja Yount

Departments

News & Notes

- 6 Nominate Your PDA Peers for the Board of Directors
- 6 Process Validation Technical Report Now Available
- 7 Three Reg Speakers Confirmed for Process Val Workshop

People

- 8 **PDA Volunteer Spotlight:** Edward Balkovic
- 10 PDA Metro Chapter Learns the Fine Art of Investigations
- 12 **Tools For Success:** 5 Reasons You Need to Be on LinkedIn Even When You Have a Job

Science

- 14 **Science Snapshot: In Print:** PDA Survey: Business Case for Pharmaceutical Quality; **Journal Preview:** March/April Issue Covers Hot Topics; **Tech Trends:** ACS Roundtable Develops App for Greener Pharma; **AB Report:** BioAB Keeps Pace With Emerging Biotech Trends; **Journal Preview:** The PDA Journal – at the Confluence of Academia, Government, and Industry

Regulation

- 32 **Regulatory Snapshot:** PDA to Comment on WHO GMP Draft Guidelines
- 33 Regulatory Briefs
- 34 Will FDA Combo Rule Help Pharma with Quality Systems?

Programs & Meetings

- 36 Learn About New Regulations at Process Val Workshop
- 36 Joint Reg Conference Offers Key Learning Objectives
- 37 Workshop Showcases Investigations Methods
- 38 Stay Ahead of the Curve at the 2013 Micro Conference
- 39 Secure Your Place for the Supply Chain Workshop
- 40 Protect Drugs, Biologics With Container Closure Systems
- 40 Experts to Discuss Assuring Glass Quality at Conference
- 41 Virus and TSE Safety Forum Focuses on Emerging Issues
- 41 Aseptic Processing – Sterilization Conference Returns to Chicago

TRI — Education

- 42 Technical Reports Mined to Create Distinct TRI Courses

Voices of PDA

- 44 **Voices of the Board:** Advancing the PDA Strategic Plan
- 46 **Editor's Message:** The Changing Validation Landscape

Contents

Features



26 U.S. vs E.U. Process Val Guidances

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



28 U.S. FDA Offering "Q" Metrics for Payers – A Good Idea

In March, the *PDA Letter* sat with Amgen's **Martin VanTrieste** to discuss the impact quality-related problems in the pharmaceutical industry is having on the marketplace for drug products. Prompting the conversation was the article by two U.S. FDA officials in which they suggested that the lack of market reward for high quality products. The FDA authors also suggest that the Agency could help consumers and healthcare payors better understand quality's important role by offering "meaningful manufacturing quality metrics." The *PDA Letter* analyzed this article and other regulatory initiatives worldwide (see the cover story of the March 2013 *PDA Letter*).

PDA's MISSION

To develop scientifically sound, practical technical information and resources to advance science and regulation for the pharmaceutical and biopharmaceutical industry through the expertise of our global membership

PDA's VISION

To be the foremost global provider of science, technology, and regulatory information and education for the pharmaceutical and biopharmaceutical community



Connecting People, Science and Regulation®

EXECUTIVE STAFF

Richard Johnson
President

Robert Dana
Sr. VP, TRI

Rich Levy, PhD
Sr. VP, Scientific & Regulatory Affairs

Georg Roessling, PhD
Sr. VP, PDA Europe

Craig Elliott
CFO

David Hall
VP, Sales

Wanda Neal
VP, Programs & Registration Services

PDA BOARD OF DIRECTORS

OFFICERS

Chair: Anders Vinther, PhD
Genentech

Chair-Elect: Harold Baseman
ValSource

Treasurer: Rebecca Devine, PhD
Regulatory Consultant

Secretary: Steven Mendivil
Amgen

Imm. Past Chair: Maik Jornitz
G-Con

DIRECTORS

Ursula Busse, PhD
Novartis

Ian Elvins
Lonza AG

Gabriele Gori
Novartis

Michael Sadowski
Baxter Healthcare

Sue Schniepp
Allergy Laboratories

Christopher Smalley, PhD
Merck

Jette Christensen
Novo Nordisk

John Finkbohner, PhD
MedImmune

Stephan Rönninger
Amgen

Junko Sasaki, *Dainippon*
Sumitomo Pharmaceuticals

Lisa Skeens, PhD
Hospira

Glenn Wright
Eli Lilly

Cover



18 Take Charge of Your Career! Practical Guidelines for Career Planning and Advancement

Careers can be summarized as the time a person spends working at their individual jobs and all of the experiences, education and professional relationships that go along with those jobs. However, career planning and advancement often defines what a person's body of work will look like and the degree of satisfaction they will gain. Many times we see people owning what they perceive to be their career, only to be taken back a step when challenged as to what they truly are striving for professionally, or put another way, what is the last seat they desire to sit in prior to retirement.

