People • Science • Regulation

PDA Letter

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Calling All Active PDA Members. Vote Now.

Online voting is now open for the 2015 PDA Board of Directors Election

PDA members, online voting has opened for the 2015 **PDA Board of Directors Election**. Take a moment and vote for your candidates of choice.

All PDA members in good standing as of **midnight on August 30, 2014 are eligible to vote**. Voting closes at **11:59 p.m. EST on November 15, 2014**. All votes cast after this date and time will not be accepted.

If you need assistance with your password or member ID, please contact PDA at +1 (301) 656-5900 or vote@pda.org.

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NOVEMBER 2014

NEW COURSE

ICH Q10 and Beyond

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The goal of the course is to enable the participants to evaluate the status of their Pharmaceutical Quality System and have ideas on how to improve it, eventually leading to operational excellence.

Recommended Practices for Manual Aseptic Processes

November 12-13 | Bethesda, Maryland

www.pda.org/map2

Provides valuable practical insights into the technological challenges associated with designing, operating and evaluating manual aseptic processing.

Quality Systems for Aseptic Processing

GSA Schedule Contract GS-02F-113BA

November 17-21 | Bethesda, Maryland

www.pda.org/quality

This five-day comprehensive training program, taught by leading industry experts, will cover risk management, sterility by design, investigations and CAPA, how to effectively implement change within a structured regulated environment and much more!

DECEMBER 2014

2014 Lyophilization Week

GSA Schedule Contract GS-02F-113BA

December 1-4 | Bethesda, Maryland

www.pda.org/lyoweek2014

Learn about the development of lyophilized products and the validation of lyophilization processes with the Fundamentals of Lyophilization and Validation of Lyophilization courses.

Quality Metrics: Performance Indicators

December 5 | Washington, DC

www.pda.org/metricscourse

This course will help you select the appropriate quality metrics, determine how best to collect the data and how to use the data to improve the Quality System.

Risk-based Qualification of Sterile Drug Product Manufacturing Systems

NEW COURSE

December 8-10 | Bethesda, Maryland

www.pda.org/risk

This new course is designed to teach students the techniques for effective qualification and validation of sterile drug product manufacturing systems.

For more information on these and other upcoming PDA education courses, please visit www.pda.org/courses

Laboratory Courses

The PDA Training and Research Institute is accredited by the Accreditation Council for Pharmacy Education (ACPE) as a provider of continuing pharmacy education.

PDA Letter

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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?

Cover Art Illustrated by Katja Yount

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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.

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

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

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BioPharm International

May 1, 2014

"Linking Drug Shortages and Quality Metrics"
— Susan Schniepp
tinyurl.com/qczdpk8

July 1, 2014

"Industry Seeks Clearer Standards for Track and Trace"
— Jill Wechsler
tinyurl.com/kafa5vv

September 1, 2014

"The Relevance of Industry Technical Associations"
— Hal Baseman
tinyurl.com/ndt5kvy

BioProcess International

May 1, 2014

"Qualification of Scale-Down Bioreactors: Validation of Process Changes in Commercial Production of Animal-Cell-Derived Products, Part 1 — Concept"
— Yuval Shimoni, Chetan Goudar, Marc Jenne and **Venkatesh Srinivasan**
tinyurl.com/k8gt476

June 1, 2014

"Industry Experts Convene in New York to Discuss Latest Innovations: A BPI Special Report"
— Alison D. Center and **S. Anne Montgomery**
tinyurl.com/kpqrkme

Drug Industry Daily

September 9, 2014

"FDA Clarifies Industry Fears of New Inspection Guidance"

FDANews

September 12, 2014

"FDA to Tackle Manufacturing Quality Issues Early in Premarket Reviews"

Healthcare Packaging

September 4, 2014

"Universe of pre-filled syringes and injection devices"
— David Hall
tinyurl.com/oqnoc76

Healthline News

July 21, 2014

"Shortages of Prescription Drugs Reported Nationwide"
— Susan J. Bliss
tinyurl.com/kb2w799

IPQ Monthly Update

July 2014

"Top Deficiencies Found in CDER's Micro Review of Submissions Include Incomplete Information on Validation of Aseptic and Terminal Processes"

"FDA Will Support Efforts to Upgrade Micro Methods and Processes, CDER Reviewer Affirms"

"FDA Cautioning Industry on Looming Initial Track and Trace Deadlines"

"APEC's Assessment of Gaps in Supply Chain Regulation Reveals Surprising Differences in Country Approaches"

IPQ News in Depth

August 23, 2014

"Transparent Discussions, Long-term Relationships and Global Event Monitoring Mark Amgen's Supply Oversight Program"

Packaging Europe

July 23, 2014

"Groninger at PDA conference in Istanbul"
tinyurl.com/m74hzvn

PHARMABIZ.com

July 10, 2014

"Adoption of technological procedures to limit microbial contamination during drug production necessary: Dr S B Rijhwani"
tinyurl.com/qzkrvfh

Pharmaceutical Compliance Monitor

May 23, 2014

"Give Me a M-E-T-R-I-C-S – Go Quality Metrics!"
— Neil Wilkinson
tinyurl.com/otr65s3

Pharmaceutical Executive

Sept. 22, 2014

"FDA Readies Quality Metrics Measures"
— Jill Wechsler
tinyurl.com/kwefm8b

Pharmaceutical Manufacturing

July 8, 2014

"Finding Pharma Manufacturing's Innovation ROI"
— Steven Kuehn
tinyurl.com/oo564o3

September 11, 2014

"PDA Prepares New Drug Shortage Prevention Guidance"
tinyurl.com/pscakl6

Pharmaceutical Technology

August 2, 2014

"Risk Reduction Top Driver for Biopharmaceutical Raw Material Development"
— Cynthia Challener
tinyurl.com/oechrtv

September 9, 2014

"PDA Announces Technical Report on Drug Shortages"
tinyurl.com/orrd9h5

ProPharma Group Newsletter

August 2014

"Should we aim for Quality or Compliance?"
— Jeff Hargroves

PDA Drug Shortages Task Force Plans 2015 Technical Report

At a press conference during the *2014 PDA/FDA Joint Regulatory Conference* in Washington, D.C., PDA announced its plans to publish a technical report on the prevention and management of drug shortages. PDA has assembled a team of volunteers representing large and small pharmaceutical and biopharmaceutical manufacturers to develop an industry guidance on this critical topic. The technical report, planned for publication in early 2015, will introduce two unique foundational concepts:

1. A risk-based triage on how to establish end-to-end controls for drug shortage risks based on criticality of the product and the overall product risk evaluation
2. A holistic framework and template for establishing a drug shortage prevention and response plan

"PDA is pleased to be working on this important initiative in support of regulatory initiatives in the U.S. and EU," said PDA President **Richard Johnson** at a press conference held at the Renaissance Hotel in Washington, D.C. during the conference. "PDA's activities in quality risk management started in 2009, and the Association has published four technical reports on the topic since then."

This series of PDA technical reports started with *Technical Report No. 54: Implementation of Quality Risk Management for Pharmaceutical and Biotechnology Manufacturing Operations,* published in 2012; three annexes to that report have subsequently been published. The new drug shortage document will continue that series.

PDA also announced at the press conference that a revised "PDA Points to Consider: Pharmaceutical Quality Metrics" document is ready for publication in the *PDA Journal of Pharmaceutical Science and Technology* later this month. The revised paper includes definitions of various quality metrics and is intended to prompt discussion at the second PDA workshop on quality metrics scheduled for this December.

PDA Chair **Hal Baseman,** ValSource, former PDA Director and RAQAB Co-Chair **Susan Schniepp,** Allergy Laboratories, and **Denyse Baker,** PDA Senior Advisor, Scientific/Regulatory Affairs, joined Richard Johnson during the press conference.

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PDA Volunteer Spotlight

Austin Caudle

- Senior Manager of Business Development
- *NSF Health Sciences*
- Member Since | 2012
- Current City | Raleigh, North Carolina
- Originally From | Charlotte, North Carolina

Companies change and people move around, but the relationships that you build at PDA are a constant

Austin's favorite board game is Monopoly

What is something you learned/ gained from PDA that you couldn't have gotten anywhere else?

Networking opportunities. I met a lot people that I would have never met. There is no way that I would have met them otherwise.

Which PDA conference is your favorite? Why?

The *PDA/FDA Joint Regulatory Conference* because the U.S. FDA officials are very engaged, and that attracts a lot of industry leaders. It gives direction for the rest of the year and helps these leaders generate ideas for their annual "toolbox."

What would you say to a PDA member who has never attended a chapter event?

Chapter events allow you to get to know people better. You develop a better rapport with people in your local area and it is easier to make a tangible difference. You are more likely to meet your next boss because they are in the same area. Five years down the road these are the people that you can count on.

What challenges do you foresee for your segment of pharma? And how can they be overcome?

Sometimes it is difficult to find the decision makers and influencers; PDA helps me to meet them and participate in conversations with them. I sat in on a planning meeting with the PDA board once. These are industry leaders.

What is the best professional leadership book you have read? Why?

Who Moved My Cheese? It was a simple, quick read and very provocative at only 50 pages. Makes you think about where you are and where you want to be.

What is your favorite joke?

Don't sweat the small stuff. It's the small things that count. So, which one is it?

What was your least favorite subject in school?

Art, because I cannot draw.

Topical Electronic Compilations from PDA/DHI in PDF Format

Written by subject matter experts, these chapters are organized by topic and excerpted from all volumes in the Contamination Control in Healthcare Manufacturing series edited by Russell L. Madsen and Jeanne Moldenhauer.

Designing and Controlling Water Systems

- Design and Sanitization of Water Systems to Prevent Contamination
  Teri C. Soli
- Use of Ozonated Water as an Aid to Contamination and Biofilm Control
  Bruce Hinke and Brian G. Hubka
- Real Time Microbial Analyzer for Water
  J. P. Jiang
- Impact of Biofilms in Contamination Control
  Lucia Clontz

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Mold and Fungal Contamination

- Fungal and Bacterial Spores
  Jim Polarine, Carol Bartnett and Dan Klein
- Understanding, Preventing, and Remediating Mold in Cleanrooms
  Ziva Abraham
- Microbial Control: Mold
  Brian G. Hubka
- Microbial Decontamination Using Chlorine Dioxide Gas
  Kevin Lorcheim

Item No. 17967

Contamination Risk Assessment

- Contamination Control Risk Assessment
  Tim Sandle
- Contamination Risks and the Patient
  Mark Hunter, Michelle Luebke, and Mark Pasmore
- New Risk Assessment Tools for Sterile Products
  Gunther Gapp
- Risk Management of Microbial Contamination Control in Aseptic Processing and Interventions Risk Assessment Model (IREM)
  Hal Baseman and Mike Long

Item No. 17968

New!

Cleaning and Disinfection

- Facility Design and Control
  Anne Marie Dixon
- Selecting an Appropriate Process Cleaning Detergent
  Mark Compo
- Assessing Resistance and Appropriate Acceptance Criteria of Biocidal Agents
  Art Vellutato
- Cleaning Validation: Process Life Cycle Approach
  Paul Lopolito and Elizabeth Rivera

Item No. 17969

Sources and Control of Microbial Contamination

- Facility Design and Control: Personnel
  Anne Marie Dixon
- Fungal and Bacterial Spores
  Jim Polarine, Carol Bartnett and Dan Klein
- Contamination Control Risk Assessment
  Tim Sandle
- Contamination Risks and the Patient
  Mark Hunter, Michelle Luebke, and Mark Pasmore
- Contamination Control in Drug Substance Manufacture
  David Fletcher
- Implementing a Contamination Control Strategy in the Biotech Industry to Effectively Maintain Microbial Contamination Control
  Jane Wyatt
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chapter update

India Chapter Addresses Aseptic Concerns, Seeks Solutions

Ranjit Menon, Zydus Hospira Oncology Ltd.

