People • Science • Regulation

PDA Letter

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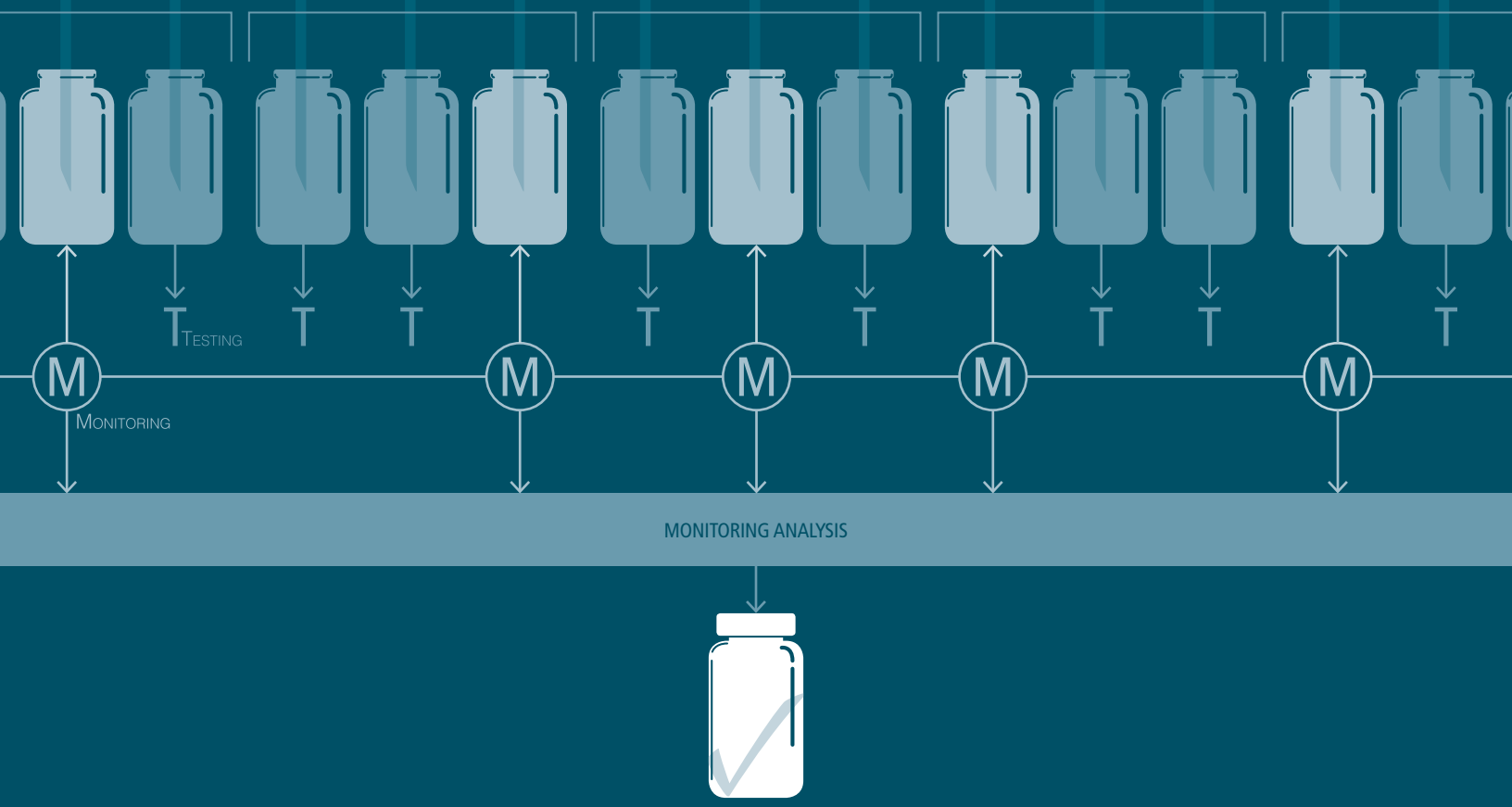

2014 PDA ANNUAL MEETING **Show Issue**

Follow the logo to find articles on the *2014 PDA Annual Meeting*

The Changing Landscape of Release Testing for Sterile Drug Products

22

What Are You Waiting For? Register Today!

The Parenteral Drug Association presents the...

2014 PDA ANNUAL MEETING

Biopharmaceutical and Sterile Manufacturing – Embracing Innovation to Meet Global Challenges

April 7-9, 2014 | JW MARRIOTT SAN ANTONIO HILL COUNTRY | SAN ANTONIO, TEXAS

PDA's premier event, the *2014 PDA Annual Meeting* will provide you with a one of a kind learning opportunity. This year the series of parallel sessions, a key and well liked feature of the annual meeting, will focus on issues and challenges related to *Biological Sciences, Product Manufacturing,* and *Quality Systems* as well as valuable peer-to peer networking events among many other benefits. Look no further than this *must attend* meeting, which has much to offer and will provide an excellent forum for learning and discussing recent innovations and interacting with industry and regulatory experts.

For the first time, this year's agenda is filled with leading FDA experts:

Thomas Arista, Investigator, CDER, *FDA*

Kalavati Suvarna, PhD, Microbiologist, CDER, *FDA*

Karen Takahashi, Senior Policy Advisor, CDER, *FDA*

Alex Viehmann, Operations Research Analyst, CDER, *FDA*

Following the conference, there will be a post-conference workshop, ***PDA Biofilm and Bioburden Workshop*** on April 9-10. The workshop will provide the latest science and best practices around microbial control for the pharmaceutical manufacturing environment. Presentations will be provided by technical experts from academia, industry, and FDA.

From April 10-11, the PDA Training and Research Institute will host six in-depth training courses. These courses for professionals involved in developing and manufacturing quality pharmaceutical products will cover a range of topics from implementation of quality risk management to process validation and verification.

EXHIBITION: APRIL 7-8
POST-CONFERENCE WORKSHOP: APRIL 9-10
COURSES: APRIL 10-11

www.pdaannualmeeting.org

Parenteral Drug Association Training and Research Institute (PDA TRI)

UPCOMING LABORATORY AND CLASSROOM TRAINING FOR PHARMACEUTICAL AND BIOPHARMACEUTICAL PROFESSIONALS

MAY 2014

2014 PDA Knowledge Management Workshop – Enabler for ICH Q8 – Q11, QRM and Continued Process Verification Course Series

May 21-22 | Bethesda, Maryland
www.pda.org/kmcourses2014

- Integration of Risk Management into Quality Systems (May 21)
- Learning and Training as Contributors to Knowledge Management (May 21-22)
- Technology Transfer – *New Course* (May 22)

2014 PDA Packaging Course Series

May 22-23 | Washington, D.C.
www.pda.org/packagingcourses2014

- Implementing Quality Risk Management for Pharmaceutical and Biotechnology Manufacturing Operations: Case Studies in the Packaging and Labeling of Drug Products (May 22)
- Pharmaceutical Package Integrity Testing: Industry Challenges, Technology and Advancement – *New Course* (May 23)

JUNE 2014

2014 Aseptic Processing Training Program

Bethesda, Maryland | www.pda.org/2014aseptic

- *Session 3:* June 2-6 and June 23-27, 2014
- *Session 4:* August 18-22 and September 22-26, 2014
- *Session 5:* October 13-17 and November 3-7, 2014

2014 PDA Pharmaceutical Supply Chain Course Series

June 5-6 | Washington, DC
www.pda.org/supplychaincourses2014

- Developing a Robust Supplier Management Process (June 5)
- Good Distribution and Storage Practices (GDP/GSP) – Securing the Supply Chain – *New Course* (June 6)

2014 PDA Virus & TSE Safety Course Series

June 12-13 | Bethesda, Maryland
www.pda.org/viruscourses2014

- Virus Contamination in Biomanufacturing: Risk Mitigation, Preparedness and Response (June 12)
- Introduction to Emerging Methods for Virus Detection (June 13)

2014 PDA Aseptic Processing-Sterilization Course Series

June 19-20 | Chicago, Illinois
www.pda.org/sterilizationcourses2014

- Recommended Practices for Manual Aseptic Processes (June 19)
- Clean Room Design, Contamination Control and Environmental Monitoring for Controlled Environments (June 19)
- Process Simulation Testing for Aseptically Filled Products (June 20)
- Validation of Moist Heat Sterilization Processes: Cycle Design, Development, Validation and Ongoing Control (June 20)