Departments

News & Notes

- 6 Four Reg Speakers Announced for Virus Safety Forum
- 6 PDA Participates in VISION PHARMA Conference
- 7 Volunteers Needed to Support PDA in St. Petersburg, Russia

People

- 8 PDA Volunteer Spotlight: Karl Kussow
- 10 NE Chapter Celebrates 25th Year with Jam-Packed Schedule
- 12 Tools For Success: 8 Reasons Why You Never Hear Back After Applying for a Job

Science

- 14 **Science Snapshot:** Technical Report Involvement Produces Career Results; **In Print:** PDA Survey: Glass Quality: 2011 and 2012 Results and Comparison; **Tech Trends:** Laser Tech Offers New Tool for Cleaning Verification; **Task Force Corner:** TF Behind TR33 Revision Expects Positive Impact

Regulation

- 32 PDA Comments on Draft Regulation—The Impact is Clear
- 34 PDA Suggests Expanding Discussions on Drug Shortages
- 35 Regulatory Briefs

Programs & Meetings

- 36 Industry and Regulators to Talk About Quality
- 36 Forum Focuses on Standardizing Inspections
- 38 The Future of Microbiology Comes to Maryland
- 39 Link Up at the Next Supply Chain Event
- 40 Protect Your Biologics From Viral Contamination
- 40 Aseptic Returns to Chicago
- 41 Quality Systems Key to Improving Investigations

TRI — Education

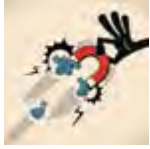
- 42 Training Offers Advancement Opportunities

Voices of PDA

- 44 PDA's Volunteer Opportunities Help Make Members the Cornerstone of the Association
- 46 Editor's Message: Responding to Member Needs: Career Development

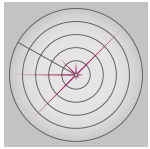
Contents

Features



28 Pharma Manufacturing Recruitment in 2013—and Beyond

Since the Great Recession took hold, the pharmaceutical manufacturing sector has held a unique position in the economy. Traditionally, and according to the U.S. Bureau of Labor Statistics, this industry has not been prone to wavering economic conditions. After all, when we are sick, we still need our medicine. We still need the innovative work of the pharmaceutical industry to keep us healthy so we can cope with all the other challenges that life brings.



30 U.S. Pharma Manufacturing Jobs in 2012

This issue's infographic uses 2012 data from the U.S. Bureau of Labor Statistics to build a profile for the state of management, science and production jobs in drug manufacturing.

PDA's MISSION

To develop scientifically sound, practical technical information and resources to advance science and regulation for the pharmaceutical and biopharmaceutical industry through the expertise of our global membership

PDA's VISION

To be the foremost global provider of science, technology, and regulatory information and education for the pharmaceutical and biopharmaceutical community