The science and technology of pharmaceutical manufacturing may be at its peak, but some of us still break out in goosebumps when we hear the words "aseptic processing." Why, you may ask? Well, this critical manufacturing process involves close coordination of people, machines and processes while also factoring in external factors such as the environment or cleanroom. Not surprisingly, aseptic processing attracts a high level of regulatory scrutiny from authorities across the globe.

A single particle (viable or nonviable) within an injectable drug vial is enough to cause various adverse drug reactions and other health hazards in people, in addition to triggering a Field Alert or recall. Recently, the Indian pharmaceutical industry has been pounded by regulators, such as the U.S. FDA and Britain's MHRA, for a number of reasons, including incidents of poor aseptic technique. To address this issue, PDA's India Chapter hosted the one-day workshop, "Aseptic Techniques & Practices," July 3, in Indore, Madhya Pradesh, which drew 140 participants from across India. Merck Millipore served as platinum sponsor for the event.

Dr. S.B. Rijhwani opened the workshop, emphasizing in his speech the importance of following correct aseptic techniques and practices. Other presen-

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tations offered more in-depth information. **Thomas Ludke** discussed aseptic challenges and solutions, sharing his experiences working with MHRA and FDA in India. **Sanjay Singh** gave advice on effectively qualifying/validating aseptic techniques as part of a strategy to avoid regulatory citations. **K.V.G.K. Raju** compared the aseptic practices within a microbiology laboratory versus the manufacturing space. **Nandu Kagvate** highlighted risk assessments for aseptic processing. **S.G. Belapure** showed how "simple mistakes" can lead to warning letters, seriously impacting a company's finances, reputation and credibility. And **K. Anand** provided a case study on investigating sources of contamination in critical areas.

All in all, participants recognized a need for additional workshops and meetings that address aseptic concerns specific to the Indian pharma industry.

Due to the overwhelmingly positive response toward this workshop, the PDA India Chapter plans additional events addressing various parenteral topics. These will be held throughout India. The chapter has also launched a quarterly newsletter for members of the Indian pharmaceutical community.

PDA Who's Who

Dr. S.B. Rijhwani, Vice President, Chairman, Indian Pharmaceutical Association (IPA)

Thomas Ludke, Vice President Operations, Hospira India

Sanjay Singh, Sr. Vice President, Aurobindo Pharma

K.V.G.K Raju, Chief Technical Officer, Gland Pharma

Nandu Kagvate, Chief Technical Officer, Xellia Pharmaceuticals

S.G. Belapure, President, Manufacturing, Zydus Cadila Healthcare Pharma

K. Anand, Global Head, Quality & Regulatory Affairs, Dr. Reddy's

PDA Parenteral Drug Association

6-7 November 2014
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Munich | Germany

The Parenteral Drug Association presents...

2014 PDA Europe Workshop

Container Closure Integrity

Regulations, Theory, Test Methods, Application and Hands-on Activities About Newest CCI Innovations

Container Closure Integrity (CCI) is an essential part of the quality of parenteral products.

The course will address:

- Regulatory and pharmacopeial requirements
- Various test methods for development of container closure systems · Microbial ingress · dye test · high voltage · vacuum decay · head space · NIR-methods · others
- The pros and cons and limitations of these methods
- Test methods used for different container/closure systems
- Impact of formulation on test results
- Inline test procedures
- The most common problems and how to avoid them
- Hands-on with equipment for several of the test methods
- Detailed discussion of applications

https://europe.pda.org/CCI2014

Aseptic Training Produces Day-to-Day Professional Results

Rebecca Stauffer, PDA

Everyone in industry knows that proper aseptic technique is vital in the manufacture of sterile projects. Not surprisingly, the "Aseptic Processing Training Program" is one of the more intense, hands-on courses at PDA's Training and Research Institute, balancing lecture with laboratory training in addition to featuring some group project work. Numerous students have attended this two-week course. The *PDA Letter* spoke with one such student, **Paulo Villanueva,** Head, Combination Products – Quality Engineering, Genentech, to learn how attending this course has served him on the job and the benefits he continues to experience from the training.

How many years has it been since you took the course?

I completed the course in 2012.

Since attending the course, how have you used the knowledge that you gained?

I apply the practical experiences gained at the course in my day-to-day activities on a regular basis. Areas where the subject matter can be applied include the development of combination products and the oversight of external manufacturing operations

This greater understanding of aseptic processing is an important aspect of an overall knowledge base that I can draw upon in order to provide guidance and make decisions that are further grounded in practical experience.

What was the biggest takeaway that you took from the course?

I left the course with a deeply ingrained appreciation for, and understanding of, the "rope model" concept. Basically, each unit operation is like an individual strand of the rope and the stronger each strand is, then the lower the risk to the product.

Much of the course time was spent in the cleanroom and microbiology lab with hands-on application of the subject matter. We learned how each strand functions and why each strand is important.

The instructors utilized a novel and compelling approach when demonstrating the importance of "first air" in the overall operation.

Prior to the course, I already understood that these elements are all important, but the interactive, hands-on course format really helped me to achieve a stronger level of understanding through experiential learning.

"Tell me and I forget, teach me and I may remember, involve me and I learn."

—Benjamin Franklin.

What would you tell someone who is already established in the field about attending the "Aseptic Processing Training Program?" What would you tell someone who is new to the industry?

It can be difficult to gain hands-on experience in aseptic processing unless your job responsibility is directly involved in the operation. This course provides a significant learning opportunity for people of various experience levels.

For those who are new to the industry, the course provides an opportunity to immerse themselves in the subject matter over a period of two separate weeks. If their future aspirations are to work directly in aseptic operations, then the course provides an opportunity to possibly accelerate the learning curve and smooth the transition into their future role.

Even for those people who already have hands-on experience in aseptic processing, the course provides an opportunity to discuss current hot topics and best practices with industry experts.

Although the faculty is comprised of industry experts, the material is delivered in a manner that makes it accessible to a broad audience. They really know how to interject humor and keep things fun.

[Editor's Note: To learn more about the "Aseptic Processing Training Program," please visit www.pda.org/courses**.]**

PDA Mourns Passing of Solomon C. Pflag

It is with sadness that PDA announces the loss of one of its former leaders. **Solomon C. Pflag,** who served as Executive Director from 1976 to 1988, passed away Aug. 22 at the age of 94. In his decade at PDA, he was well known for his wise counsel, knowledge of the pharmaceutical industry, and commitment to PDA's mission.

During his tenure at PDA, a number of initiatives occurred. The Association prepared a formal response to the U.S. FDA on the proposed guidance, *Good Manufacturing Practices for Large Volume Parenterals*. PDA also established intercommunications with the Pharmaceutical Manufacturers Association. Validation received greater emphasis by PDA. Student and Retiree memberships were added to PDA's classes of members. An Internationalization Committee was established with the goal of developing cooperative exchange programs between PDA and international associations. By 1981, membership in PDA had grown from a small handful to 1300.

Solomon served in the U.S. Navy from December 1942 to July 1975. Upon his retirement in 1975, he had risen to the rank of captain, the highest in the Navy's Medical Service Corps., and was commanding officer of the Naval Medical Material Support Command, headquartered in Philadelphia. His administrative experience in this area was one of the factors that led to his appointment at PDA.

He was born in New York City and received a bachelor's degree from St. John's University. During World War II, Solomon served in the South Pacific, and upon his return earned a master's degree in pharmacy at the University of Iowa.

He is survived by his wife, Frances; daughter, Sandra White; and two twin grandsons, David and Brian White.

Donations in his name may be sent to the Friends of the Jewish Chapel at the U.S. Naval Academy, Suite 22, 326 First St., Annapolis, Md. 21403.

PDA extends its condolences to the Pflag family.

PDA Seeking New Volunteers for Upcoming Projects

Jon Hill, PDA

PDA volunteer interest profiles help connect volunteers with upcoming projects. After you create or update your profile, we will reach out to you with volunteer opportunities that suit your skills and interests. With over 1,500 volunteers contributing to PDA, our community is thriving. Join us at pda.org/volunteer!

Speaking at a conference is one of many ways to volunteer as a PDA member

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Chapter Involvement Proves a Worthwhile "Adventure"

Rebecca Stauffer, PDA

SOUTHERN CALIFORNIA

Chapter Secretary and Program Chair **Stefany Goldman** doesn't hide her enthusiasm when she talks about how she became involved in the chapter.

"It was a work assignment that turned into a whole adventure," she says excitedly.

In 2012, the company she worked for at the time, SGS Life Science Services, sent her to the *2012 PDA Annual Meeting* in Phoenix, Ariz. as an exhibitor. This was Goldman's first involvement with PDA. While at her booth, Southern California Chapter Board member **John Holmgren** stopped by, accompanied by a former coworker of hers. After an introduction, she and Holmgren began talking and she learned about the chapter's upcoming vendor night aboard a cruise ship. Seizing the opportunity for a "captive audience," she made plans to exhibit as a vendor. While attending the vendor night, Goldman learned of a job opening, and thus, found a new job through her new connections at the chapter.

"After that I kept in contact with John," She says. "I really wanted to give back. It was such a great experience for me. I figured this was such a great networking opportunity—I even found a new job out of it—how can I give back?" ➤

Stefany Goldman Timeline

Work Experience	PDA Experience
Strategic Account Director, February 2014-present BusinessOne Technologies	**January 2014** Elected Secretary/Program Committee Chair for PDA's Southern California Chapter
Business Development Manager, July 2012-February 2014 NSF Pharmalytica	**Mid-2012** Joins PDA Exhibits at *2012 PDA Annual Meeting* Exhibits at Southern California Chapter Vendor Night
Business Development Manager, 2010-June 2012 SGS Life Sciences	
Senior Project Manager, 2007-2010 Catalent Pharma Solutions	
Client Relations Manager, 2004-2007 Asteres, Inc.	
Account Manager, 1998-2004 Medimpact Healthcare Systems	

The sky's the limit with Stefany's PDA involvement

The Parenteral Drug Association presents...

PDA Europe Parenterals 2014

4-5 November 2014
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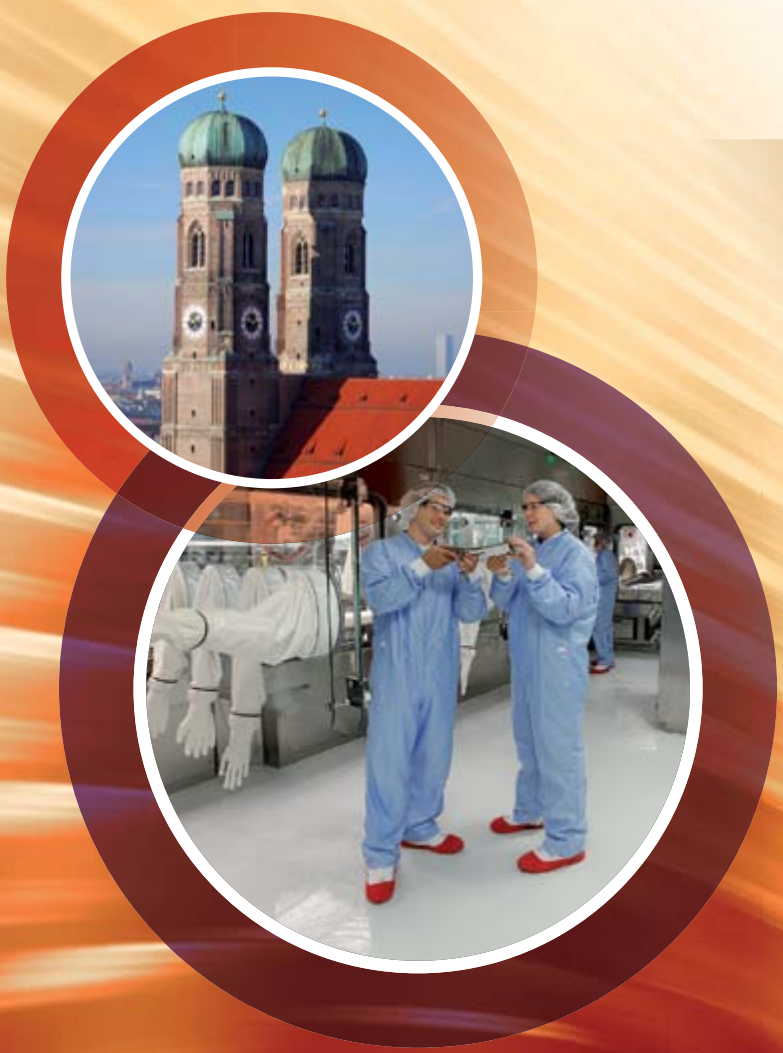

PDA Education Program

6-7 November 2014
PDA Workshop on Extractables & Leachables

6-7 November 2014
PDA Workshop on Endotoxins and Pyrogens in Parenterals Manufacturing

6-7 November 2014
PDA Workshop on Container Closure Integrity

6-7 November 2014
Training Course on Utilization of Statistical Methods for Pharmaceutical Production Monitoring

6-7 November 2014
Training Course on Process Validation

6-7 November 2014
Training Course on Technology Transfer

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Goldman began attending chapter meetings regularly.