For more information on these and other upcoming PDA TRI 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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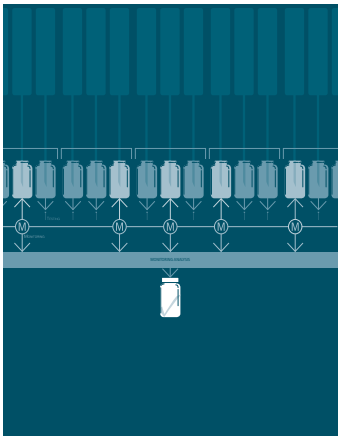
Cover



Cover Art Illustrated by Katja Yount

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2014 PDA ANNUAL MEETING

FDA Will Have Its Say

This year's *PDA Annual Meeting* will feature a number of regulatory speakers from the U.S. FDA in addition to our industry and scientific experts. The following is a list of confirmed FDA speakers, all with CDER, lined up to deliver presentations at this year's Annual Meeting:

- **Karen Takahashi**, Senior Policy Advisor, will discuss FDA warning letters on data integrity issues in Session C, April 7, at 11:15 a.m.
- **Thomas Arista**, Investigator, CDER, will present on aging facilities in Session E, April 7, at 2:45 p.m.
- **Alex Viehmann**, Operations Research Analyst, will talk about statistics-based sampling and testing as part of process validation in Session I, April 8, at 11:15 a.m.
- **Kalavati Suvarna,** Consumer Safety Officer, will provide an update on the PDA bioburden and biofilm technical report at Breakfast Session I on April 8; she will also speak about the Agency's perspective on bioburden and biofilm control at the postconference workshop on April 10 at 1:15 p.m. in Plenary Session 5.

To view an agenda listing the dates and times these individuals will speak, please visit www.pdaannualmeeting.org.

SONNENHOF

PDA Europe supports the children's hospice „Sonnenhof"

which is located close to the PDA office in Berlin, Germany. If you also wish to support this project, please visit http://bjoern-schulz-stiftung.de/sonnenhof.html or ask for information Melanie Decker at decker@pda.org.

2014 PDA ANNUAL MEETING

Got a Particular Interest? Attend a PDA Interest Group Meeting at Annual

All attendees of the *2014 PDA Annual Meeting* have the opportunity to attend a PDA interest group meeting. These meetings will be held on April 7–8. Below is a schedule of all Annual Meeting interest group sessions. We've marked whether the interest group falls under the Biotechnology Advisory Board (BioAB), Science Advisory Board (SAB) or Regulatory Affairs/Quality Advisory Board. Please visit www.pdaannualmeeting.org for more information about these sessions.

Monday, April 7

4:30 — 6 p.m.

Blow/Fill/Seal Interest Group (SAB)

Lyophilization Interest Group (BioAB)

Management on Outsourced Operations Interest Group (RAQAB)

Microbiology/Environmental Monitoring Interest Group (SAB)

Packaging Science (SAB)

Process Validation Interest Group (SAB)

Visual Inspection of Parenterals (SAB)

Tuesday, April 8

4 p.m. — 5:30 p.m.

Filtration Interest Group (SAB)

Inspection Trends Interest Group (RAQAB)

Prefilled Syringes Interest Group (SAB)

Quality Risk Management Interest Group (RAQAB)

Quality Systems Interest Group (RAQAB)

Vaccines Interest Group (BioAB)

PDA Volunteer Spotlight

Harald Stahl, PhD

- Senior Pharmaceutical Technologist
- *GEA Pharma Systems*
- Member Since | 2008
- Current City | Steinweiler, Germany
- Originally From | Siegen, Germany

Every day is a learning day

Not only does Harald experiment in his career but he also likes to experiment in the kitchen as a cook!

Why did you choose to join PDA?

I had known **Georg Rößling**, who is the VP of PDA in Europe, for many years; and, when Georg started to focus the vision of PDA Europe, he asked me if I would be interested in sharing my lyophilization knowledge. I was both flattered and delighted. Shortly after, I became the lyophilization interest group leader for Europe.

Of your PDA volunteer experiences, which have you enjoyed the most?

Organizing the annual lyophilization conferences is a great pleasure. It keeps me up to date with the latest developments and discoveries in freeze drying; it provides great networking opportunities and allows me to stay in touch with experts from other companies who are keen to share their expertise.

How can PDA benefit someone who is established in the pharmaceutical industry?

PDA offers access to state-of-the-art information from experts in their field. Being a PDA member also means you get to interact with the smartest and most experienced professionals in the industry. Pharmaceutical science and technology is always evolving; being involved with PDA means you're never out of touch.

What is your favorite thing about being a PDA member?

It's an open forum for knowledge exchange; the combination of events, publications and meeting new connections has been invaluable for both my personal and professional development. It's an elite group of experienced experts without being elitist.

How has your field changed since you started your career?

As with many areas of the pharmaceutical industry, there is more competition, there is intense pressure from the regulatory agencies, and, even now as we slowly recover from the economic downturn, finance and cost issues remain key drivers.

What would you tell someone who is just starting out in the industry?

Keep an open mind; there's always something new to learn and you never know where that knowledge might come from. The pharmaceutical industry is changing every day, and every day is a learning day.

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Delaware Valley Chapter Welcomes New Officers

Chapter President Jason Mattis, GlaxoSmithKline

On behalf of the Delaware Valley PDA Chapter, I'd like to personally welcome the new chapter officers to the Delaware Valley chapter board.

Art Vellutato Jr., who was chapter president for 14 years, has finally stepped down. He had been instrumental in the success of the Delaware Valley Chapter from providing financial support when it faced bankruptcy in 2002 to expanding Vendor Night to raise money and scholarships for the local Delaware Valley Science Fair students. Over the many years, he was able to leverage his vendor relationships to attract quality speakers and sponsors for chapter events.

In addition, he has been very active at the global PDA level and often served as an instructor for PDA's Training and Research Institute courses, leading to his receiving the James P. Agalloco Award for his outstanding performance as a TRI instructor.

He will be greatly missed and leaves quite a legacy for the new officers to fill.

The following were elected as officers for PDA's Delaware Valley Chapter in 2014:

- President: **Jason Mattis**
- Vice President: **Nancy Fulginiti**
- Treasurer: **William O'Connor**
- Secretary: **Matthew Schmidt**

PDA Who's Who

Jason Mattis, Senior Scientist, GSK

Nancy Fulginiti, Executive Director, Sandoz, a division of Novartis

William O'Connor, Investigator, GlaxoSmithKline

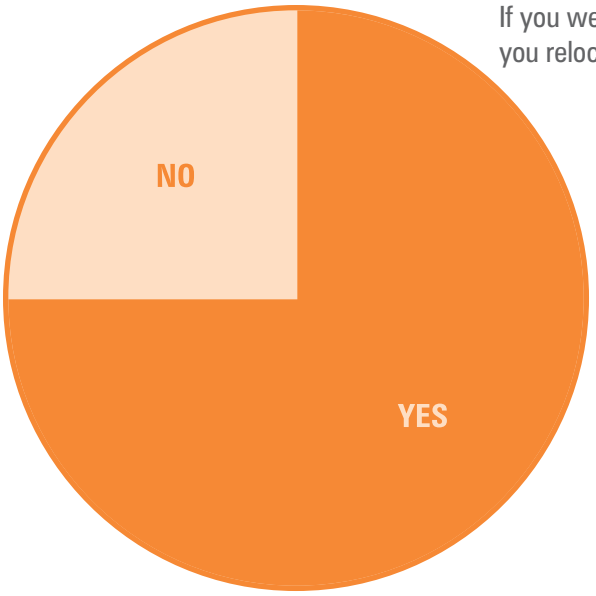
Matthew Schmidt, Product Coordinator, Merck

PDA Pulse

PDA Members Willing to Relocate Abroad

PDA members hail from all across the world. In addition, PDA has 24 chapters scattered across North America, Europe and the Asia-Pacific region. Considering that more employers seek candidates with international expertise, we recently asked members if given the opportunity to relocate overseas, would they?