Connecting People, Science and Regulation®

EXECUTIVE STAFF

Richard Johnson
President

Robert Dana
Sr. VP, TRI

David Hall
VP, Sales

Wanda Neal
VP, Programs & Registration Services

Craig Elliott
CFO

Amelia Townsend
Director, Marketing Services

Rich Levy, PhD
Sr. VP, Scientific & Regulatory Affairs

Georg Roessling, PhD
Sr. VP, PDA Europe

PDA BOARD OF DIRECTORS

OFFICERS

Chair: Anders Vinther, PhD
Genentech

Chair-Elect: Harold Baseman
ValSource

Treasurer: Rebecca Devine, PhD
Regulatory Consultant

Secretary: Steven Mendivil
Amgen

Imm. Past Chair: Maik Jornitz
G-Con

DIRECTORS

Ursula Busse, PhD
Novartis

Ian Elvins
Lonza AG

Gabriele Gori
Novartis

Michael Sadowski
Baxter Healthcare

Sue Schniepp
Allergy Laboratories

Christopher Smalley, PhD
Merck

Jette Christensen
Novo Nordisk

John Finkbohner, PhD
MedImmune

Stephan Rönninger
Amgen

Junko Sasaki, *Dainippon*
Sumitomo Pharmaceuticals

Lisa Skeens, PhD
Hospira

Glenn Wright
Eli Lilly

Cover



22 Should Scientific Data Determine Cytotoxic Limits?

Over the past few years, regulatory bodies have explored the issue of exposure limits during the manufacture of cytotoxic drugs in multipurpose facilities. A recent draft EMA guideline and the proposed revisions to chapters 3 and 5 of the EU GMPs appear to propose the use of toxicological data along with some rather stringent and apparently not scientifically based criteria to determine exposure limits when working with potent/highly potent drugs.

Cover Art Illustrated by Katja Yount

Departments

News & Notes

- 6 What Does PDA Offer You? New Benefits Guide Available
- 6 Over 30 Regulators Appearing at PDA's Sept. Events
- 7 PDA Honors Contributors at Annual Meeting Banquet

People

- 8 PDA Volunteer Spotlight: Daikichiro Murakami
- 10 Missouri Valley Chapter Explores Process Validation Topic
- 12 PDA Photostream: 2013 PDA Annual Meeting

Science

- 18 **Science Snapshot:** PDA Surveys Enhance Industry Knowledge, Support TRs; **Journal Preview:** May–June Issue Explores Drug Delivery, Other Topics; **Tech Trends:** Single-Use Technology Can Reduce Oxidation; **Journal POV:** Microbial Risk in Pharmaceutical Manufacturing and ICH Q9; **Interest Group Corner:** Sterile Processing IG Explores Investigations Issues
- 20 Important Considerations for Aseptic Processing Validation

Regulation

- 34 PDA Comments on European GDP Guidelines
- 37 Regulatory Briefs

Programs & Meetings

- 38 Are You Current?
- 40 Workshop Addresses Monoclonal Antibody Complexities
- 41 Protect Your Biologics From Viral Contamination

TRI — Education

- 42 In-House Aseptic Training Offers Many Advantages

Voices of PDA

- 44 PDA Technical Reports: Built on a Foundation of Science
- 46 Awards, Photos, History, Podcast and a Correction!

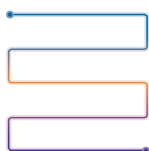
Contents

Features



28 **BD Moves into Sterile Injectables Market**

This March, BD Rx, a wholly owned subsidiary of BD (Becton, Dickinson and Company), received approval for the first product in the company's line of BD Simplist™ prefilled injectables. BD Rx plans to roll out 20 to 30 more generic sterile injectable drug products over the next few years, including some products that have been in the news as being in shortage. This development has occurred at a time when significant numbers of generic injectables are in shortage, a situation the *PDA Letter* analyzed in the March 2013 cover story. Becton Dickinson opened a facility in 2010 in Wilson, N.C. specifically dedicated to manufacturing these products—the first U.S. facility dedicated to sterile manufacturing built in many years.



32 **Sterile Product Manufacturing: A History**

This issue's infographic highlights key moments in the history of the manufacture of sterile products within the industry.

PDA's MISSION

To develop scientifically sound, practical technical information and resources to advance science and regulation for the pharmaceutical and biopharmaceutical industry through the expertise of our global membership

PDA's VISION

To be the foremost global provider of science, technology, and regulatory information and education for the pharmaceutical and biopharmaceutical community



Connecting People, Science and Regulation®

EXECUTIVE STAFF

Richard Johnson President	Craig Elliott CFO	Robert Dana Sr. VP, TRI	David Hall VP, Sales
Wanda Neal Sr. VP, Programs & Registration Services	Rich Levy, PhD Sr. VP, Scientific & Regulatory Affairs	Georg Roessling, PhD Sr. VP, PDA Europe	Amelia Townsend Director, Marketing Services

PDA BOARD OF DIRECTORS

OFFICERS

Chair: Anders Vinther, PhD <i>Genentech</i>	Chair-Elect: Harold Baseman <i>ValSource</i>	Treasurer: Rebecca Devine, PhD <i>Regulatory Consultant</i>	Secretary: Steven Mendivil <i>Amgen</i>	Imm. Past Chair: Maik Jornitz <i>G-Con</i>
--	---	--	--	---