"First, I was just volunteering as a member, and then as I heard people needed help with certain initiatives—especially the program committee—I thought to myself, 'I can help with that,'" she says, adding, "Through my new job, I had access to a lot of different subject matter experts in the industry and it felt like I could bring some good speakers to the table. So I started becoming involved with the program committee."

Her initial involvement with the program committee expanded over time, and in 2013, she was elected Program Chair in addition to Chapter Secretary.

In fact, Goldman advises members who want to get involved with their chapters to attend a couple of meetings to gauge the needs of the chapter. She also recommends talking directly with chapter leaders.

"For me, it was talking to John directly, saying 'how can I become more involved,'" she expresses, "So, it was just sitting in meetings and hearing how they needed help."

Her chapter also works on initiatives throughout the year, offering more opportunities for involvement. In addition, "we've actually had members suggest initiatives during the meeting and then the board will vote on it."

Goldman continues to leverage her volunteer work to advance in her career. While the position she found through the vendor night in 2012 was more of a lateral move, she has "climbed the ladder" even further.

"The experience as a board member and as a chapter officer helped me find an even better position and fit for me, working as Strategic Account Director for BusinessOne Technologies, a pharma/healthcare data technology company, which combines project management, sales, and client relationship management all into one, something I had been working toward for several years," she exclaims.

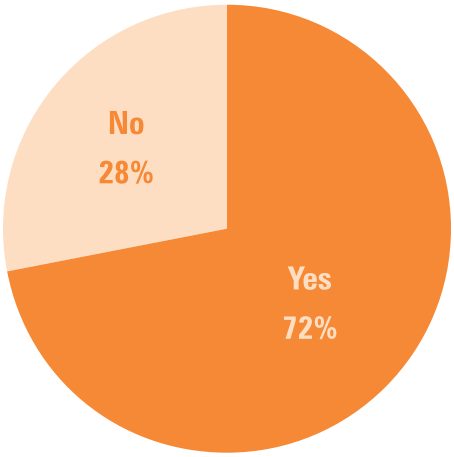
Looking ahead, Goldman hopes to move into a Director of Account Management or Director of Project Management position. She has also become involved in a lot of quality-focused discussions within her company, utilizing knowledge she has gained through courses offered by her chapter. No matter which direction her career goes, Goldman has no plans to quit her chapter involvement any time soon and encourages members to look to their local chapters to gain knowledge, explore volunteer opportunities and network with leaders in the industry.

PDA Pulse

PDA Members Embrace Social Media

Social media sites such as Facebook, LinkedIn, Instagram, Twitter, etc. dominate our lives now. Not surprisingly, when a small sample of PDA members were asked if they use social media, 72% said yes while over 27% said no.

PDA itself is also venturing out on social media. Check out our twitter feed at twitter.com/pdaonline or join our LinkedIn group to grow your connections and expand your scientific and regulatory knowledge. In addition, we continue to explore other social media options for our members, so stay tuned! Or rather, stay connected…



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This unique workshop presents internationally harmonized quality risk management principles from actual case studies of practical implementation.

Sessions will include:

- Quality Risk Management Expectations and Incorporation into National Requirements – Global Regulatory Perspective
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- Use of QRM in Facility and Process Design
- The Road to Better Risk Identification and Root Cause Analysis The Use of QRM
- QRM in the Drug Lifecycle
- And much more

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EXHIBITION: NOVEMBER 3-4 | COURSES: NOVEMBER 6

snapshot

PDA Hosts SUS Workshop with FDA, Other Industry Groups

Robert Repetto, PhD, Pfizer, and Richard Levy, PDA

The PDA Single-Use Systems (SUS) Technical Report Team recently completed a technical report for publication, and members continue to be involved in defining best practices for single-use technology. With the pace at which SUS technology is being deployed, and the variety of ongoing industry activities in support of that application, this spring PDA hosted a cross-organizational workshop to help coordinate all SUS industry activities, harmonize these efforts and encourage the development of standards specific to single-use technology.

On May 14, 30 participants from a number of key organizations involved with SUS converged on the PDA headquarters. The organizations represented included: the American Society for Testing and Materials (ASTM), American Society of Mechanical Engineers Bioprocessing Equipment group (ASME-BPE), BioPhorum Operations Group (BPOG), Bio-Process Systems Alliance (BPSA), Extractables and Leachables Safety Information Exchange (ELSIE), PDA, U.S. FDA (CDER and CBER), Product Quality Research Institute (PQRI) and the U.S. Pharmacopeial Convention.

There were two objectives of the workshop: to promote a harmonized approach for supporting SUS activities within the industry to minimize duplication of efforts and communicating ongoing single-use initiatives among group members. To accomplish these, the morning and afternoon sessions were organized as follows: overview of the SUS organization landscape, review of current SUS activities, exercises covering prioritization of SUS activities, discussion and wrap-up.

The morning session was centered on the groups' ongoing single-use activities. Group members came to the consensus that since overlap or duplication of efforts is a real issue, there should be efforts to prevent conflicting guidance. This would entail working together to find the most suitable path forward for publishing technical content for standard-setting organizations. The development pathway from con-

Continued at left on page 19

PDA Journal *Top 10*

PQRI Content Continues to Draw High Readership Levels

Below are the top ten articles from the *PDA Journal of Pharmaceutical Science and Technology* read during the month of August.

1. PQRI Special Section – *Review*
Diane Paskiet, et al. "The Product Quality Research Institute (PQRI) Leachables and Extractables Working Group Initiatives for Parenteral and Ophthalmic Drug Product (PODP)" September/October 2013

2. PQRI Special Section – *Research*
Dennis Jenke, et al. "Extractables Characterization for Five Materials of Construction Representative of Packaging Systems Used for Parenteral and Ophthalmic Drug Products" September/October 2013

3. Review
Anthony Cundell, "Justification for the Use of Aseptic Filling for Sterile Injectable Products" July/August 2014

4. Technology/Application
"Gary" Guiyang Li, Shawn Cao, Nancy Jiao, and Zai-Qing Wen, "Classification of Glass Particles in Parenteral Product Vials by Visual, Microscopic, and Spectroscopic Methods" July/August 2014

5. Review
Stephen E. Langille, "Particulate Matter in Injectable Drug Products" May/June 2013

6. Case Study
Ernie Jenness and Sue Walker, "Advantages of Single-Use Technology for Vaccine Fill-Finish Operations" July/August 2014

7. Technology/Application
Volker Rupertus, Bernhard Hladik, Uwe Rothhaar, and Volker Scheumann, "A Quick Test To Monitor the Delamination Propensity of Glass Containers" July/August 2014

8. Technology/Application
John K. Towns, "Human Factors Studies for Injectable Combination Products: From Planning to Reporting" July/August 2014

9. Technology/Application
A. Hamid Mollah, Harold S. Baseman, Mike Long, and Anurag S. Rathore, "A Practical Discussion of Risk Management for Manufacturing of Pharmaceutical Products" May/June 2014

10. Conference Proceeding – Introduction
Lixin Xu, et al. "Role of Risk Assessments in Viral Safety: An FDA Perspective" January/February 2014

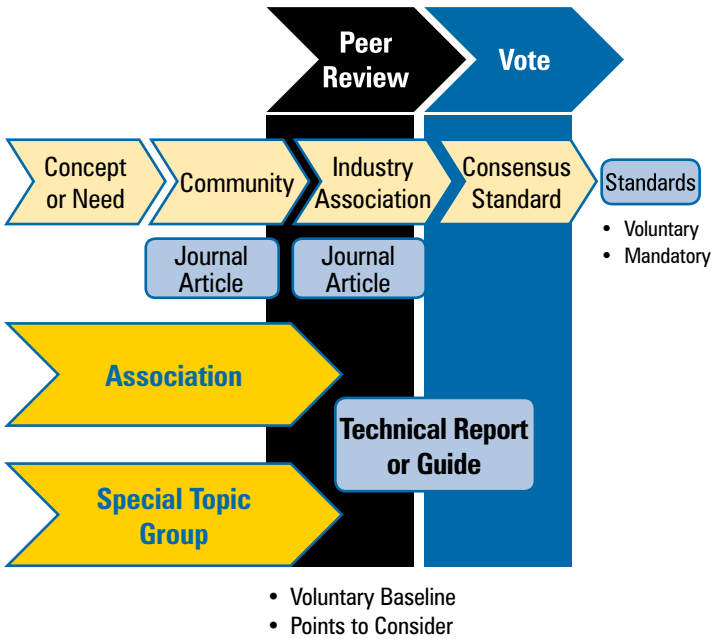
Members can access journal content from the past two years for free at journal.pda.org.

PDA Hosts SUS Workshop with FDA, Other Industry Groups continued from page 18

cept to standard should be rigorous and result in attainable best practices for industry. In order to achieve this, participants proposed a multiorganizational approach to best utilize the expertise and mission of each of the organizations. The figure below outlines how a concept or identified technical need could be developed through industry working groups and publications with increasing levels of rigorous peer review, eventually becoming a well-vetted industry standard, when appropriate (see **Figure 1).**

The afternoon session focused primarily on specific single-use technology topics. Participants voted to prioritize the topics most in need of best practices or standards. An outline of specific single-use technology topics from the technical report were grouped in five categories: end user processes, single-use test methods; single-use materials, components, films; SUS design; compliance and other SUS-related topics. According to votes, participants felt that test methods and end user processes were in most need of standards or best practices. The top five subtopics were integrity verification, particle measurement methods, integrity measurement methods, extractables testing and leachables testing. These topics are discussed in the PDA technical report and will be addressed as well in future documents from other organizations, such as BPSA (particles and integrity measurement) and BPOG (extractables testing), but ideally, specific test methods could be developed by a standard-setting organization as a next step. Many of the task force members are also members of one or more of these standard-setting organizations, and so will be able to continue to debate these topics with industry peers, consequently improving the methods through the standard-setting organizations' review process.

Figure 1 Pathway from Concept to Standard



Continued at middle on page 41

snapshot

Task Force *Corner*

Single-Use Systems TR Takes Holistic Approach

Rebecca Stauffer, PDA

The choice of what technology to implement for a new product is one of the most important decisions a company's senior management will have to make. Should the company move away from traditional multiuse systems to single-use technology? How does a company determine when it makes sense to switch to single-use systems?