Close to 75% would locate overseas if given the chance. Clearly, our members are responding to this demand for a more "global" employment background!



Take PDA's 2014 Process Validation Survey Today

Members of the TR 60 Technical Report Team have decided to make a follow-up survey to receive feedback and how industry is implementing the **2011 FDA Guidance, Continued Process Verification**, and the **challenges of process validation**.

All information collected by **March 12** will be presented at the *2014 PDA Annual Meeting* during the Process Validation IG session.

Please note that this survey will remain open until **May 14** and the identity of survey respondents will be blinded and not revealed to the Task Force members, or in any publication or presentation of the results of the survey.

All survey respondents who chose to provide their contact information will receive the survey results for free as well as any advance presentations or publications.

Take the 2014 PDA Process Validation Survey at www.pda.org/2014PVsurvey today and help PDA help you.

2014 PDA ANNUAL MEETING

Network with Fellow PDA Members

PDA has arranged some exciting and fun events for our members at the upcoming *2014 PDA Annual Meeting* in San Antonio, Texas. We urge members to attend these events, which also offer opportunities for networking. Come join us and enjoy unforgettable memories!

April 6

8th Annual PDA Golf Tournament

On Sunday, show off your swing at the 8th Annual PDA Golf Tournament, held between 7 a.m. and noon at the AT&T Canyons Golf Course. This course, which opened in 2010, features 36 holes designed by **Pete Dye and Greg Norman,** two of the most respected World Golf Hall of Fame members. AT&T Canyons Course sits adjacent to a nature reserve, offering breathtaking views. $230 per person; price includes tee time, valet, cart, range of balls, tournament management and lunch.

8th Annual Walk/Run

Be a hero to individuals with developmental disabilities and join us at the 8th Annual Walk/Run to benefit The Arc of San Antonio! This event will be held 7–10 a.m. at the JW Marriott Hill Country Resort and Spa, and will offer the choice between a 5K run or one mile walk over the hills of the property. This year the funds will help benefit the lives of individuals with developmental disabilities in the San Antonio area. The first and second place winners of the walk and run will receive a prize. $35 per registered attendee or guest; price includes race bib and healthy refreshments.

Meet and Greet Reception

Once you've registered, we invite you to mingle with other attendees at a reception between 3 p.m. and 6 p.m. Relax and chat with old friends as well as introduce yourself to some new folks. Sit back, enjoy some refreshments and let everyone know how your flight went.

April 7

Networking Gala Reception

After a long day full of informative presentations delivered by expert speakers, join fellow attendees in the Exhibit Hall at 6 p.m. for an hour and a half of networking while you enjoy some refreshments.

April 8

PDA Dine Around

At this optional event, dine with colleagues from a selection of restaurants, including Acenar, Biga on the Banks, Boudro's, Fogo de Chao, Little Rhein Steak House, Luke River Walk, Mi Tierra Café and Paesano's Riverwalk. Transportation will be provided and departs promptly at 6 p.m. from the Exhibit Hall entrance. Interested participants can register at the PDA Concierge Service inside the Exhibit Hall April 7 and 8.

Boat Tour

Take a cruise down San Antonio's popular River Walk on this optional guided boat tour. Tickets are available online at riosanantonio.com/rivertours or onsite. Tours are approximately 35 minutes and depart from Historia, under the Market Street Bridge and Alamo Street. The price is $8.25 for general admission tickets.

Additionally, there will be further opportunities for networking during daily luncheons held in the Exhibit Hall. Refreshment breaks will offer further opportunities for mingling as well as opportunities to chat with exhibitors.

Members can also take advantage of the Latana Spa at the JW Marriott Hill Country Resort and Spa and receive a 15% discount on massage therapy, body treatments, facial skincare, nail care, finishing touches and treatments for two. If you're interested, it's recommended that you book in advance by calling (210) 276-2300 or online at www.jwlantanaspa.com/Spa-Reservations/Book-Appointment-Online-13.html. To receive the discount, the booking code is PDA.

PDA Visitors | PDA Headquarters

On Feb. 21, the new 2014 PDA Board of Directors convened at the Bethesda, Md. headquarters. During their meeting, Board members had the opportunity to visit stations highlighting PDA's departments and learn more from staff members.

The 2014 Board of Directors discusses objectives for 2014.

Jason Brown of PDA's Programs and Meetings department discusses conference planning with Martin VanTrieste.

Hal Baseman, the new Chair, shows off his numerous ribbons to Membership Director Hassana Howe.

PDA Training and Research Institute staff pose in front of their poster. (l-r) Oscar Bermudez, James Wamsley, Stephanie Ko and Bob Dana

Craig Elliott, CFO, and Jennifer Bell, show Rebecca Devine, Junko Sasaki and Joyce Bloomfield, the Accounting team's poster.

The Publishing team takes a break from the *PDA Letter* to present their own poster to the new board.

TOOLS FOR SUCCESS

Brought to you by the PDA Career Center.
Go to www.pda.org/careers for the latest opportunities.

You WILL Get Googled... Are You Afraid?

Joshua Waldman, author of *Job Searching with Social Media For Dummies*

I TELL my clients that they will be Googled as surely as it will rain in Portland. The latest survey said that 81% of employers *will* Google candidates.

Online reputation management is a critical piece of your online job search. There is just no getting around it.

Quick story, when I Googled my name one year ago, I was a convicted felon and a prolific New York gynecologist, neither profession was something I wanted to be connected to. So I embarked on a campaign to bring the real "me" to Google's first page. Now, my LinkedIn Profile comes up on Google's first page.

Job seekers, follow these easy steps below to finally get a handle on your internet reputation!

Assess the Current State of your Online Reputation

1 Google your name and notice how many times the real you comes up on first page, and on the first three pages.

2 Use Pipl.com to search your name… does the real you come up?

3 Depending on these results, you may have a lot of work ahead of you to begin to rebuild your name. Use this data to figure out how much time you need to be spending on this project.

Bury the Dead, Plant a Tree

1 Traditional SEO (search engine optimization) suggests that the more times your name shows up on highly reputable websites, the higher it will rank on the results page.

2 So in order to knock down the stuff you don't want, you have to build the stuff you do want.

3 Collect a list of professional portfolio items that you can share…and post them on the appropriate sites. For example, if you have developed PowerPoint presentations, then load them onto SlideShare.com with your name all over it. If you wrote articles, then publish them on ezineArticles. If there are videos of you, put them on YouTube.

4 Now, link as many of these shared portfolio items together. Link your SlideShare to your LinkedIn, Link your YouTube video to your VisualCV and so on.

5 Establish as many online portfolios as you can. In addition to LinkedIn, and VisualCV, you can set up Xing.com, Facebook Fan Page, Twitter, Plaxo and hundreds more.

Don't expect results right away, sometimes this can take several months depending on how many other search results you are trying to displace. Be patient and stay consistent in your efforts.

About the Author

Joshua Waldman is an expert on leveraging social media to find employment. Watch his exclusive video ,"3 Secrets to Getting Job Interviews by Next Week" (careerenlightenment.com/training) to learn the three secrets no one wants you to know about getting hired. He is the founder of Career Enlightenment, which offers professional LinkedIn profile writing (liprofile.com).

Your Local PDA Connection

Are you curious about the issues unique to your region?

Another layer of PDA leadership resides at the grassroots level in the Chapter organizations. Regional PDA Chapters provide local services to the membership, including translations of PDA publications, networking social events, student scholarship and annual regulatory and technical conferences. Each Chapter is managed by volunteer leaders.

Learn more about your local Chapter at www.pda.org/Chapters

snapshot 2014 PDA ANNUAL MEETING

Technical Report No. 62 Provides Aseptic Processing Guidance for Industry

Rebecca Stauffer, PDA

Are you currently manufacturing products in an aseptic manual operation? Or are you just interested in gaining insight into manual aseptic processing? If you answered "yes" to either question and you plan to attend the *2014 PDA Annual Meeting,* **Carol Lampe,** Independent Consultant, urges you to attend Session H, "Sterile Processsing", April 8 at 10:45 a.m. During this session, she will discuss *Technical Report No. 62: Recommended Practices for Manual Aseptic Processes*.