DIRECTORS

Ursula Busse, PhD <i>Novartis</i>	Ian Elvins <i>Lonza AG</i>	Gabriele Gori <i>Novartis</i>	Michael Sadowski <i>Baxter Healthcare</i>	Sue Schniepp <i>Allergy Laboratories</i>	Christopher Smalley, PhD <i>Merck</i>
Jette Christensen <i>Novo Nordisk</i>	John Finkbohner, PhD <i>MedImmune</i>	Stephan Rönninger <i>Amgen</i>	Junko Sasaki, <i>Dainippon</i> <i>Sumitomo Pharmaceuticals</i>	Lisa Skeens, PhD <i>Hospira</i>	Glenn Wright <i>Eli Lilly</i>

Cover



28 Management, We Have a Problem

Over the past decade, several large pharmaceutical companies have entered into consent decrees with the U.S. FDA and it seems that the Agency has increased its use of this enforcement tool. So far, very few companies have been successful in terminating a consent decree with the FDA. One of the few companies that successfully completed the items agreed upon with the FDA, and demonstrated continuous compliance with cGMPs, is Abbott Laboratories. This article discusses the main pitfalls in dealing with a consent decree and methods for handling one.

Cover Art Illustrated by Katja Yount

Departments

News & Notes

- 6 Over 30 Regulators Scheduled to Speak in Sept.
- 7 PDA Selected as 2013 Best of Bethesda Winner
- 7 PDA in the News

People

- 8 **Volunteer Spotlight:** Ghada Haddad
- 9 Meet Some Most Valuable PDA Volunteers (MVPs)
- 10 Southern California Chapter Cruises to a Successful Night
- 12 **PDA Photostream:** 2013 PDA/FDA Container Closure Components and Systems Workshop; 2013 PDA/FDA Glass Packaging Conference; 2013 PDA/FDA Process Validation Workshop; 2013 PDA/FDA Pharmaceutical Supply Chain Workshop
- 18 Association Membership Impacts Hiring Decisions
- 18 PDA Thanks Chapter Leaders for Attending Annual Meeting
- 19 **Tools For Success:** 10 Ways to Get Ahead in a Bad Economy

Science

- 20 **Science Snapshot:** **Technical Report Watch:** Technical Report No. 3 Revised; **Meeting Preview:** Interest Group Meeting Schedule; **Interest Group Corner:** New Interest Group Tackles Combination Products; **In Print:** Setting Controls for Endotoxins; **Tech Trends:** Parenterals Enter the Regenerative Medicines Era; **Task Force Corner:** Task Force Plans Revision to Technical Report No. 27
- 26 Low Endotoxin Recovery (LER) in Drug Products

Regulation

- 40 **Regulatory Snapshot:** July/August 2013 RAQAB Quarterly Report; **Interest Group Corner:** Procedure Follow Through is a Major Concern; **Meeting Preview:** Interest Group Meeting Schedule
- 42 About Continued and Continuous Process Verification
- 44 Human Factors Remains Prime Topic for Industry, U.S. FDA
- 46 PDA Comments on Risk Assessments for Excipient GMPs

Programs & Meetings

- 48 Explore the Evolving Regulatory Landscape
- 48 New Technologies Highlighted at Virus Detection Conference
- 50 Learn the Latest in Analytical Methods this October
- 51 Micro Conference Offers an Overview of Hot Topics
- 52 Prevent Inadequate Investigations by Attending Workshop
- 53 Hone Your Skills at the Visual Inspection Forum
- 53 Meet European Prefilled Syringe Suppliers This Fall

TRI — Education

- 54 Three New QRM Courses Follow Joint Reg Conference

Voices of PDA

- 56 Voices from the Board: PDA and U.S. FDA Working Together to Prevent Drug Shortages By Developing Sound Quality Metrics
- 58 Editor's Message

Contents

Features

34 Regulators to Offer Perspectives on Investigations, Metrics at Joint Regulatory Conference

The PDA Letter spoke with **Rick Friedman**, Associate Director, OMPQ, CDER, and **Mahesh Ramanadham**, PharmD, Acting Team Leader, OMPQ/OC, both from the U.S. FDA and members of the planning committee for the *2013 PDA/FDA Joint Regulatory Conference*. Friedman is also the co-chair for the subsequent *2013 PDA/FDA Improving Investigations Workshop*. Friedman and Ramanadham were excited to discuss topics of interest that will be discussed at the conference and workshop.