Long-awaited *Technical Report No. 66 (2014): Application of Single-Use Systems in Pharmaceutical Manufacturing*, scheduled for publication this month, will offer a comprehensive overview of all facets of single-use implementation within a pharmaceutical company's manufacturing stream for both chemically synthesized small molecules and bioprocess production of large-scale biopharma products. The technical report will show how to effectively develop a single-use manufacturing strategy that addresses technical, quality and business considerations using a flexible approach. In addition, the report will also include considerations for determining when it might be appropriate for a company to switch from conventional multiuse technologies (e.g., stainless steel) to single-use. A single-use system should ultimately solve a specific process problem or goal valuable to the product development state under consideration.

Concepts of supply chain and supplier management will also be highlighted in the report, since regulators traditionally do not audit single-use equipment manufacturers—their quality systems typically based on ISO, not cGMP. Yet regulators require single-use end users ensure the equipment meets the same GMP requirements for traditional operations. This report will highlight supplier auditing and management strategies consistent with approaches utilized for other outsourced activities.

The report will offer points of consideration for readers to help them establish concepts and define terms, but it is not intended to serve as a specific set of standards.

The PDA Single-Use Systems Technical Report Team behind TR-66 consists of members from both the United States and Europe, representing regulatory authorities, biopharmaceutical manufacturers, vaccine producers, gene therapy experts, small molecule manufacturers, industry suppliers, and members of the Bio-Process Systems Alliance. While developing the technical report, the task force held two U.S. and two EU-based workshops to discuss and refine the concepts outlined in the report. **Robert Repetto,** Senior Director, Pfizer, and **Morten Munk,** Vice President, Business Development, co-chair the team.

Technical Report No. 66 will be available for purchase at the PDA bookstore (www.pda.org/bookstore). PDA members will be able to download the report for free.

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Particulate Matter Control Key to Preventing 483 Observations

Romain Veillon, GSK Vaccines

Visual inspection, especially the detection of particles, remains a focus of concern regarding product manufacturing control, quality assurance and regulatory compliance. Recently, issues relating to glass delamination triggered the start of an increasing trend in particulate matter-related recalls. In the United States from 2008–2012, 22% of all injectable product recalls were associated with visible particulate matter. The number of particle-related U.S. FDA 483 observations also rose; from six in 2009 to 22 in 2013. This is likely an indication of heightened sensitivity of both regulators and manufacturers, rather than a measure of decreasing product quality. Protein aggregation, with its many facets, in biopharmaceutical products has also contributed to increased interest in particulate matter control, even if these inherent particles are product-related and not the result of a lack of manufacturing process control.

Due to these reasons and others, visual inspection continues to be an important element of the manufacturing process and the quality assurance of injectable products.

To learn the latest trends in visual inspection, PDA Europe invites you to attend the *2014 Visual Inspection Forum.* This is a unique opportunity to learn more about visual inspection and to discuss inspection challenges with the experts. Special attention will be given to validation case studies for visual inspection markets.

The Forum will provide a summary of information on the human health risks associated with particulate matter and ongoing compendia activities in the United States and Japan. There will also be presentations showcasing examples of beneficial systems, tools and methods of data analysis used to support a robust inspection program. Practical case studies will be discussed concerning the automated inspection field and associated defect control strategy. New challenges in inspection will be covered for blow/fill/seal and lyophilized product inspection. The program will also cover critical aspects linked to defect kits, inspection process design and how to keep the right balance between sensitivity and specificity.

To learn more, please visit https://europe.pda.org/VisInsp2014.

Quality Culture Not Just Technological; Skills Key, Too

Walter Morris, PDA

Upgrading skillsets is one of the keys to helping companies improve their quality culture and preventing/mitigating drug product shortages. And many experts have made this point in recent in publications and presentations.

For example, Sandoz's **Andreas Brutsche,** Global Head of Quality Assurance, discussed the challenges a manufacturer like Sandoz faces in implementing plans to mitigate and prevent drug product shortages at the *PDA Drug Shortages Workshop* in September. A big part of Sandoz's business continuity planning involves what would be expected—facility, technology and equipment upgrades. But another key aspect, Brutsche explained, is defining behaviors expected in a culture of quality, and then developing a plan to ensure it is executed and controlled.

Elements of this plan including building the personnel skills in those who can lead change and excel in pharmaceutical operations. Brutsche noted that Sandoz has spent a lot of time recently shifting away from "management management" to "technical management."

During a discussion of risk management earlier in the same workshop, a workshop participant asked why companies cannot employ technologies on the shop floor so that operators can monitor the manufacturing process in real-time. While some companies are exploring this pathway, other participants cited the lack of technical skills as a barrier.

Robert Keiffer, who sits on PDA's Drug Shortages Task Force, has written on the skills needed for a strong quality culture. His paper, "The Changing Role of Quality Assurance in the Pharmaceutical Industry," published in the July/August 2014 *PDA Journal of Pharmaceutical Science and Technology,* outlines skills today's quality professionals must have beyond knowledge of the GMPs.

A broad range of skills are now required, Keiffer says, and many of the new skills are based on new expectations set in ICH Q10. Among these are:

- Leadership
- Strategic planning
- Management
- Supply Chain
- Training and Development

Most importantly, Keiffer argues that quality professionals must be great salespeople. "We need to sell quality at all levels and to everyone in all departments," he writes. "To do that, we need to be clear on what we want to sell and *why* it is important."

Keiffer previewed his views in a June PDA Letter article "Today's Challenges for QA Personnel."

Anders Vinther, Sanofi Pasteur, and **Jennifer Magnani,** Genentech, outlined the future role of quality professionals as a "combination of a financial officer, an operations manager, a regulatory compliance officer, an educator, and a motivational speaker", in their article, "Can Quality Solve the Equation?", published in the Nov/Dec 2012 PDA Journal.

Vinther, Magnani and Keiffer agree that the traditional role of quality as a reactive "police" has not been effective. Vinther and Magnani put it this way:

> *How do you picture the traditional role of quality? Reviewing deviation reports and batch records in the office and then letting manufacturing know where documentation has to be improved prior to Quality releasing the batch? Testing the final products with limited testing controls throughout the manufacturing process? Maybe. That is the reactive approach to the job. Many see the traditional role of Quality as the "police" who ensure law and order (current good manufacturing practice [cGMP] compliance and quality, unadulterated products). Certainly Quality has always had and will continue to play this role, but in order to solve the equation that our industry is facing today it is essential that Quality take on a few different roles.*

Vinther and Magnani provide some details in the paper about each of the roles they feel quality professionals must embrace. ➤

As the financial officer, they postulate that the quality unit should "know all the cost structures of the company's quality elements," which include prevention and the cost of failure. The key here is that the quality group should be adept at changing the conversation about good quality from consideration of cost to a focus on value.

The role of operations manager for quality means getting better control over the supply chain. "Checking the raw materials when they hit the loading dock is not good enough anymore," wrote Vinther and Magnani. They go on to outline various ways the quality professionals should be engaged within the company as operation managers.

Regarding quality's role as a regulatory compliance officer, the two authors outline activities revolving around quality risk management and knowledge management.

As educators, quality personnel need to shift from resolving existing deviations to facilitating dialogue among relevant players in the operation to jointly develop solutions that will help reduce repeated mistakes and improve processes. The quality professional also must be capable of enlightening personnel in operations and other divisions about the rationale behind GMP requirements that apply to their specific functions.

As the motivational speaker, Magnani and Vinther argue that the quality unit does not own quality and it is their job to make sure everyone across the enterprise feels responsible for manufacturing product of the highest quality.

Magnani and Vinther previewed their Journal article with a handy table in the July/August 2013 *PDA Letter* that outlines the various roles and ten questions that can be used to evaluate how well the quality unit is performing each role. They also intend to submit a series of papers to the Journal to flesh out this concept further.

PDA just launched a Quality Culture Metrics Survey as part of its quality metrics and drug shortages efforts. This survey will inform the upcoming *PDA Pharmaceutial Quality Metrics Conference* in December. Results will be published.

As industry and regulators continue to explore ways to improve quality and the quality culture across the pharmaceutical enterprise, PDA and its members are in the forefront finding solutions!

Site Visits Offer PDA Staff View of Industry In Action

Janie (Jahanvi) Miller, PDA

In every career there are many things to be learned, challenges to be overcome, and progress to be made, but internal support systems are one of the most effective ways of managing these obstacles.

In many work environments little attention is given to developing staff to function or share knowledge interdepartmentally. PDA recognizes this and the fact that our employees come from diverse disciplines. In January 2014, PDA's Scientific and Regulatory Affairs Senior Project Managers, **Janie (Jahanvi) Miller** and **Joshua Eaton,** launched a series of staff development programs such as brown bag sessions where each of the departments presented on their areas of expertise.

On June 27 and July 25, as part of the internal development opportunities for staff, PDA held site visits. **Richard Johnson,** President and CEO, along with Miller, led an effort for PDA staff to attend guided tours of MedImmune's pilot and bioprocessing plants.

Ken Fontaine led the tour at the Frederick site of the commercial manufacturing area. **Thomas Mitchell, Ken Herko** and **Ian Hart** led the onsite tours at the Gaithersburg pilot plant. During the Gaithersburg visit, the PDA staff also visited the laboratories as an added bonus. This part of the visit included:

- Electrophoresis with **Unita PeriOkonny** and **Bernardo Guzman**
- Immunoassay with **Chris Herbstritt**
- Bioassay with **Tian Zhou**
- Chromatography with **Tom Mitchell**

The PDA staff was very engaged given how knowledgeable and passionate the guides had for their work. The *PDA Letter* staff, in particulate, was very inquisative.

PDA would like to thank **Thomas Pamukcoglu,** Senior Director of Quality Assurance Commercial Operations, and **Patricia Cash,** Senior Director of Analytical Biochemistry, both of MedImmune, who worked with PDA to facilitate these site visits.

Courtesy of MedImmune, Frederick, Md.

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20-22
PDA 9th Annual Global Conference on Pharmaceutical Microbiology
Bethesda, Maryland
www.pda.org/microbiology2014

20
Pre-Conference Workshop: Automated Visual Inspection – A Practical Approach
Berlin, Germany
https://europe.pda.org/PreWSVisual2014

21-22
Visual Inspection Forum
Berlin, Germany
https://europe.pda.org/Visual2014

22-23
Single-Use Systems for Manufacturing of Parenteral Products
GSA Schedule Contract GS-02F-113BA
www.pda.org/sus

23-24
PDA 9th Annual Global Conference on Pharmaceutical Microbiology Course Series
Bethesda, Maryland
www.pda.org/microcourses2014

23-24
An Introduction to Visual Inspection
Berlin, Germany
https://europe.pda.org/TCVisInsp2014

28-30
Validation of Biotechnology-Related Cleaning Processes
GSA Schedule Contract GS-02F-113BA
Bethesda, Maryland
www.pda.org/biotechcleaning

30
PDA Southeast Chapter Fall Conference
Durham, North Carolina
www.pda.org/SEFALL

NOVEMBER

3-5
2014 PDA/FDA Pharmaceutical Quality System (ICH Q10) Workshop on Quality Risk Management
Baltimore, Maryland
www.pda.org/ICHQ10

4-5
Parenterals
Munich, Germany
https://europe.pda.org/Parenterals2014

6-7
Extractables & Leachables
Munich, Germany
https://europe.pda.org/WSEL2014

6-7
Container Closure Integrity
Munich, Germany
https://europe.pda.org/CCI2014

6-7
PDA Workshop on Endotoxins and Pyrogens in Parenterals Manufacturing
Munich, Germany
https://europe.pda.org/WSParenterals2014