The *PDA Letter* spoke with Lampe, who took the time to answer some questions regarding her presentation.

PDA Letter: Technical Report No. 62 has been out since July 2013. Can you tell us why it is important and who can benefit from using it?

Lampe: There are a number of areas within the pharmaceutical industry that employ manual aseptic processing (MAP). These are listed in the introduction of the report and include (but are not limited to) vaccine preparation, cell culture, gene therapy, IND/IMP manufacturing, clinical and commercial manufacturing and pharmacy formulation and dispensing. Until this point, there had not been a guidance document that discusses some of the practical considerations when dealing with process simulations for monitoring MAP.

For a MAP, the human being replaces the filling equipment/capping equipment. It is also acknowledged that human beings are the major contributor (80% or greater) to contamination in an aseptic process when they are present. Combining these two concepts places a strong emphasis on the need for a robust design of the MAP itself and the process simulation used to evaluate the operator's aseptic technique. This technical report addresses some of these considerations, and hopefully provides the user with additional tools for designing and evaluating their specific process.

PDA Letter: What are your objectives in speaking about the report at the upcoming *PDA Annual Meeting?*

Lampe: First of all, if it is possible to automate a process, that would be the ultimate goal. That being said, there will always be processes that cannot be automated. The intent is to bring greater awareness to the increased risks surrounding manual aseptic processing design and media fills. I would also hope it will generate more conversations about manual aseptic processing and the tools that would keep the gloved hand from touching product contact surfaces. If we talk more about our needs and frustrations, we may see more sterile disposable tools become commercially available for manual aseptic processing.

PDA Letter: Do you think there is room for additional technical reports on this topic?

Lampe: The guidance that we wrote was a broad brush stroke on manual aseptic processing. We tried to address a number of manufacturing concerns, but certainly did not get into high detail. There is any number of additional technical reports that could be pursued in specific technologies. Additional guidance could be given on in the area of quality control sampling—including sterility test sampling. Based on comments that we received from the Science Advisory Board and the Board of Directors, they would like to see additional details on MAP of nonaqueous drug products. They also requested additional information in the chapters, "Equipment, Components and Container/Closure" and "Process Time Limitations."

About the Expert

Carol Lampe is an independent consultant. She spent 31 years at Baxter in corporate sterility assurance and served as a technical expert on aseptic processing.

Call for Volunteers – Aging Facilities Task Force

The Aging Facilities Task Force, co-chaired by **Glenn Wright** and **Maik Jornitz**, is seeking volunteers.

The task force will address the pressing topic of aging facilities and the need to update or refurbish such facilities, processes and analytics. The task force will likely be divided into different subgroups responsible for facilities, processes and analytics. Each subgroup will address current problem areas, how to overcome such issues and rectify them, and the regulatory requirements to implement renewal, optimization and modernization plans.

If you have any questions, please do not hesitate to contact Glenn (wright_glenn_e@Lilly.com) or Maik (mjornitz@gconbio.com).

If you are interested in joining the task force, please contact **Morgan Holland** at holland@pda.org.

Task Force *Corner*

Mycoplasma Task Force Makes Strides; Plans to Convene at *2014 PDA Annual Meeting*

TF Chair Barbara J. Potts, PhD, Potts and Nelson Consultants

The PDA Mycoplasma Task Force was established in 2006. The participants were divided into four subgroups (mycoplasma detection, filtration, emerging issues and raw materials). 40% of the task force comprises European members while the other 60% comprises individuals from the United States. Task force members come from biotechnology companies, academia and regulatory agencies.

Past accomplishments include *PDA Technical Report No. 50: Alternate Methods for Mycoplasma Testing,* published in 2010, three workshops, a special section on mycoplasma in volume 38 of *Biologicals* ***(1),*** a PDA proceedings book on the 2006 workshop and two mycoplasma surveys. Current accomplishments include an article slated for publication in the May–June 2014 issue of the *PDA Journal of Pharmaceutical Science and Technology* focused on the development of a method for consistent filtration of mycoplasma. Additionally, the task force has contributed to a collaborative study to establish the first World Health Organization International Standard for mycoplasma DNA for NAT-based assays ***(2).***

Looking ahead, a second PDA technical report on mycoplasma filtration is in progress and a fourth mycoplasma workshop is planned for Sept. 29–30 in Berlin, Germany. An update on the content of the upcoming mycoplasma filtration technical report will be presented at the *2014 PDA Annual Meeting* on April 8 in San Antonio, Texas, during the Filtration Interest Group meeting. The task force will meet face-to-face at the *PDA Annual Meeting* April 9 from 1–4 p.m. in a task force-only meeting. A longstanding tradition of celebrating the group's productivity with cosmo drinks will follow that meeting.

I want to thank all of the task force members that have contributed to all of our past projects as well as our future offerings.

References

1. Potts, B. and Hayflick, L. eds. "Mycoplasma." Special section, *Biologicals* 38, no. 2 (2010).
2. Hanschmann, K-M.O., et al. "Collaborative Study to Establish the 1st World Health Organization International Standard for Mycoplasma DNA for Nucleic Acid Amplification Technique (NAT)-Based Assays." World Health Organization. Geneva. 2013. tinyurl.com/osb7u7y

About the Author

Barbara Potts, PhD, specializes in the control of adventitious agents (viruses, bacteria, mycoplasma and prions) from a compliance, science and business focus.

2014 PDA ANNUAL MEETING Tech *Trends*

Radiation Sterilization Creates Opportunities, Challenges

Rebecca Stauffer, PDA

The use of radiation sterilization in the industry has grown considerably, although certain forms are used more often than others. According to **Byron Lambert,** PhD, Sr. Associate Fellow, Sterilization Science, Abbott Vascular, the most commonly used form of radiation sterilization in pharma is gamma sterilization, while e-beam sterilization comprises one-fifth of the market. Even less common is X-ray sterilization. Companies have a few options when it comes to these novel sterilization practices, yet regulatory concerns must still be addressed.

In his presentation at the upcoming *2014 PDA Annual Meeting* ***(1),*** Lambert will address the regulatory aspects of radiation sterilization.

"Some of the topics of my talk will address the changing regulatory standards environment of terminal sterilization," he said. "This applies to all terminal sterilization modalities."

In addition, Lambert will address the challenges of using newer forms of sterilization for combination products as well as temperature-sensitive products.

"Many combination products include plastics and other materials that are sensitive to the temperatures involved with moist heat," he said. "The focus of my talk is how the medical device sterilization world is changing due to sensitive combination products, with resulting opportunities for the pharmaceutical industry. By sensitive combination products, I mean medical devices that have incorporated pharmaceuticals, biologics, temperature sensitive bioabsorbable materials or active electronics."

Lambert urged the following individuals to consider attending his presentation:

- Manufacturers of sensitive combination products exploring ways to avoid moving to aseptic processing due to material compatibility issues.
- Manufacturers who might be able to move from aseptic processing to gentle terminal sterilization processes.
- People interested in regulatory affairs and the changing landscape for terminal sterilization processes.

Reference

1. Lambert, B. "Session H: Novel Sterilization Practices (e.g., E-Beam Terminal Sterilization)." Presentation at the 2014 PDA Annual Meeting, Tuesday, April 8, 2014, 11:15–11:45 a.m., San Antonio, Texas, April 2014 www.pdaannualmeeting.org

About the Expert

Byron Lambert, PhD, is currently a Sr. Associate Fellow, Sterilization Science and Director of Preclinical Research, R&D, for Abbott Vascular. His focus is on finding terminal sterilization solutions for sensitive combination devices that have material compatibility challenges.

2014 PDA ANNUAL MEETING

Biotech Manufacturing Getting Smaller, Flexible

Robert Dream, HDR Company

The need for flexible, multiproduct biopharmaceutical manufacturing is growing.

By 2016, five of the top ten biopharmaceuticals are expected to be monoclonal antibodies (MAb's). Compared with other biopharmaceutical products, MAb's are large proteins that require relatively high doses—and traditionally necessitate high-volume manufacturing process equipment/systems and facilities. Many biopharmaceutical facilities are still designed as traditional fixed equipment/systems facilities, with fixed piping and vessel layout and large bioreactor volumes. Such facilities require a significant financial investment with high total installation costs.