36 cGMPs Continue to Evolve as U.S. FDA Expands Regulatory Authorities Under FDASIA

The U.S. Food and Drug Administration Safety and Innovation Act (FDASIA), passed last year, includes provisions that give the U.S. FDA greater statutory authorities with regard to cGMPs. The PDA Letter spoke with **Cathy Burgess**, Partner, Alston & Bird, who will speak about the evolution of cGMPs as they relate to the FDASIA legislation during the third plenary session at the upcoming *2013 PDA/FDA Joint Regulatory Conference*.



38 Common Elements of a Consent Decree with the U.S. FDA

This issue's infographic looks at some of the common elements of consent decrees.

PDA's MISSION

To develop scientifically sound, practical technical information and resources to advance science and regulation for the pharmaceutical and biopharmaceutical industry through the expertise of our global membership

PDA's VISION

To be the foremost global provider of science, technology, and regulatory information and education for the pharmaceutical and biopharmaceutical community



Connecting People, Science and Regulation®

EXECUTIVE STAFF

Richard Johnson
President

Robert Dana
Sr. VP, TRI

David Hall
VP, Sales

Wanda Neal
VP, Programs & Registration Services

Craig Elliott
CFO

Amelia Townsend
Director, Marketing Services

Rich Levy, PhD
Sr. VP, Scientific & Regulatory Affairs

Georg Roessling, PhD
Sr. VP, PDA Europe

PDA BOARD OF DIRECTORS

OFFICERS

Chair: Anders Vinther, PhD
Genentech

Chair-Elect: Harold Baseman
ValSource

Treasurer: Rebecca Devine, PhD
Regulatory Consultant

Secretary: Steven Mendivil
Amgen

Imm. Past Chair: Maik Jornitz
G-Con

DIRECTORS

Ursula Busse, PhD
Novartis

Ian Elvins

Gabriele Gori
Novartis

Michael Sadowski
Baxter Healthcare

Sue Schniepp
Allergy Laboratories

Christopher Smalley, PhD
Merck

Jette Christensen
Novo Nordisk

John Finkbohner, PhD
MedImmune

Stephan Rönninger
Amgen

Junko Sasaki, *Dainippon*
Sumitomo Pharmaceuticals

Lisa Skeens, PhD
Hospira

Glenn Wright
Eli Lilly

Cover



28 Roadmap to External Manufacturing Partnerships

The pharmaceutical industry is increasingly reliant on outsourcing to progress products from development through commercial registration. The times of building large facilities and staff to support all facets of drug development and registration is becoming less and less common and only achievable by the largest of companies. Instead, companies now share responsibilities with specialized external manufacturing partners (EMPs) to build tangible value, focusing on core competencies. A strategic partnership is an asset that adapts as the product pipeline, technology platforms and requirements develop over time.

Cover Art Illustrated by Katja Yount

Departments

News & Notes

- 6 Cast Your Ballots for PDA Officers and Directors

People

- 12 **PDA Volunteer Spotlight:** Stefan Merkle
- 14 **Chapter Update:** Canada Chapter Explores Logistics Concerns
- 15 **Chapter Update:** PDA India Chapter Hosts Inaugural Convention
- 15 **PDA Pulse:** PDA Members Prefer Both Print and Online Versions of the PDA Letter
- 16 **PDA Photostream:** 2013 Advanced Therapy Medicinal Products
- 18 **Tales from the Trail:** President Takes PDA Message Across the Globe
- 20 **Tools for Success:** PDA Chair Recommends Escaping Comfort Zone to Achieve Success

Science

- 22 **Science Snapshot:** Microbiology Technical Reports Offer New Best Practices; **Journal Preview:** September–October Issue Looks at Leachables and Extractables; **Tech Trends:** Industry Seeks Sterility Test Answers for PET Drugs; **In Print:** Suggestions for Developing Load Patterns for Continuous Tunnels
- 24 Expanded Microbiologist Role in Process Design, Operations?