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EVENTS

6-7
Utilization of Statistical Methods for Pharmaceutical Production Manufacturing
Munich, Germany
https://europe.pda.org/TCUtilization2014

6-7
Process Validation
Munich, Germany
https://europe.pda.org/TCAsepticProcess2014

12-13
Recommended Practices for Manual Aseptic Processes-Lab
Bethesda, Maryland
www.pda.org/map2

17-21
Quality Systems for Aseptic Processing
GSA Schedule Contract GS-02F-113BA
Bethesda, Maryland
www.pda.org/quality

DECEMBER EVENTS

1-4
2014 Lyophilization Week
GSA Schedule Contract GS-02F-113BA
Bethesda, Maryland
Www.pda.org/lyoweek2014

2-3
Outsourcing/Contract Manufacturing Conference
Berlin, Germany
https://europe.pda.org/Outcon2014

2-4
2014 PDA Pharmaceutical Quality Metrics Conference
Washington, DC
www.pda.org/metrics2014

3-4
Managing Outsourced Operations
Berlin, Germany
https://europe.pda.org/Managing002014

5
2014 PDA Pharmaceutical Quality Metrics Conference Course Series
Washington, DC
www.pda.org/metricscourse

8-10
Risk-based Qualification of Sterile Drug Product Manufacaturing Systems
Bethesda, Maryland
www.pda.org/Risk

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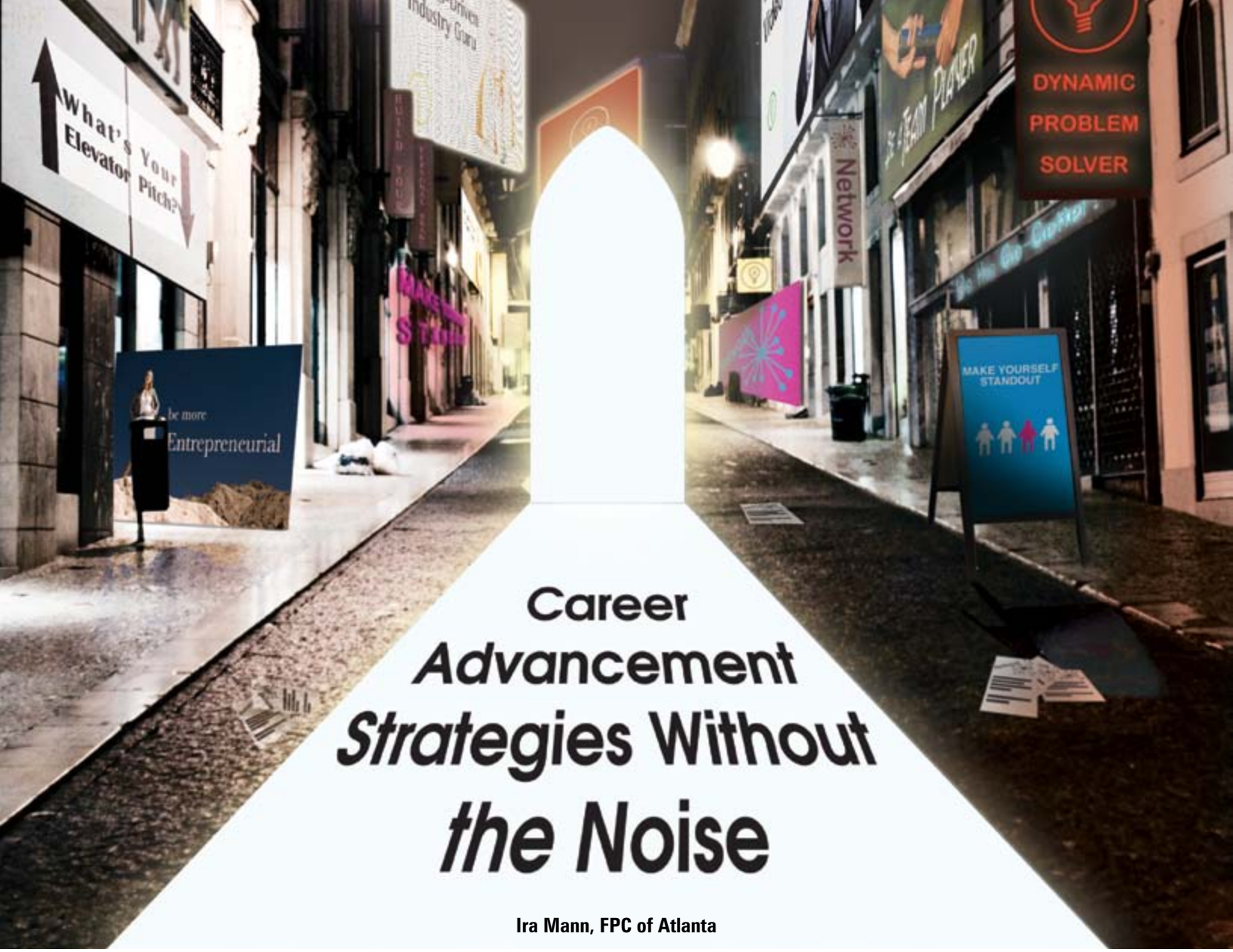

Career Advancement Strategies Without the Noise

Ira Mann, FPC of Atlanta

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?

These are common questions asked of my team. Even if you are not looking, the answers should still matter to you as career planning means thinking about your next career move even when you are not actively looking.

The Good News and the Bad News

First, the bad news. Like you, every week I get bombarded with "noise." There are so many sources providing input and suggesting direction. Many even conflict with one another. Unfortunately, there is no way to muffle these conflicting pieces of information.

Now, the good news. Every week, I speak with many different pharmaceutical and biopharmaceutical industry executives (both current and future) who not only serve as authoritative sources of information themselves but also point me in the direction of additional resources from which I can draw some viable conclusions. The first conclusion is that you are already looking in the right place; the *PDA Letter* can serve as one such career resource. The fact that you are tuning into it and what its members speak about, means you've been able to hone in on a reliable source amidst the clamor.

What's in Demand?

You've probably already seen the roles listed here as being "in demand" for the past couple of years, and will most likely continue to encounter them. While the titles continually remain the same, however, that doesn't mean the *skills* sought remain constant.

Functional areas where companies seem to have consistent needs include:

- Quality assurance, quality engineering and quality systems leaders focusing on harmonization
- QA leaders who specialize in external quality
- Senior, principal and other high level individual contributors who focus on improving CAPA plans and investigation processes
- Cleaning validation professionals
- Automation/process control validation engineers
- Quality and regulatory professionals who understand drug combination and/or drug delivery devices
- Process engineering and manufacturing technology professionals
- Senior managers and directors in procurement and supply chain

Skills Sought and In-Demand Positions

The following are areas where you will see new emphasis. By gaining experience in these areas, you may positively impact your career.

- Ability to lead the deployment of QbD, QRM and other ICH Q8–Q11 topics
- Development and support of drug combination and/or drug delivery devices (e.g., autoinjectors, pens, self-administered devices, etc.) as well as the understanding to lead compliance and regulatory departments in this changing regulatory environment
- Evaluation and implementation of single-use technology including bioreactors, filters, bags, connectors and tubing
- Particulate prevention, testing and reduction

Article at a Glance

— Quality-related personnel top companies' lists of in-demand roles

— Showing leadership requires developing Executive Presence

— Design your resume to be reviewed in under six seconds

An employer wants someone who can minimize the obstacles. Your ability to do so can be communicated though challenges previously faced

- Maintaining consistency in the manufacturing processes
- Improvement of investigations and CAPA processes
- Global/multisite harmonization success (most often of quality systems and validation processes)
- Quality "on the floor"
- External quality oversight
- Protection of the global pharmaceutical supply chain
- Cold chain challenges including packaging and validation
- Automation and control systems
- Risk-based validation methods
- Risk identification and analysis
- Finally, there also seems to be a large increase in the volume of high-level individual contributors

Much of the information above was also confirmed by a FPC of Atlanta survey of U.S. FDA-interfacing biologics and pharmaceutical leaders. According to the results:

- Over 55% of respondents included QbD and Quality Risk Management as the skills to be in highest demand over the next three years,
- Ranking second was single-use technologies, including disposable bioreactors,
- Other skills showing increasing emphasis included cold chain, cleaning validation and cell line management, and
- Industry niches indicated to be driving the most demand included biosimilars, cell-based therapies, monoclonal antibodies, orphan drugs and personalized medicine.

Moving Beyond Technical Skills

We, as professionals, have the ability to lead, and also the ability to program ourselves. So, what "programming" do companies want in Quality, Regulatory, Manufacturing and Process Science professionals, especially for those at the Director and VP levels?

They want to know that you are an expert at what you do and at the challenges they need you to handle—and not just the standard (or job description) responsibilities expected of someone at that level. Closely correlated, they also want to know you can tackle challenges that aren't necessarily in the job description.

When they talk with you, they want to hear that you can effectively communicate your expertise; that you can impart that expertise on others; and that you can get others moving toward needed or targeted goals. (Hence, the increased emphasis on "influence without authority" and the growth of situational and behavioral questioning.)

They need to hear you can communicate clearly, and demonstrate a track record of accomplishments relating to relevant responsibilities. If you do not communicate effectively, then your likelihood of successfully navigating the interview process is compromised. Your resume should include enough detail regarding your accomplishments and responsibilities to open the door, but you must be able to communicate your ability to be effective.

They don't want to think you are impatient or impulsive. Taking action quickly does not mean doing it without thought or strategy. Examples you give should demonstrate thought, strategy and action. Unfortunately, prospective employers can quite easily draw conclusions of impatience, impulsiveness or desperation before they even speak with you or look at your resume. How? By applying indiscriminately to a multitude of roles solely based on title or location—especially within the same company. It is simply just not realistic to imply that you are a good fit for such variety. Besides the potential of losing credibility,

the employer may be left to wonder which role is most appropriate for you, and likely cannot allocate the time necessary to determine where you best fit.

An employer wants someone who can minimize the obstacles. Your ability to do so can be communicated through challenges previously faced and the successful results achieved.

They want to know you can communicate your strategic leadership abilities and that your skills and knowledge base have kept pace with current industry requirements and direction.

In a related FPC of Atlanta survey regarding the most desired traits for Director and higher level candidates, "Strategic Leadership" was a runaway winner. Immediately following were "Technical Depth" and then "Technical Leadership." Surprisingly, "Successful Career Trajectory" finished lower than these three. These are encouraging results if you are someone who is considering a lateral move or a move geared toward increasing your technical depth.

Executive Presence

With strategic leadership such an important factor, it makes sense to review how you project an Executive Presence. While many articles have been written on the subject, here is what should come across in your interviews and on your resume:

- **The ability to make tough decisions.** While this trait is more clearly described and discussed during the interview, the decisions you make and their results can be shown on your resume.
- **Communication.** When communicating verbally, you should be clear, you should be confident and you should be approachable. You should also sound natural. If you don't, practice by making recordings of yourself, listening and refining your delivery.
- **Confidence.** But avoid overconfidence.
- **Passion.** Your passion and your strengths should come out when you answer the "tell me about yourself" question, the "why are you qualified for this role" question or questions where you need to demonstrate via example.
- **Being audience-centric.** When speaking, an executive tailors his conversation to the audience. How you speak with a hiring manager differs from how you speak with a team of subordinates.
- **Remaining calm in a storm.** Your resume can summarize your successful navigation and your live presentation can walk through such successes and demonstrate how you navigated challenges with poise.

Now, How About My Resume?

First, let me tell you something that may surprise you—I'm not a big fan of resumes. The first time I speak with someone, it is preferably because they were recommended or referred. As such, it is usually without having seen their resume. In this manner, do you know what needs to stand out about them? It is how their accomplishments and skills are presented as well as their overall communication. That is what has to grab and keep my attention. In other words, it is you the person, not you the flat piece of paper (i.e., resume).