Recent increases in cell culture yields/titer have led to significantly reduced bioreactor volume requirements. This fact is opening the door for single-use manufacturing technologies, such as presterilized assemblies of single-use bags, tubing and filters that are only used once and then disposed of. With a financial investment reduction and simplified installation, single-use technology could be more appealing than other fixed technologies.

As follow-on (biosimilar) versions of these become available in the coming years and personalized therapies evolve, fractionation of the biopharmaceuticals market will continue, thus increasing the need for smaller batch sizes and campaign-based production schemes.

A growing need for flexible, multipurpose and more cost-effective manufacturing will have a significant impact on the design of the production facilities in the future.

Combining single-use technology and high-yield processes could further reduce the price tag for comparable facilities. This combination is being pursued in a number of biopharmaceutical facilities today—the full effect is truly a new biopharmaceutical manufacturing paradigm shift.

Additionally, as products that contact the surface are used only once, single-use technology runs a much lower risk of batch-to-batch contamination, which is of particular importance in multipurpose facilities. A facility based on single-use technology is easy to reconfigure and can, therefore, be ready for a new product in a matter of days. This flexibility translates to reduced development timelines and thus accelerated time-to-market peak. In an increasingly fractionated market the need for speed to secure

market share is more important than the initial minimal cost of manufacturing. And with remarkably increased cell titer, the cost contribution from the manufacturing facility is limited compared with development costs.

This is where the facility lifecycle enters the picture—with single-use technology…it becomes possible to optimize facility installations based on anticipated lifecycle stages. For instance, the strategy could be to start with just one single-use bioreactor to get material for clinical trials and then upgrade the facility with additional bioreactors later in anticipation of market supply production while clinical trials are taking place. As the next pipeline product must be developed, the facility can change the lifecycle stage back to clinical production and the extra bioreactors can be moved to a market supply expansion facility. Such a strategy becomes possible because the manufacturing system is so decoupled from the facility building itself.

As an interesting side effect, environmental impact studies show that single-use technology is perhaps 50% less energy intensive than fixed reusable manufacturing. It may appear counterintuitive, but the emissions from disposing single-use material are more than offset by elimination of the cleaning and sterilization processes required for reusable technology, because heating up many tons of water and metal is extremely energy intensive. Full implementation of high-yield processes and single-use technology results in facilities with a markedly reduced carbon footprint per kg product compared to the fixed facilities of the 1990s.

In reality, the important issue is not stainless steel or single-use technology, but rather how technologies could be combined to provide the most productive and cost effective process in a fast and predictable way. Today, new biopharma manufacturing facilities have to be smaller and more flexible, efficient and cost-effective, and able to adapt quickly to changes on market demand. In the end, it is not really about technology, but more about product and process know-how to get to the market.

[Editor's Note: The author will present "Multi-Product Facility Risk-Based Control Strategies" in Session E, "Facilities," at the *2014 PDA Annual Meeting*, April 7 at 2:15 p.m.**]**

About the Author

Robert Dream is an industry leader with 29+ years of experience, including 15 years of executive leadership experience, in the consumer product, pharmaceutical, biotechnology, and life sciences industries.

Industry Looks to Future of Drug Delivery Options

Program Planning Committee Co-chair Adalberto Ramirez, Amgen

2014 PDA Universe of Prefilled Syringes and Injection Devices • Huntington, Calif. • Oct. 6–10 • www.pda.org/prefilled2014

During the past decade, the healthcare industry has made enormous progress in bringing new products to the market to improve patients' quality of life. We are fortunate to see that innovation continues to flourish for the benefit of the patients. One of these innovations is the prefilled syringe and other drug delivery solutions.

As you are aware, drug delivery continues to face challenges. This market needs to improve in the administration, compliance, safety, costs and accuracy of dosing by taking an integrated approach to develop prefilled syringes and injection devices for tomorrow's success. Aging populations, increased regulatory scrutiny, increased competition in global markets, cost pressures and protecting the supply chain are among the many challenges faced by our industry.

New advances in materials of construction, automated manufacturing processes, injection processes, safety devices and technology improvements create a dynamic environment in the drug delivery device arena. Regulatory requirements, industry experience and evolving market trends are critical considerations to ensure a complete understanding of the application of prefilled syringes and injection devices to drug delivery. The challenges of new product introduction and support of existing products require that companies be aware of new developments.

In response to this trend, PDA developed an exhaustive program for the *2014 Universe of Prefilled Syringes and Injection Devices* conference. We have selected "Improving Patient Outcomes through Innovation" as the theme for the conference.

This conference brings together industry and regulatory experts to share their experiences, new developments, regulatory considerations, challenges and trends in this exciting area. The topics will benefit those looking for a basic understanding of prefilled syringes and injection devices as well as those looking for a more in-depth presentation of current challenges.

Sessions will cover topics such as:

- Quality infrastructure and issues
- Patients' needs/points of view
- New development of glass syringes
- New technologies and trends in manufacturing processes
- Injection devices: critical attributes and risk management
- Regulatory and compliance aspects
- And more!

2014 PDA ANNUAL MEETING

A Biosimilar By Any Other Name is Still a Biosimilar

John Geigert, PhD, BioPharmaceutical Quality Solution

Biosimilars go by many names—"biosimilar biological products" (United States), "similar biological medicinal products" (Europe), "follow-on biologics" (Japan), "subsequent entry biologics" (Canada) and "similar biotherapeutic products" (World Health Organization)—but they all have one thing in common: they are biologics that are similar to an already approved biologic product in terms of quality, safety and efficacy. From a regulatory perspective, 2013 was a busy year for biosimilars.

Game Changers

This past year, biosimilars became "legitimate" products for established biopharmaceutical companies. Amgen was the first to "come out," and clearly stated in a press release that biosimilars were now part of their corporate strategy. Another game changer this past year was EMA's approval of the most complex biosimilar product to date: a monoclonal antibody.

What's in a Name?

When it comes to biosimilars, the international nonproprietary name (INN) has become a controversial subject, with pharmaceutical companies and associations lining up on both sides of the issue. Some want the INN to be unique to each biologic. They argue that this permits quicker identification and reporting of adverse events. Others want the INN to be the same for the biosimilar and the brand name reference biologic.

Quest for the U.S. Market

Not all expected milestones were achieved in 2013. Despite the U.S. FDA issuing draft guidances in early 2012 on how they intended to regulate biosimilars, only limited progress has been made since then.

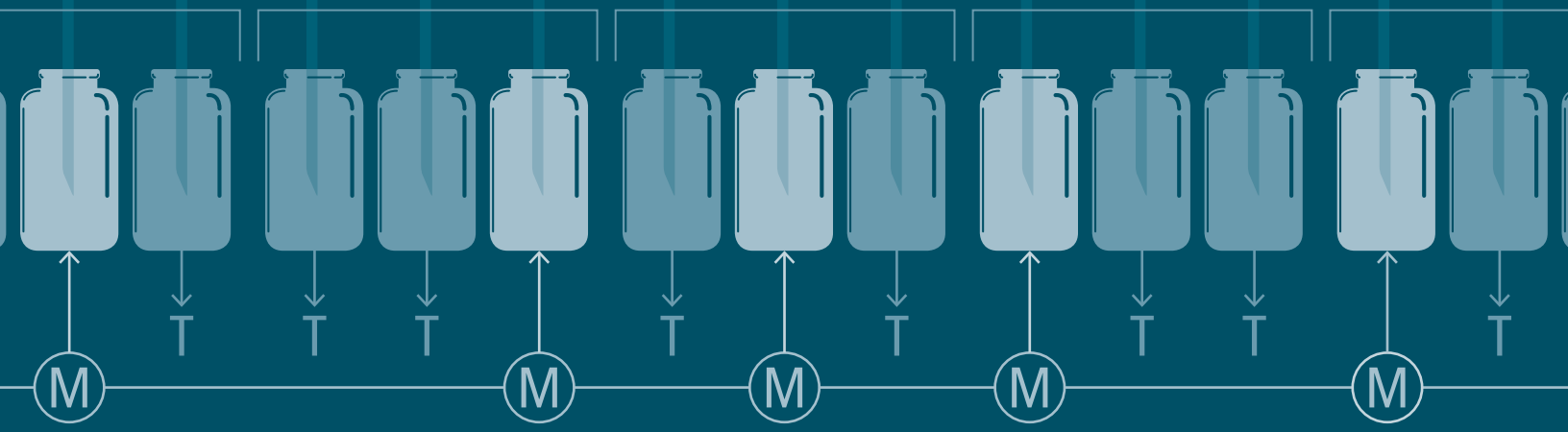
Hopefully, 2014 should see the guidances finalized, opening up the last major market for biosimilars.