Regulation

- 38 **Regulatory Snapshot: Interest Group Corner:** Interest Groups Discuss Supply Chain Issues at Joint Meeting During Supply Chain Workshop; **Haily's Comments:** KFDA Reorganization
- 40 PDA Comments on Risk Identification in Shared Facilities
- 41 Regulatory Briefs

Programs & Meetings

- 42 Change is the Only Constant for Microbiologists
- 43 Save the Date for the 2014 PDA Annual Meeting
- 44 PDA to Explore Quality Metrics at December Conference
- 45 Check Out New Viral Detection Technology this Fall

TRI — Education

- 46 TRI Offers Menu of Aseptic Processing Course Options

Voices of PDA

- 48 **Voices of the Board:** PDA Expanding Discourse With Global Regulators
- 50 Editor's Message

Contents

Features



32 **Micro Contamination Prevention Remains Big Concern for Manufacturers of Nonsterile Products**

The microbiological control of finished nonsterile products remains a prime concern among pharmaceutical manufacturers. The paucity of regulatory guidance does not help. In 2011, **Erik Greb** wrote: "So far, no regulatory authority has set formal microbial-control standards for the manufacture of nonsterile dosage forms".



36 **Biopharmaceutical Manufacturing Outsourcing in 2013**

This issue's infographic uses data from BioPlan Associates' 2013 survey of biopharmaceutical manufacturers to highlight outsourcing trends within the industry.



ATTENTION READERS:

We'd like your input on the PDA Letter. Please complete our Readership Survey, available online at www.surveymonkey.com/s/JBQWRF7. The survey ends Sept. 30.

PDA's MISSION

To develop scientifically sound, practical technical information and resources to advance science and regulation for the pharmaceutical and biopharmaceutical industry through the expertise of our global membership

PDA's VISION

To be the foremost global provider of science, technology, and regulatory information and education for the pharmaceutical and biopharmaceutical community



Connecting People, Science and Regulation®

EXECUTIVE STAFF

Richard Johnson
President

Robert Dana
Sr. VP, TRI

David Hall
VP, Sales

Wanda Neal
VP, Programs & Registration Services

Craig Elliott
CFO

Amelia Townsend
Director, Marketing Services

Rich Levy, PhD
Sr. VP, Scientific & Regulatory Affairs

Georg Roessling, PhD
Sr. VP, PDA Europe

PDA BOARD OF DIRECTORS

OFFICERS

Chair: Anders Vinther, PhD
Genentech

Chair-Elect: Harold Baseman
ValSource

Treasurer: Rebecca Devine, PhD
Regulatory Consultant

Secretary: Steven Mendivil
Amgen

Imm. Past Chair: Maik Jornitz
G-Con

DIRECTORS

Ursula Busse, PhD
Novartis

Ian Elvins
Elvins & Associates

Gabriele Gori
Novartis

Michael Sadowski
Baxter Healthcare

Sue Schniepp
Allergy Laboratories

Christopher Smalley, PhD
Merck

Jette Christensen
Novo Nordisk

John Finkbohner, PhD
MedImmune

Stephan Rönninger
Amgen

Junko Sasaki, *Dainippon*
Sumitomo Pharmaceuticals

Lisa Skeens, PhD
Hospira

Glenn Wright
Eli Lilly

Cover



18 Key Factors for Validating A Disposable System

Adopting and implementing single-use systems involves more than a simple use of disposable items. Essentially, adopters expect to transfer critical control parameters like sterility and cleanliness to a third party. The validation and quality control strategy followed by the end user will then shift to a process of building a partnership with the supplier to gain assurance and set measurable performances.

Cover Art Illustrated by Katja Yount

Departments

News & Notes

- 7 Attention PDA Bookworms, We Want to Hear From You!
- 7 Membership Survey Now Online

People

- 8 **PDA Volunteer Spotlight:** Melissa Seymour
- 10 Student Chapter Leader Recognized as Member of the Year
- 10 **PDA Pulse:** PDA Members Prefer Electronic Resources for Sterilization Intel
- 13 **Tools For Success:** Follow These 3 LinkedIn Tips if You Recently Changed Careers

Science


- 14 **Science Snapshot:** PDA Talks PUPSIT in Dublin at EU Regulations Meeting; Follow-Up on Low Endotoxin Recovery (LER) in Biologics; **Tech Trends:** Molded Vials Offer New Territory for Manufacturers; **Task Force Corner:** Anticipated TR Offers Single-Use Roadmap