Some say public speakers or lecturers have approximately seven to ten minutes to get and hold an individual's attention. With conversation in general, 60 seconds is a common number. With selling, ten seconds is often a rule of thumb.

When it comes to your resume, though, those numbers don't apply. With a resume, you also have to grab someone's attention but the rule of thumb here is six seconds.

There are countless articles on how to write your resume. Some are really good. But put a large group together, even a good group, and you're still faced with what I talked about in the beginning—noise. To keep it simple, here are four rules I suggest you to try to incorporate:

1. **Easy on the eyes—** Less paragraphs, more bullets and more white space.
2. **Relevancy—** When a resume is quickly reviewed, correlated key words will pull someone in for a closer look.
3. **Progression—** Show it if you have it. If you've been promoted, show it. Don't just show ten years at one company with only one title. Show how you've progressed and why you earned that promotion.
4. **Accomplishments—**Quantify them if possible. Think about PowerPoint presentations you've viewed. Which caught your attention more? The ones lacking quantified data or the ones showing such via numbers and percentages?

Conclusion

Searching for a new job is something that happens over a period of time. Career advancement and the strategies you choose to use are an ongoing process. They are interlaced with what you are doing now, what you want to be doing eventually, and all of your future jobs along the way. So, even if you are still in the early stages of your career, these strategies are something you should, and can, exercise control over if you program yourself accordingly.

There's a din of career advice out there—a raucous chorus of conflicting information from varying sources. I hope this information helps to drown out the "noise."

About the Author

Ira Mann leads nationwide Biotechnology, Pharmaceutical and Medical Device contingent and retained searches as the Senior Director of Quality, Validation & Regulatory Affairs Executive Search and Professional Development for FPC of Atlanta, a recruiting firm specializing in placements across the United States. With more than 13 years in the recruiting industry, he is an expert at placing top professionals in the Quality, Validation, Regulatory Affairs, Cold Chain, Environmental Monitoring and Sterilization specialties.

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Reduce Human Error in a GMP Facility

Claire Newcombe, Applied Biopharm Consultancy, Shanon McKenna , PAREXEL, Anthony Newcombe, PhD, PAREXEL

Pharmaceutical companies often cite human error as the sole cause of a manufacturing deviation or noncompliance issue ***(1).*** For medical device manufacturers, identifying and reducing the occurrence of human error is commonly part of the regulatory and overall risk management process ***(2,3),*** but for pharmaceutical facilities, the assessment of human error in the workplace is not always so rigorously assessed during deviation investigations. Common corrective actions for human error within a GMP production facility often include retraining or awareness sessions combined with document updates or revisions that include additional document checks and signatures. In most cases, however, there is often no scientific rationale that human error was the actual root cause. The ultimate goal of a root cause investigation within a production facility is to identify the underlying cause of why an incident occurred so that the most effective solution can be identified. Yet corrective actions focused on retraining typically do not fix the true root cause as to why the deviation occurred, and generally will not prevent a reoccurrence of the issue. There may be some merit in retraining programs, but to prevent the same, or similar error occurring again, the retraining should include improved or modified procedures. Simply retraining using existing protocols is unlikely to address the recurring errors. If staff have been trained on the current versions of the procedures, it is difficult to justify, in many cases, why retraining should be included as a preventative action ***(4–7).***

The purpose of a root cause investigation that suggests human error is not to determine what went wrong, but to establish why the actions seemed appropriate at the time and prevent reoccurrence. As such, there is often a regulatory perception that in some cases, staff retraining may be misused as a preventative measure for production incidents, with the perception that there is a lack of understanding of what constitutes human error ***(1).*** Most production deviations that occur and are classified as human error are actually due to poorly designed systems, including the structure and content of production documents or Standard Operating Procedures (SOPs). To identify events that are due to human error, it is important to collate metrics and trend the type of errors in the workplace, but also identify if the same error has reoccurred by different production operators, as this provides an indication of an inherent issue in the system design.

Regulatory guidance for pharmaceutical development and manufacture are moving towards a science- and risk-based approach ***(8).*** There is now a regulatory expectation for pharmaceutical manufacturers to develop and document scientific rationales for classifying and preventing human error ***(1).*** Integrating human error reduction tools within a quality system, however, need not be cumbersome or complicated. Many pharmaceutical companies utilize the Talsico human error reduction methodology, to categorize human error ***(9)*** and also to develop effective strategies for prevention **(Table 1).**

As part of a continuous improvement program, a manufacturing site could establish procedures that provide guidance on what is classified as human error within the production facility and the associated indicators of such events. A manufacturing site could also consider a simple checklist or questionnaire ***(1)*** to assess human error associated with a particular procedure, and include this methodology as part of the deviation process. Alternatively, more elaborate root cause analysis tools such as Ishikawa's Fishbone analysis ***(10)*** can be utilized with a longer term strategy to integrate human error reduction into root cause analysis investigations and CAPA programs. Once the type of human error has been established, it may be possible to evaluate the error hierarchy **(Table 2)** to define appropriate corrective actions based on strategies to reduce the error from reoccurring. Actions may include specific engineering solutions for error proofing, such as preventing the unlocking of a door unless a switch is in an "off" position, permitting safe access to potentially hazardous areas (gamma irradiation chambers, for example), or using equipment connectors of a specific size or shape to prevent human error. Human error prevention using attention activators within production documents, such as batch records and SOPs has also shown to be effective. Simple attention activators within production documents

Table 1 Categories of human error that may occur within a production facility

Cause of Human Error	Description
Learning gap	Training not provided or undertaken. For example, performing a task when not trained or not trained on the latest procedures.
Memory gap	Training provided but not remembered. For example, forgetting to record a batch record entry. May be a potential risk for read and understand training for critical activities.
Inconsistency	Training has been provided but potential variability in the process if the procedure is not adequately described. For example, conductivity meter calibration: probe depth in solution or measurement with or without stirring or agitation.
Application	The procedure is known but applied incorrectly. For example, rounding of calculations entered into a batch record.
Omission	The procedure is known but a step or action is missed. For example, a blank field not completed in a batch record.
Decision	An incorrect decision. For example, deciding to remove or bypass a faulty detector if procedures do not adequately describe how to manage the event.

Table 2 Strategies for human error prevention (in order of effectiveness)

Strategy	Effectiveness	Description
Error proof	High	Eliminate all potential for human error. For example, use of specific connectors for bioprocess equipment so that it is impossible for the incorrect connection to be made.
Error prevention	High–Medium	Ensure documents do not rely on operator memory and utilize attention activators within documentation to prevent errors from occurring. Attention activators may include (in order of effectiveness): change in pattern, change in color, shape (i.e., use of boxes for text, symbols using different color) and text format (bold, italic, size). Use of color in quality documents should align with emotional associations. For example, green=go, red=stop. It is also easier to detect changes or omissions in patterns; the use of columns and rows also helps to prevent errors.
Resilience	Medium–Low	Provide the option to "undo" the error, often utilizing additional attention activators or an undo or confirmation option when using electronic systems.
Redundancy	Low	Duplication of effort or resource in an attempt to reduce error. For example, multiple checks and signatures. Redundancy is the least effective strategy for human error reduction but one of the most common corrective actions.

that have shown to be highly effective in preventing human error include changes in document pattern, color, shape and text format (bold, italic, size, etc.), yet many production documents do not contain any specific formatting that has been included to prevent errors. A common corrective action for human error is the duplication of effort or resource. This often includes multiple checks and signatures (such as within production batch records). Such redundancy is often the most utilized action but is the least effective strategy for human error reduction **(Table 2).**

It is important to exercise caution before deciding that human error is the cause of a production deviation. In some cases, human error may indeed be the cause of an incident, but in many cases human error is a symptom of an underlying problem, rather than the cause. It is clear that the regulators are expecting a shift from simply complying with GMP toward demonstrating that a pharmaceutical organization has an effective pharmaceutical quality system, including procedures to manage human error in the workplace.

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About the Authors

Claire Newcombe is the owner and consultant at Applied Biopharm Consultancy, supporting the development and production of biopharmaceuticals. She worked previously as an independent QA consultant

Continued at bottom on page 41

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Solid Dosage Operator

- Fewer restrictions on movement and on-the-floor behavior
- Requires less understanding of why's and how's
- Training is less intense
- Can rely on standard job aids such as paper checklists

Special thanks to **Timothy Gillum,** PhD, Baxter; **James Vesper,** LearningPlus; and **David Matsuhiro,** Cleanroom Compliance, **James Wamsley,** PDA TRI, for their assistance with this infographic.

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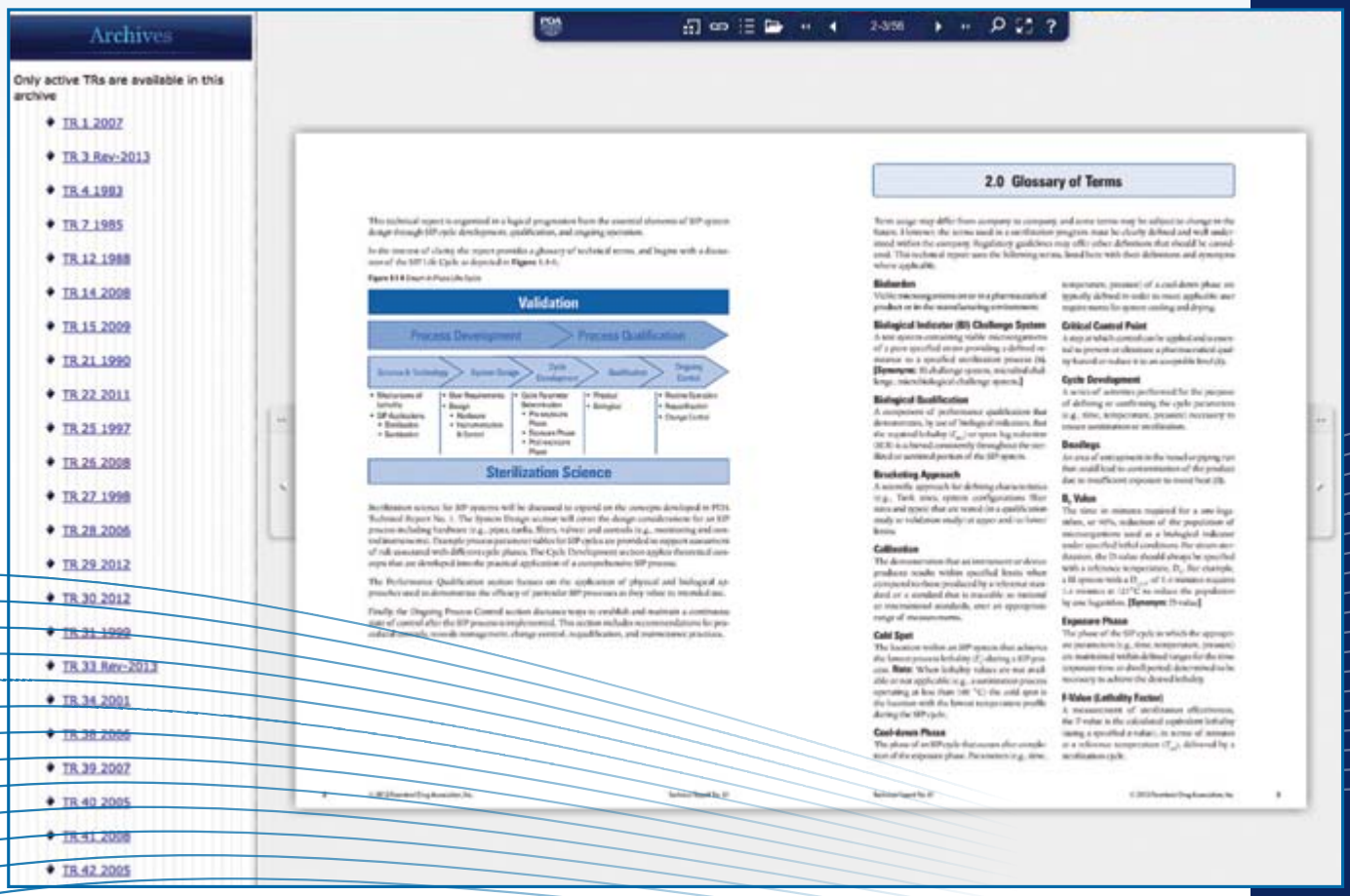

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snapshot

RAQAB *Update*

RAQAB Quarterly Report Q3—New Members and Addressing Compounding cGMPs

Denyse Baker, PDA

RAQAB Welcomes New and Returning Members

RAQAB recognizes and thanks **Barbara Jengtes** for her three years of service to the board and wishes her well in her other PDA endeavors. Also stepping down in 2014 are **Lauren Melton** (two years) and **Hailey Park** (one year). We thank them for their time on the board as well. Three new RAQAB members started their terms on July 1. **Mirko Gabriele** is a first-time member who brings a European perspective and expertise in small molecule and biotech API manufacturing, tech transfer and quality. **Karen Ginsbury** returns to the board for a new term, bringing her cross-industry viewpoint and experience with biotech APIs and sterile drug products. **Janeen Skutnik-Wilkinson** has also returned for a new term, bringing expertise in vaccines and quality. She will also resume the role of regional liaison to Korea.