John Geigert, PhD, President, BioPharmaceutical Quality Solutions, will be teaching a new PDA Training and Research Institute course on biosimilars, "Biosimilars–Understanding the CMC Challenges of Meeting 'Similarity'" in conjunction with the *2014 PDA Annual Meeting* in San Antonio, Texas, April 10. For more information and to register, please visit pdaannualmeeting.org/courses.

2014 PDA ANNUAL MEETING

The Changing Landscape of Release Testing for Sterile Drug Products

Walter Morris, PDA



Has the time finally arrived when parametric release and real-time release testing can be implemented for sterile drug products without a sterilization phase, even those manufactured in aseptic processes?

It has, according to Pfizer's **Jeffrey Weber** and industry consultant **Robert Tomaselli.** With the proliferation of combination products and small-batch manufacturing for biotech products, movement away from traditional quality testing is not only ideal, it is essential. Both will make their case at the *2014 PDA Annual Meeting* (Session O: "Parametric Release," April 9, 8:30 a.m.).

The *PDA Letter* talked to the two experts about their presentations. Below, we present our interview with Weber first, followed by our interview with Tomaselli.

Real-Time Release for Small Biotech

PDA Letter: Hi, Jeffrey. You will be talking about modular manufacturing suites currently under development by Pfizer for the production of small-lot size biopharmaceuticals. A key feature is that these suites will be replicated exactly to reduce qualification and validation efforts. Where does real-time release fit in here?

Weber: Nobody today is actually releasing commercial product onto the market with real-time release testing for sterile products. We believe that is the case; we would be surprised to find out somebody else is. But what we are talking about is the complete paradigm shift that we need from the industry to move towards this concept. Some of the framework has been outlined in the guidances but no relief from testing requirements has been laid out. Pfizer is going to discuss the current state, the future state—the technical tools we believe for continuous manufacturing verification as well as the regulatory changes or relief that we will need to make it possible.

PDA Letter: So it is Pfizer's intention to achieve real-time release—is that the regulatory goal?

Weber: That is the goal with this system, because we do not gain much if I manufacture in a small suite—and many of these modules are the size of a small mobile home or even smaller—there is not much benefit if we can manufacture product with a reduced footprint if I still require all of the environmental testing, of classic sterility or compendial testing. The challenge with small manufacturing suite would be having several trailers of analysts trying to perform the required classic testing.

PDA Letter: So you are saying that doesn't make sense economically or for efficiency?

Article at a Glance

- Analytical tools for real-time release testing are available.
- Real-time release/parametric release offers continuous verification of quality.
- Are the days of the sterility test numbered?

Weber: Right, we lose the economy of scale in that regard. Because if I have a large facility—if I have one analyst doing water testing, it doesn't matter if I have a 100 or 150 samples. But now if I have a small site, it does matter if I go from ten to 20 because it is a matter of whether that colleague has to do four hours of water testing or ten hours of water testing per batch. That is where we are seeing this push. We are seeing a drive toward smaller and smaller lot sizes and more potent product.

One of the drivers for this talk within Pfizer is to expose the industry in a wide forum on the drive for these new systems. We've seen it with PAT where initially many companies thought it was just a way to eliminate lab jobs and the shift in that was actually towards making better processing decisions. So even if I perform my compendial tests for bioburden, I already have an assurance of the testing, I am merely checking a box. We talk about sterility assurance level—this is infinite sterility assurance.

PDA Letter: You're talking about greater control? Better process understanding?

Weber: Yes.

PDA Letter: Pfizer must be pretty confident that you are going to achieve real-time release testing. Are you moving toward parametric release?

Weber: The manufacturing suites are being developed. We are confident that we will have skids that will be capable to deliver high quality products. The key to real-time release testing is the continuous testing requirements to assure process controls. The analytics are key, currently two of the four components we need are commercially available. This is also an opportunity for Pfizer to seek companies to drive into the development of a liquid sterility test or liquid bioburden system, as well as surface bioburden—a standoff type system is what we are seeking; consider a nonwiping, nonsurface contact instant bioburden assay.

From previous projects, we also learned our lessons for implementing new manufacturing concepts. Often, the regulatory acceptance and industry understanding can take as long if not longer than the technology development.

PDA Letter: What analytical components are already in place? You said two of four.

Weber: Four components are needed. If you look at an aseptic filling suite, to assure the product is sterile, the vial is sterile, the environment and as part of the environment the air. So for the air, we look at HVAC. So that would be a system like BioVigilant IMD air or Biotrak or BioLaz, an enhanced particle counting system. Enhanced particle counting is more than just particle counting, it provides biohits or biocounts information. Typically these systems do not have one biocount for one CFU. We know there is an offset there but we know how to address that.

The next component we look at is 100% integrity testing. This is off the shelf, systems available. We can use high voltage systems that are common to blow fill seal. But we can do 100% integrity tests…

The two that are nearing completion is both our 100% volume testing for the product as it is put into the vials. We believe systems like the online water bioburden analyzers—systems that are flow cytometry-based units—will give us the ability to look at 100% of the volume that is put into our vials and any counts regardless of whether we can culture it will be excluded from the lot because they are a variance. So we are going to exclude them for subsequent investigation or destruction depending on [how] the validation and quality systems are designed.

And then the final piece is a surface monitoring system. It has been demonstrated already in feasibility and we will show some numbers on this, but the ability [exists] to illuminate a surface with 400 to 500 nanometer range of light and look at intrinsic autoflourescence from surfaces and we've been able to detect 1–6 bacterial cells per square cm.

PDA Letter: This could be one of the most exciting talks of the Annual Meeting.

Weber: I hope so. The fundamental shift, and this is the big shift from microbiology moving towards analytics and rapid micro moving towards PAT, is the time domain. We are going to move from today, where I take one sample per lot or 20 vials per freezer load, and going toward individual continuous process information for every vial. So I will be able to identify the HVAC, what the surface, what the fill was for every vial coming down the line, and if I there is any variance, I am going to exclude that vial from the lot.

It is really time-based, or temporal information, is what the crux of this system is.

PDA Letter: It sounds like Pfizer is really taking advantage of using quality metrics. Does this really raise the level of control?

Weber: Yes. It is moving to a situation where, rather than trying to control an environment, and to put in as many safety nets as we can to assure quality, to this one of continuous verification. So we have a testing component which is real time but then also having good robust quality surrounding that. But you are exactly right, it is not lesser quality or more quality; it is continuous verification of the quality.

PDA Letter: What about media fills? Would you be able to drop them?

Weber: Yes. It is a funny area we operate in. We realize that media fills will be a part of demonstrating control and providing assurance, also from our point of view to do performance qualification... to demonstrate the vendors are supplying us the materials we want.

One other important point on this system is we are looking at an advanced aseptic filling vial. So imagine a presterilized, presealed closed container. That is part of it too. So there is an aseptic interface that we fill with, similar to what you would see with an aseptic connector. So that is one of the subtleties to this system as well, because otherwise we have to look at the concerns of how do I know my vials are coming in washed? How do I know that the air across them [is] free from contamination? We want to eliminate that risk as well. Or maybe shift it to a larger facility where we can make millions of vials in a controlled environ-

ment rather than try to do that in each one of these smaller modular manufacturing suites.

Parametric Release for Combo Products

PDA Letter: Why has parametric release traditionally been accepted for devices but not terminally sterilized drug products?

Tomaselli: One of the biggest, I think to start from, is that the GMPs are different. Because there's a GMP requirement for drugs and biologics that says you have to have an end product test. And it is assumed to be a sterility test. There is not the same requirement in the device regulations. And also just in terms of technology, terminal sterilization is a very well-defined process with very clear [well-defined and controlled] parameters. And you can demonstrate an exponential kill rate and an easy extrapolation to give you assurance to the 10^{-6} or greater, so it's a very, very different thing than drugs.