Regulation

- 32 **Regulatory Snapshot:** RAQAB Quarterly Report Q3 2013
- 34 Track and Trace Offers Way to Combat Counterfeiting
- 36 United States is Now a Listed Country in the European Union
- 36 2013 U.S. FDA Guidance Finalizes 2009 Guidance

Programs & Meetings

- 38  Polymer Offers Potential Glass Alternative
- 38 Navigate the Industry by Attending Next Year's Annual Meeting
- 40 Conference Addresses Viral Contamination Challenges
- 41 Participate in Quality Metrics Discussion this December

TRI — Education

- 42 TRI Provides a Different Type of Learning Experience

Voices of PDA

- 44 **Voices of the Board:** PDA Leads Development of New Aseptic Technology
- 46 **Editor's Message:** The PDA Letter: Not Just for Single Use

Contents

Features



23 **New Technologies Bring Device Training to Patients**



As patients, healthcare providers and other industry participants increase the demand for treatments that improve lives, there remains a significant preexisting condition within the healthcare industry: patient adherence. Most treatment outcomes rely heavily on adherence and compliance to ensure healthy outcomes. Therefore, the future success of new treatments is directly associated with solutions designed to improve adherence rates, making the timing optimal for new designs to accelerate the transfer of knowledge related to these treatments.



28 **Company Relies on Comprehensive Approach to Address New Combo Product Rule**



Earlier this year, the U.S. FDA issued its final rule on cGMPs for combination products, which went into effect this July. This new rule specifies that companies manufacturing combination products can satisfy cGMPs by demonstrating compliance with applicable rules on a separate basis of by meeting the cGMP regulation and relevant 21 CFR 820 requirements or meeting quality system regulations (QSR) and 21 CFR requirements. The *PDA Letter* spoke with **Katja Kotter**, Director of Regulatory Affairs and Quality Compliance, Vetter Pharma, who will speak about the new FDA guideline at PDA's upcoming *Universe of Pre-filled Syringes and Injection Devices* conference.



30 **SUS Supply is a Complex Journey**

This issue's infographic explores the complex journey that accompanies supplying a single-use system using information from the upcoming PDA technical report on the subject.

PDA's MISSION

To develop scientifically sound, practical technical information and resources to advance science and regulation for the pharmaceutical and biopharmaceutical industry through the expertise of our global membership

PDA's VISION

To be the foremost global provider of science, technology, and regulatory information and education for the pharmaceutical and biopharmaceutical community



Connecting People, Science and Regulation®

EXECUTIVE STAFF

Richard Johnson
President

Robert Dana
Sr. VP, TRI

David Hall
VP, Sales

Wanda Neal
VP, Programs & Registration Services

Craig Elliott
CFO

Amelia Townsend
Director, Marketing Services

Rich Levy, PhD
Sr. VP, Scientific & Regulatory Affairs

Georg Roessling, PhD
Sr. VP, PDA Europe

PDA BOARD OF DIRECTORS

OFFICERS

Chair: Anders Vinther, PhD
Genentech

Chair-Elect: Harold Baseman
ValSource

Treasurer: Rebecca Devine, PhD
Regulatory Consultant

Secretary: Steven Mendivil
Amgen

Imm. Past Chair: Maik Jornitz
G-Con

DIRECTORS

Ursula Busse, PhD
Novartis

Ian Elvins
Elvins & Associates

Gabriele Gori
Novartis

Michael Sadowski
Baxter Healthcare

Sue Schniepp
Allergy Laboratories

Christopher Smalley, PhD
Merck

Jette Christensen
Novo Nordisk

John Finkbohner, PhD
MedImmune

Stephan Rönninger
Amgen

Junko Sasaki, *Dainippon*
Sumitomo Pharmaceuticals

Lisa Skeens, PhD
Hospira

Glenn Wright
Eli Lilly

Cover



Cover Art Illustrated by Katja Yount

32 Crossover Moves

In basketball, a well-executed crossover move gives the ball handler a clear path to the basket. There, she can either dish off for an assist or score an easy layup. The *PDA Letter* staff has identified another kind of crossover move—the career crossover. This happens when a professional with a long track record in the industry leaves to join a regulatory agency, or vice versa. When played well, this crossover opens up a clear path to professional growth and fulfillment. The *PDA Letter* editors interviewed six individuals who executed this move in recent years.