In addition to five sets of comments in 2014 so far, RAQAB has completed three additional ballots, including approval of a new coleader for the Quality Risk Management Interest Group and a new leader for the European Quality Systems Interest Group. A ballot was also completed for the PCMO technical report on technical transfer. Significant efforts have been spent on the "Speak Up" for Quality Culture goal, resulting in presentations at this years' *PDA/FDA Joint Regulatory Conference* and next year's *PDA Annual Meeting.*

PDA Response to FDA's Proposal for Interim GMPs for Compounding Outsourcing Facilities

Task Force members, **Susan Schniepp, Alan Burns** and **Christopher Smalley** reviewed the U.S. FDA draft guidance titled *Current Good Manufacturing Practice—Interim Guidance for Human Drug Compounding Outsourcing Facilities Under Section 503B of the FD&C Act* and developed these comments.

> *PDA supports FDA's efforts to clarify GMP requirements for compounding pharmacies but has reservations regarding this guidance. Current available regulations are already in place to be utilized by this industry. The draft guidance has the potential to further confuse the current situation which has resulted in objectionable conditions and harm to patients. PDA recommends that FDA reconsider whether the draft guidance is needed or if existing GMPs (21 CFR parts 210, 211) cannot be applied as is.*
>
> *PDA considers human drug compounding in advance of a physician's orders, without a valid prescription, or for interstate distribution, to be pharmaceutical manufacturing. To ensure patient safety and product quality, the cGMP requirements applied to licensed pharmaceutical manufacturers should be applied to human drug compounding outsourcing facilities. Applying the same standard to compounding outsourcing facilities as applied to pharmaceutical manufacturers is imperative for parenteral products given the potential risks to patient safety. PDA is concerned that some of the reduced requirements could compromise product quality but we are most apprehensive about the noticeable relaxing of some of the sterility requirements included in the draft guidance. Creation of this type of secondary standard does not guarantee a continuous supply of safe and effective medications but rather opens the door for other specialty products, such as personalized medicines, to be produced under conditions that do not meet current industry interpretation of the GMP regulations.*

Global Regulatory News Updates

The regional liaisons to RAQAB are reporting with increasing frequency the tendency of some smaller countries and developing markets to reject ICH standards in favor of WHO principles. There appears to be a feeling among these health authorities that ICH is too closely linked to big pharma. PDA will continue to monitor this trend and continue to comment on WHO draft guidance documents.

The trend of revisions to qualification and validation guidelines has continued in many regions. So far in 2014, draft documents have come out from the EMA (*Annex 15: Qualification and Validation* and process validation guidelines for biotech APIs), from the Chinese FDA (*Qualification and Validation Guidance*) and most recently from the WHO (*Supplementary Guidelines on Good Manufacturing Practices: Validation: Appendix 7: Non-sterile Process Validation*). RAQAB has drawn upon the deep expertise of the Process Validation Interest Group led by **Scott Bozzone** and **Vijay Chiruvolu** as well as Biotechnology and Science Advisory Board members to develop comments in this arena.

PDA Who's Who

Barbara Jengtes, Managing Director, Regulatory Affairs, PhACT GmbH

Lauren Melton, Strategic Regulatory Director, Alnylam

Hailey Park, Associate Deputy Director, South Korean Ministry of Food and Drug Safety

Mirko Gabriele, Tech Transfer Manager, Patheon

Karen Ginsbury, President, PCI

Janeen Skutnik-Wilkinson, Partner, NSF Health Services

Susan Schniepp, Vice President, Quality and Regulatory Affairs, Allergy Laboratories

Alan Burns, Vice President, Quality Operations, Romark Laboratories

Christopher Smalley, PhD, Director, BioSterile Validation, Merck

Scott Bozzone, PhD, Sr. Manager, Quality Systems & Compliance – Validation, Pfizer

Vijay Chiruvolu, PhD, Director, Amgen

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Quality Metrics: Measuring the Quality Culture

Joyce Bloomfield, Merck

Which metrics exemplify the strength of your quality culture and maturity of your quality system? How do you integrate these ideas into a new set of objective metrics for consideration by industry and the U.S. FDA? Are you ready for the new drug inspection protocol approach? How will you measure up to expectations?

Throughout 2014, FDA continued to capitalize on the authority granted through the Food and Drug Administration Safety and Innovation Act (FDASIA), by developing prospects that will provide inspection relief to industry. These prospects include the right to obtain records in lieu of, or in advance of, an inspection.

PDA members facilitated the prospect of inspection relief through the Association, and FDA co-chaired the *Pharmaceutical Quality Metrics Conference* held in December 2013. Through interactive sessions and workshops, industry members and FDA helped to shape the future of quality metrics definitions that led to the PDA "Points to Consider" paper published in 2013. To further refine the metrics definitions discussed at the 2013 conference, a session was held at the *2014 PDA Annual Meeting* on quality metrics where PDA gathered direct feedback from industry participants on the metrics proposed in PDA's Points to Consider document.

This year's *Pharmaceutical Quality Metrics Conference* will further build on the quality metrics established by the industry, and bring together key FDA and private sector quality leaders to continue metrics that measure the health of a quality culture and quality system maturity. FDA will update the participants on the latest developments and direction to utilize quality metrics to create a "balanced scorecard" for industry. Plenary sessions will be used to kick off interactive breakout sessions that will explore development of new metrics that cover quality culture attributes that provide for objective measures of a quality culture and system maturity. Session readouts will be discussed among industry and FDA panelists, and the final session will highlight a discussion on FDA's next steps for quality metrics led by **Janet Woodcock,** MD, Director, CDER, FDA.

For more information, please visit www.pda.org/metrics2014. To learn about the PDA TRI course that follows the conference, visit www.pda.org/metricscourse.

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For more information, visit www.pda.org/quality

2014 Lyophilization Week (December 1-4)

GSA Schedule Contract GS-02F-113BA

Two courses will be taught during this week: Fundamentals of Lyophilization (Dec. 1-2) and Validation of Lyophilization (Dec. 3-4). Learn more about the development of lyophilized products and the validation of lyophilization processes by signing up for both classes during this informative week!

For more information, visit www.pda.org/lyoweek2014

NEW COURSE Risk-based Qualification of Sterile Drug Product Manufacturing Systems (December 8-10)

This course will use a combination of lecture and hands-on application at the PDA Training and Research Institute and will make extensive use of the Aseptic Processing Suite. You will be walked through the planning, protocol development, execution and troubleshooting of the qualification of various drug product manufacturing systems.

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Continuing the ICH Q10 Implementation Journey

Emma Ramnarine, Genentech, and Ursula Busse, PhD, Novartis

ICH Q10, *Pharmaceutical Quality System (PQS),* has increasingly become one of the more frequently referred to guidelines over the last six years. It provides a comprehensive model of a quality management system throughout the product lifecycle, with the goal of accomplishing product realization, establishing and maintaining a state of control, and facilitating continual improvement. The guideline encourages a structured approach for managing knowledge from development through the commercial life of a product until discontinuation. ICH Q9, *Quality Risk Management (QRM)* further gives principles and details for application of quality risk management. QRM and knowledge management are described in ICH Q10 as the two **enablers** that ensure the objectives of an effective PQS are met.

While both ICH Q9 and Q10 have been published for several years, and the terms "QRM" and "knowledge management" are commonly heard and used, the pharmaceutical industry is still on a learning curve in regards to implementing these enablers. QRM is further along in its implementation maturity, especially with use of risk assessment tools. But we are still learning that risk assessment is just one part of the whole risk management process: "risk assessment ≠risk management." For knowledge management, the industry is still in the early stages of the journey. Other industries, such as IT and aerospace, are fairly familiar with knowledge management, and can provide "lessons learned."

The PQS is intended to function as one holistic system. How do you build and make all the parts work together as one intact system? How do you implement and realize Q10? These are part of the discussions PDA has been driving through ICH Q10-focused workshops and trainings. In 2010, PDA cosponsored an ICH Q8, Q9 and Q10 training in the United States, Europe and Japan. Over the last few years, PDA has also been offering focused ICH Q10 workshops.

This year's PDA ICH Q10 workshop will center on the implementation of these two PQS enablers. We welcome and encourage you to take advantage of this excellent opportunity for information sharing and dialogue on QRM and knowledge management. For more information, please visit www.pda.org/ichq10. To learn about the PDA TRI course following the workshop, please visit www.pda.org/q10course.

PDA Hosts SUS Workshop with FDA, Other Industry Groups continued from page 19

Many additional topics identified by the group as key are addressed in the PDA technical report. These include: interchangeability of materials or components, supplier quality systems and regulatory requirements, use of supplier documentation and verification practices, standard versus custom designs, supplier qualification, sterility, material and supplier qualification, operator training, process leachables, risk management, SUS handling and leak prevention, and supply chain management. While some of these receive more attention than others in the technical report, meeting participants concurred the report will serve as an authoritative resource for suppliers, end users, regulators and standard-setting organizations, and that PDA has become a key driver in the development path of single-use standards.

Going forward, the groups' representatives agreed to focus on proactive alignment through ongoing industry meetings and to develop a conflict resolution forum. PDA's next focus will be to develop a consensus around quality systems and compliance issues within the single-use space. All in all, PDA hopes this meeting will serve to drive harmonization within the SUS industry.

Reduce Human Error in a GMP Facility continued from page 32

at BTG (formerly Protherics UK Ltd) and also within microbiology laboratories at the UK Health Protection Agency, London, UK.

Shanon McKenna is a human factors and usability expert specializing in medical device testing and regulatory compliance. She has over a decade of experience implementing medical technology solutions and holds certifications in business process analysis and systems modeling.

Anthony Newcombe is a Principal Consultant at PAREXEL, advising and consulting on all aspects of pharmaceutical development relating to Biological and Biotechnology Products. He worked previously within Global Industrial Operations at GSK Biologicals and also at Pfizer in the UK and Ireland.