In the area of drugs there are some drugs that can be terminally sterilized. There's a few that I know of, that I've dealt with. And in those cases, the [U.S.] FDA has shown in the recent guidance documents on parametric release that they're willing to accept it. It's just that I think a lot of pharmaceutical companies don't know how to go about putting their story together. First, knowing the process well enough to say it's under control, knowing all the process parameters, etc., and then putting their story together for submission to the FDA. I think they're hesitant in doing that.

But it has been done—and the FDA has shown a willingness, even in their guidance document on parametric release for moist heat sterilized products, they say that this approach could also be used for other types of terminal sterilization processes, including radiation. So, they opened it up for that.

PDA Letter: How does parametric relate to the FDA's goal of making risk-based decisions, particularly with the Agency's push for companies to share quality metrics with the FDA?

Tomaselli: Well, this is one of the things I really want to bring up in my presentation. Really, parametric release in some respects is an advanced form of product release testing in the sense that, through Quality by Design and design space concepts that have been developed and promulgated by FDA, they're encouraging us to know our processes. So, if you have a terminal sterilization process for a drug or biologic, potentially, you do need to know what the critical parameters are, what the ranges are, and that they're controlled, and you need a process for ensuring that they remain under control. And really parametric release allows you to take advantage of that, and it also acknowledges the fact that a sterility test is really not of much value, as we all know statistically.

A parametric release approach, where you really do know all the critical parameters and you've got them completely under control and your monitoring process says that they are under control every time you make this product or terminally sterilize this product, that's far better than taking a couple dozen samples and running a sterility test on them. In fact, it isn't even appropriate, I would say with a terminal sterilization process, to simply accept—it is no longer acceptable to say, "Well, I don't know what the critical parameters are but I did a sterility test and it came back with no growth."

PDA Letter: Are you saying sterility test shouldn't be performed for terminally sterilized products?

Tomaselli: Well, certainly in the device field, if you know your process and you know what all the critical parameters are and you control them adequately and you use certain monitors to ensure that those processes are still under control. A lot of this is outlined in TR-30 ***(1).*** At least in the drug world, sterility testing is considered just totally worthless. It really is. In all respects, it's a worthless test.

PDA Letter: Should aseptically produced combo products be eligible for parametric release?

Tomaselli: You know, I've been advocating for the concept of parametric release for aseptic processes for some time. I've put together some ideas in terms for what it would take to do that, but that's still not been accepted.

No, I'm talking about a process where you have different constituents that are combined, let's say, into a copackaged product, and the release process or the sterility assurance program could be for the terminally sterilized constituents in their primary packages, a parametric release process could be applied for.

PDA Letter: Describe parametric release for readers. Also are you saying the ST is never conducted?

Continued at bottom of page 32

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2014 PDA ANNUAL MEETING

Innovations Offer Solutions for Vaccine Supply Limitations

Rebecca Stauffer, PDA

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

As the Chief Operating Officer at Takeda Vaccines, **Rahul Singhvi** is on the front lines of ensuring a stable supply of these important prophylactics.

"Vaccines are very complex and the manufacturing processes that are used to make these vaccines are sometimes very old," he said. "The regulatory burden to support upgrades to the processes to make them more cost effective or to increase capacity has limited the extent to which manufacturers have pursued these improvements."

The reason for this lies not only in the complexity of the product but also the failure to take advantage of better analysis tools. Without comprehensive analytical tools, he said, "it becomes very difficult for a manufacturer to upgrade a process and take the risk of the product not changing on them in terms of its safety characteristics or its efficacy. And because of that risk, manufacturers tend to leave the process alone."

Singhvi will discuss the complex issue of vaccine shortages and offer solutions at the *2014 PDA Annual Meeting* in San Antonio, Texas (Opening Plenary Session, 8:45 a.m., April 7).

In Singhvi's experience, the problem of vaccine supply limitations is more of an issue in the United States and Western Europe.

"Other manufacturers in countries like India and China have created manufacturing processes that are more productive; however, they don't have the clinical data and the regulatory wherewithal to launch those products in countries like the U.S. or Western Europe," he said.

Hundreds of tests are needed to release a lot

But even if the problem is restricted to the United States and Western Europe, how can companies address these manufacturing shortfalls and ensure stable supply of product?

The answer, Singhvi said, lies in improved characterization of the product.

"These days there are much better analytical tools that are available that can do more in-process testing and understand the nature of the product," he said. "And by having better characterization of the product that can also enable analytical comparability and provide a pathway for continuous improvement of the manufacturing process over time."

These new analytical tools include the following, according to him.

- **Cryo-electron microscopy:** This process can be used for generating reconstructions of particles to build a 3-D model of the particle.
- **Biacore®:** This tool allows for analyzing antigen epitopes.
- **Mass spectrometry:** This tool allows for analysis of the composition of impurities.

These enable manufacturers to build quality into the process, providing "body of information" that shows if the various lots being produced are similar.

"And that helps everybody in moving forward in terms of making processes more productive and reducing cost of goods," he said. "Technologies that provide for better characterization of the product will ensure that different facilities are also producing the same product, so the regulators are going to be much more comfortable with approving those facilities."

Supply Chain Challenge Also Key

Along with the manufacturing process itself, Singhvi pointed out the complex nature of the vaccine supply chain. Vaccines require a lengthy shelf life as well as cold chain as the products are vulnerable to degradation. This presents problems when product is shipped to or through various temperature zones.

"The second issue is that the number of quality control tests that one has to go through in order to release a vaccine lot is fairly large," he added. "Hundreds of tests are needed to release a lot, and when I say hundreds, I mean from raw materials to the end product—the quality control tests could be ➤

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2014 PDA UPCOMING EVENTS

MARCH EVENTS

17-21
Fundamentals of Aseptic Processing – Session 1
Bethesda, Maryland
www.pda.org/apfundamentals1

18-19
PDA/PICs API Training Course
Johannesburg, South Africa
https://europe.pda.org/API2014

18-19
An Introduction to Visual Inspection
Berlin, Germany
https://europe.pda.org/TCVisInspMarch2014

18-20
PDA Education@INTERPHEX
New York, New York
www.pda.org/education@interphex

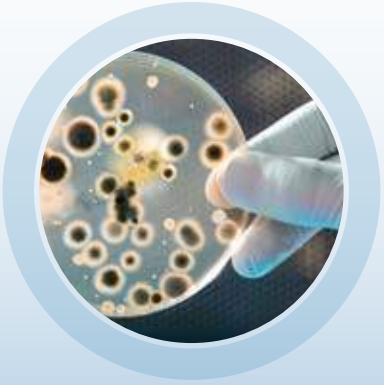
20
Interest Group Meeting on Visual Inspection
Berlin, Germany
https://europe.pda.org/IGVisInsp2014

25-26
Modern Biopharmaceutical Manufacturing
Lyon, France
https://europe.pda.org/Biopharm2014

27-28
Environmental Monitoring
Lyon, France
https://europe.pda.org/Environ2014

27
Dedicated or Shared Facilities? A Risk-Based Approach
Lyon, France
https://europe.pda.org/TechTrans2014

March 31–April 9
2014 Aseptic Processing Training Program – Session 2
Bethesda, Maryland
www.pda.org/2014aseptic2



APRIL

1
Interest Group Meeting on Freeze Drying
Berlin, Germany
https://europe.pda.org/IGFreezeDrying2014

1-2
Trends in Aseptic Manufacturing
Bologna, Italy
https://europe.pda.org/AsepticManu2014

2
PDA Metro Chapter Day Symposium
Somerset, New Jersey
www.pda.org/metrosymposium

3
Media Fills
Bologna, Italy
https://europe.pda.org/MediaFills2014

7-9
2014 PDA Annual Meeting
San Antonio, Texas
www.pdaannualmeeting.org

9-10
PDA Bioburden and Biofilm Workshop
San Antonio, Texas
www.pdaannualmeeting.org/bioburden2014

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EVENTS

10-11
2014 PDA Annual Meeting Course Series
San Antonio, Texas
www.pdaannualmeeting.org/courses