Departments

News & Notes

- 6 Put Your Touch on the *PDA Letter*
- 6 Readership Survey Winner Announced
- 6 Attention PDA Bookworms!
- 7 PDA In The News

People

- 8 **PDA Volunteer Spotlight:** Claudio Cappai Correa
- 9 Metro Chapter Examines Warning Letter Trends
- 9 Singapore Becomes Latest PDA Chapter
- 10 UK Chapter's Single-Use Systems Workshop Proves Worthwhile
- 11 **PDA Pulse:** Hiring Managers 50/50 on Foreign Language Proficiency
- 12 PDA/FDA JRC "Neophytes" Provide Real-Time Updates
- 14 **Tools For Success:** Crash and Burn: Toxic Errors in a Resume
- 16 PDA Photostream: 2013 PDA/FDA Joint Regulatory Conference

Science

- 22 **Science Snapshot:** Risk Assessment During Drug Product Design: Being Proactive; Journal **Preview:** Tech **Trends:** Autoinjectors Present Challenges and Future Outlook; Task Force **Corner:** Blow/Fill/Seal Task Force Promises "Robust" TR
- 24 Validation and Qualification of Sterile Filtration for INDs
- 28 ATMPs Offer Exciting Drugs, Face Age-Old GMP Challenges

Regulation

- 42 **Regulatory Snapshot:** Interest Group **Corner:** Clinical Trial Materials IG Explores Outsourcing Models; Interest Group **Corner:** Metrics Should be "Meaningful," Advises Regulator
- 44 FDA Public Meeting Addressed FDASIA Supply Chain Provisions
- 45 Another Successful ICH Q10 PDA/FDA Workshop
- 46 **PDA Comments:** What Constitutes Limiting Inspections
- 47 Regulatory Briefs

Programs & Meetings

- 49 Reinvent the Future in April at the 2014 PDA Annual Meeting
- 50 Maximize Your Knowledge
- 51 Biopharm Manufacturing Conference Keeps Pace
- 52 Parenteral Packaging No Longer an Afterthought

TRI — Education

- 54 2013 – Another Good Year for PDA TRI

Voices of PDA

- 56 Enhancing Value for Our Global Membership
- 57 President's Message
- 58 Editor's Message

Contents

Features



38 A Sampling of Sought-After Industry/U.S. FDA Jobs

This issue's infographic looks at some recent job openings in industry and regulatory.



40 Reports from the 2013 PDA/FDA Joint Regulatory Conference

Around 1300 people participated in the 2013 PDA/FDA Joint Regulatory Conference, held in Washington, D.C. Sept. 16–18. This was the highest attendance figure in the history of this annual event, as asserted by PDA Chair, **Anders Vinther**, PhD, during the opening plenary session.

PDA's MISSION

To develop scientifically sound, practical technical information and resources to advance science and regulation for the pharmaceutical and biopharmaceutical industry through the expertise of our global membership

PDA's VISION

To be the foremost global provider of science, technology, and regulatory information and education for the pharmaceutical and biopharmaceutical community



Connecting People, Science and Regulation®

EXECUTIVE STAFF

Richard Johnson
President

Robert Dana
Sr. VP, TRI

David Hall
VP, Sales

Wanda Neal
VP, Programs & Registration Services

Craig Elliott
CFO

Amelia Townsend
Director, Marketing Services

Rich Levy, PhD
Sr. VP, Scientific & Regulatory Affairs

Georg Roessling, PhD
Sr. VP, PDA Europe

PDA BOARD OF DIRECTORS

OFFICERS

Chair: Anders Vinther, PhD
Genentech

Chair-Elect: Harold Baseman
ValSource

Treasurer: Rebecca Devine, PhD
Regulatory Consultant

Secretary: Steven Mendivil
Amgen

Imm. Past Chair: Maik Jornitz
G-Con

DIRECTORS

Ursula Busse, PhD
Novartis

Ian Elvins
Elvins & Associates

Gabriele Gori
Novartis

Michael Sadowski
Baxter Healthcare

Sue Schniepp
Allergy Laboratories

Christopher Smalley, PhD
Merck

Jette Christensen
Novo Nordisk

John Finkbohner, PhD
MedImmune

Stephan Rönninger
Amgen

Junko Sasaki, *Dainippon*
Sumitomo Pharmaceuticals

Lisa Skeens, PhD
Hospira

Glenn Wright
Eli Lilly