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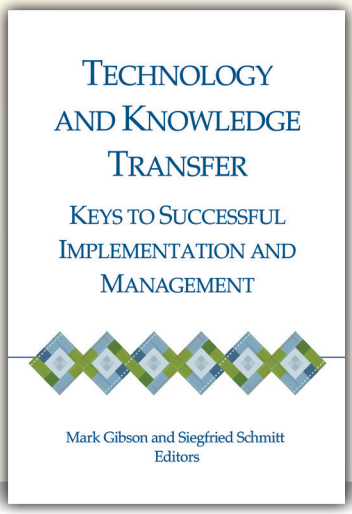

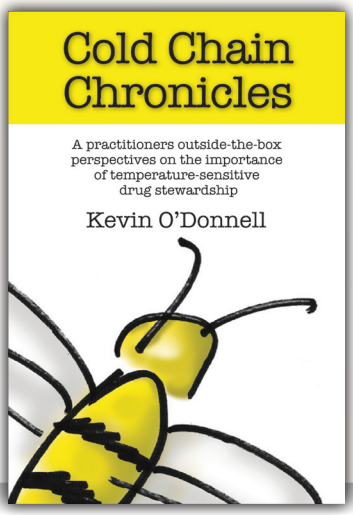

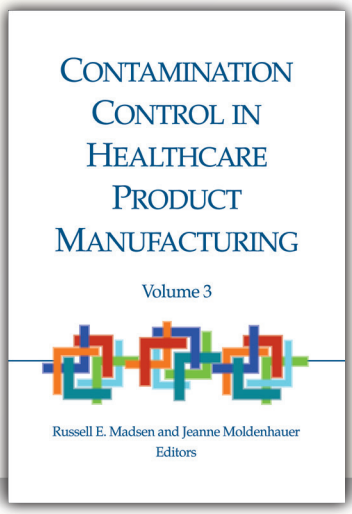

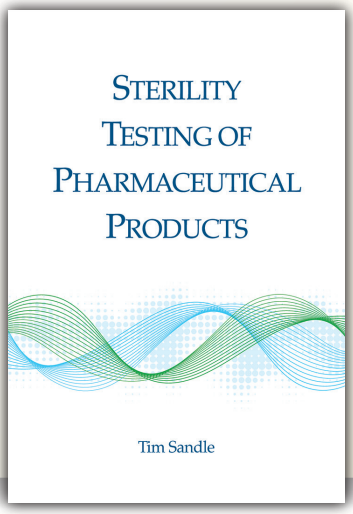

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Report from the ATMP Conference

Industry, Regulators Collaborate on ATMPs

Joshua Eaton, PDA

While the field of advanced therapy medicinal products (ATMPs) continues to mature, the process remains slow. Because they are classified as medicinal products, advanced therapeutics face the same requirements as any other medicinal product submitted for Market Authorization, as outlined under current European pharmaceutical manufacturing guidelines. Not surprisingly, the challenge of complying with these regulatory expectations in terms of quality, safety and efficacy was a recurring theme throughout discussions at PDA's *Advanced Therapy Medicinal Products* conference in June in Madrid.

In particular, the complex nature of these products can make it difficult to determine what constitutes a complete control strategy. Speakers **Jean-Hugues Trouvin,** PharmD, Professor, Universite Paris Descartes, **Jean Stanton,** Director, Regulatory Compliance, Johnson & Johnson, and **Karen Walker,** Global Head Biologics and Biopharma Ops, QA, Novartis, brought attention to this topic. All noted how crucial it is to establish critical quality attributes (CQAs) and a quality target product profile (QTPP). The challenge with complex products like ATMPS, however, is ascertaining when those metrics are correct.

Many developers of small molecule pharmaceuticals have embraced QbD principles, but ATMP developers cannot apply QbD principles as strictly to their products. A possible path to initiating QbD for ATMPs could entail prioritizing product development to achieve the level of product control and understanding needed to progress through commercial development. Product knowledge will evolve throughout the development process, so flexibility and adaptability along with a risk-based approach are keys to successful CQA determination. The speakers recommended developing the QTPP as early as possible as a strategy. As Stanton noted, however, the QTPP cannot be successfully created in a silo; a multidisciplinary team is required to properly assess the CQAs that feed into the QTPP. Beyond this point, but still related to product development and understanding, reliable functional assays should be in place to determine how the product really works long before administration to the patient.

Safety concerns such as unexpected toxicity, inappropriate cellular differentiation and cross-reactivity are of special interest to the regulators tasked with approving ATMPs. **Margarida Menezes Ferreira** of Infarmed (Portugal's regulatory authority) noted that a consistent, safe and effective product is required for Market Authorization and reiterated the paramount importance of product characterization. She also recommended that ATMP developers take time to meet with their respective regulatory authorities to discuss expectations and solutions. Trouvin spoke to this point as well, pointing out that the regulatory bodies understand the difficulties in developing ATMPs, are willing to collaborate further and have acted accordingly. Of particular note, the EMA has modified some regulatory guidelines specifically to allow for the peculiarities and challenges of ATMPs (*Guideline on the risk-based approach according to annex I, part IV of Directive 2001/83/EC applied to Advanced therapy medicinal product;* issued Feb. 2013). This guidance details a greater flexibility and allowances for nontraditional background qualification, assays and methods. The Committee for Advanced Therapies will review applications on case-by-case basis showing that there is no one standard road to approval. The key, as repeatedly stated throughout the conference, is well-validated and well-characterized products and processes.

As the presentations progressed, speakers pointed out how pharmacovigilance and long-term risk monitoring has allowed some technologies to continue development as well as aided in the approval of other ATMPs, notably Genzyme's matrix-induced autologous chondrocyte implantation (MACI) therapy for the treatment of cartilage damage.

Practical considerations discussed included the marketing and distribution of tissue-based products, such as whether a company should apply for a CE mark first or go to market via another route. Ferreira responded that products have to be CE marked for their intended use in order to be distributed in the European Union. The problem arises, however, that—just as with many pharmaceuticals—ATMPs do not always end up being prescribed for their original intended use. Even beyond approval, since the target populations are often very small, reimbursement concerns were noted as one of the many hurdles for companies trying to develop successful ATMPs.

The promise of ATMPs is being realized, as seen with ChondroCelect (autologous cartilage repair therapy from TiGenix), Glybera (a gene therapy from UniQure that aids in fat digestion for those with defective enzymes), and Provenge (Dendreon's autologous cellular immunotherapy for the treatment of prostate cancer). Support from regulatory bodies is behind them as evidenced by the collaborative process developed to work through the development and approval processes. Both parties understand that there is no one way, uniform answer, or magic solution for a successful application, and that development of ATMPs is not a "tick box" exercise as has been developed over the years with small molecule pharmaceuticals.

While more changes and challenges may be in store now that the EMA issued a draft guidance on the classification of ATMPs in June, the will and dedication to persevere in developing lifesaving and life-changing ATMPs is alive and well.

Glenn E. Wright, Eli Lilly and Company

Based in Science for the Improvement of our Industry

PDA's love affair with the science of pharmaceutical manufacturing is well over 65 years old now, and the romance continues. When I look back on PDA history and my 25+ years in the industry, there is always one PDA founding principal that resonates with me, "To foster and advance, in the interest of public health, the art and science of parenteral therapy." We have come a long way since this principal was established in 1946 as part of PDA's Certificate of Incorporation, but this drive for science continues to be the underlying force within the organization. The original *Technical Report No. 1: Validation of Steam Sterilization Cycles,* issued in 1978, has been a great symbol of the power of good science. It became the standard reference for well over 20 years before being updated in 2007. That is a real testament to the quality of science that continues within PDA today. At last count there have been over 60 science-based technical reports released (not including updates) as well as a wide selection of PDA books and, of course, the countless scientific articles in PDA's *Journal of Pharmaceutical Science and Technology.* There is truly a lot of science going on in PDA.

When I consider the types of science that PDA focuses on, I see three distinctive disciplines. The first is applied manufacturing science that directly correlates to manufacturing and products like sterile filtration, container closure integrity and viral clearance. The second is quality science that relates to quality processes like risk management and CAPA. And the third is regulatory science that relates to regulatory processes such as new product submission and postapproval change requirements. These scientific disciplines are reflected in the many activities (meetings, interest groups, workshops, training, etc.) that PDA offers to its members.

You might not know it but on the ground floor of the PDA headquarters in Bethesda, Md. is PDA's Training and Research Institute (TRI). It's a one-of-a-kind facility that allows for hands-on research and training with laboratories, cleanrooms, filling lines, autoclaves, etc. I still remember serving on the Board of Directors in the late 1990s when we approved funding for the buildout of this incredibly important endeavor. The magnitude of resources from both a capital and headcount perspective made each of us on the board a bit nervous as we voted to approve, but we knew the industry needed it. And we were right! Thanks to PDA's commitment, TRI remains a bright star, having completed over 17 years of serving industry, regulators and academia. Just related to training activities, in 2013 the Institute provided over 60 training courses to more than 1300 participants.

So what does the future hold for PDA? PDA is based in science with a long tradition of providing the science needed to advance our industry and benefit the public health. As a membership organization, it's the members that have shaped PDA's past and it will be its members that shape its future. As a member how will you shape our future? Getting involved is the first step. There are many ways to contribute to the science of PDA. Join an interest group or task force, volunteer on a planning committee, request to present at a meeting, submit a journal article to PDA's *Journal of Pharmaceutical Science and Technology* or a poster for an upcoming meeting.

If you would like to become more active in PDA please contact PDA's Volunteer Coordinator **Jonathan Hill** at hill@pda.org or by phone at +1(301) 656-5900, ext. 164. Our future depends on it.

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Upgrading Skills: A Never-Ending Endeavor

When I first broke into the business of writing about pharmaceutical quality control and regulations, the only skill I needed to bring to the table was my ability to write clean, coherent copy. However, after just my first attempt to contribute to *"The Gold Sheet"* (a section on USP dissolution testing—I'll never forget it), I learned quickly that my writing skills were perfectly fine for an academic setting, but not at all good for the newsroom. It took nearly a year and several failed attempts before my copy could get past the careful eye of my editor. But I adapted and, in the process, upgraded my skills.

In addition, as part of a two-man team, I had to become a much better editor. Not only was I required to carefully edit my own work, but I had to get accustomed to helping improve the work of a much more experienced writer/editor. This was daunting, but I upgraded my skills. Next, I joined PDA as the editor of the *PDA Letter,* but soon found myself managing the design and production process. Again, my skills had to be upgraded and improved. Soon I had a writer working for me, then a designer. This led to upgrading my management skills and my people skills. So I did.

Next, I was promoted to Director of Publishing, with responsibility for the PDA Journal editors, converting the Journal from print to electronic and so on. Once again, my skills had to be improved in order to meet these challenges. Now, I edit podcasts and soon will also edit videos and am working to create a new online presentation of the *PDA Letter*. In addition, I use Twitter (@Walt_PDA) and work hard to use LinkedIn and soon, PDA Connect. All of these require new skills. And earlier this year, I was asked to take over management of the press and press releases. I helped organize PDA's first press conference and create a new online tool for the press to register for PDA conferences. Again, all of this done after taking time to upgrade my skills.

I'm grateful for these opportunities to improve myself, learn and excel. I love the challenges. I'm also grateful for the mentors who helped me along the way, particularly **Bill Paulson** of IPQ, who was my editor at *"The Gold Sheet"*, and PDA's **Rich Levy,** who has counseled me continuously on my management capabilities.

So, you might be out there facing the fact that you need new skills. Quality professionals, plant operators, regulatory affairs staff, and even company management must work harder than ever to improve the quality culture across a pharmaceutical enterprise. This is forcing people to take on roles that they never thought they would have to perform before, and to do so, gain new skills. This issue is meant to bring light to the sea change taking place across the industry. And PDA is the right organization to help our members gain the skills and knowledge they need to excel in the new quality paradigm under construction today.

The *PDA Letter* podcast is available at www.pda.org/pdaletter.

PDA Letter

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