21
PDA Missouri Valley Chapter Event: Quality Metrics
Kansas City, Missouri
www.pda.org/missourimetrics

21-25
2014 PDA Biotechnology Week
Bethesda, Maryland
www.pda.org/biotechweek2014

22-24
Environmental Mycology Identification Workshop
Bethesda, Maryland
www.pda.org/mycology

28-30
Management of Aseptic Processing
Bethesda, Maryland
www.pda.org/apmanagement

29-30
Vaccines & Beyond Workshop
Brussels, Belgium
https://europe.pda.org/Vaccines2014

MAY EVENTS

19-20
2014 PDA Knowledge Management Workshop – Enabler for ICH Q8-Q11, WRM and Continued Process Verification
Bethesda, Maryland
www.pda.org/km2014

20-21
2014 PDA Packaging Conference
Washington, DC
www.pda.org/packaging2014

21-22
2014 PDA Knowledge Management Workshop – Enabler for ICH Q8-Q11, WRM and Continued Process Verification Course Series
Bethesda, Maryland
www.pda.org/KMcourses2014

22-23
2014 PDA Packaging Course Series
Washington, DC
www.pda.org/packagingcourses2014

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several hundred. And in fact, the quality control testing can account for 70% of the manufacturing time. The requirement of these prophylactic vaccines to be safe puts an enormous burden of testing on each lot of vaccine."

Yet, Singhvi understands the reasoning behind this regulatory burden.

"You want the regulators to ensure that the product that is going into a healthy person—in many cases, a healthy child—that it is absolutely not going to cause any adverse effect, so therefore, it is appropriate for regulators to impose those tests," he said. "But it makes the supply chain extremely complicated."

He went on to mention that it's not like regulatory authorities such as the U.S. FDA are unaware of this burden. In fact, due to the threat of pandemics since the early 2000s, the Agency has allowed for the shortening of the cycle time in the event a vaccine needed to reach the market quickly. There are sterility tests available now that can potentially be completed within one week. Normally, sterility tests take about two to three weeks. These types of innovations are now trickling down into the regular vaccine market.

These innovations that resulted from the pandemic threats now allow "for the manufacturers to do more analytical and more characterization work [which] will help the FDA to then be more comfortable with maybe lesser tests over time."

Overall, new innovations and improved technology go to the heart of Singhvi's presentation.

"I do believe that technology has a role to play," he said, emphasizing that these newer technologies are useful in the vaccine space since vaccines are low-volume products manufactured in a scaled down environment. In particular, he singled out single-use systems.

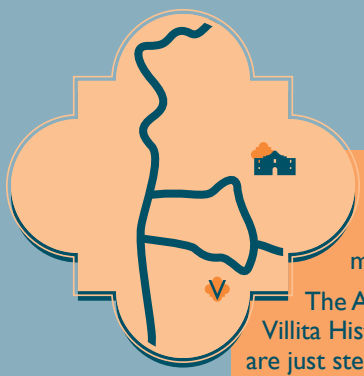
"In that kind of scaled environment, single-use technologies could be very valuable. That can allow for the supply of vaccines to be distributed so you could have multiple facilities that can give you continuity of supply. If one facility goes down, that doesn't mean that you have complete stockouts. You can have several facilities producing the vaccine," Singhvi explained.

Ultimately, he expressed that the use of new technologies in vaccine manufacturing will help ensure a more stable supply, reducing the threat of product loss and ensuring these medically necessary products remain available and continue to benefit patients.

About the Expert

Rahul Singhvi is responsible for global supply of Takeda vaccines. He has extensive experience in both vaccine development and manufacturing.

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



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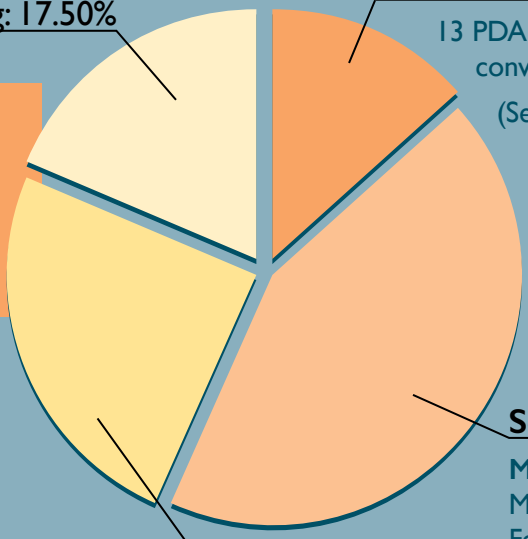

Networking: 17.50%

Association Business: 13.75%

13 PDA interest groups will convene during the meeting

(See page 7)

Science: 43.75%

Mark McClellan, MD, PhD, Senior Fellow, Director of the Health Care Innovation and Value Initiative, at Brookings, and a former U.S. FDA Commissioner will deliver an opening plenary presentation.

Regulation: 25%

Kalavati Suvarna, PhD, Consumer Safety Officer, CDER, U.S. FDA will speak at both the Annual Meeting and in the following Bioburden and Biofilm Workshop.

The Changing Landscape of Release Testing for Sterile Drug Products continued from page 24

Tomaselli: No, actually once you've gained parametric release, the sterility test is no longer needed. In fact, you can't go back to the sterility test because you have some issue with your process. That is the danger. You really have to be under control in your process and you have to identify the critical process parameters and ensure that every time you make product that those parameters are within the design space you created for it. And you can't just say "Hmm…one of those parameters in a given run—in a given sterilization process—well, one of those parameters is out, so I'll go back to the sterility test and if the sterility test is ok, I'll just pass it." You have to set those and that's it.

PDA Letter: Would companies drop the sterility test if possible?

Tomaselli: Absolutely! In other words, this is a great example where they would actually be following ICH Q8, Q9 and Q10. Here's an advantage you can have for terminally sterilizing processes for your combination product where you can actually eliminate a poor test and focus on the critical process parameters that you should be identifying and controlling. It's in line also with the new guidance on process validation which says you need to know your processes, all the critical parameters, know the risks, control the risks, control the process, to have a validated process. The need for a sterility test when all of that is in place is superfluous.

PDA Letter: How can a combo product maker use PDA Technical Report No. 30, which you helped revise recently?

Tomaselli: The reality is, as you know, TR-30 is about moist heat sterilization, and it was a great exercise. Now, the reality is that very few combination products have a moist heat sterilized component. Most of them are gamma or EO sterilized. And so if there were a combination product where one of the constituent parts was moist heat sterilized, you could just use TR-30 to gain parametric release. It's an option. And the FDA has accepted that, with certain caveats.

Obviously, there are more instances where the combination product has a constituent that is terminally sterilized through EO—ethylene oxide—or ionizing radiation, e-beam or cobalt six gamma radiation. In those cases, I think TR-30 fits. Although the parameters for moist heat obviously are different from those for radiation and EO, the approach is the same. So, you can easily modify the approach that is in TR-30 to create a sterility assurance program that would include parametric release for a constituent that was both moist heat sterilized or radiation sterilized or EO sterilized. So, it's a really good roadmap for that.

Reference

1. Sadowski, M., et al. *PDA Technical Report No. 30 (Revised 2012): Parametric Release of Pharmaceutical and Medical Device Products Terminally Sterilized by Moist Heat.* Bethesda, MD: Parenteral Drug Association, 2012.

Continued at middle of page 42

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snapshot

RAQAB Follows Comprehensive Commenting Process

Denyse Baker, PDA

For most of its history, PDA has interacted with global regulators by providing comments to draft publications. Most global health authorities have a process of developing new laws, regulations, guidelines or guidances that require public input. PDA has actively responded on behalf of its members, representing their scientific and technical interests to regulators, and is recognized for preparing scientifically sound comments that focus on issues with the potential to significantly affect the regulatory arena for years to come.

In order to best serve PDA members and the industry, make efficient use of PDA resources, and maximize the impact of the comments, the Regulatory Affairs/Quality Advisory Board (RAQAB) has defined a scope and process for regulatory commenting that aligns with the interests of PDA. This commenting process begins with surveillance of draft guidance documents, proposed changes or additions to GMP regulations, and other health authority announcements. Publications relating to technical areas such as aseptic processing, manufacturing and testing, process engineering, biotechnology, microbiology and process validation are specifically targeted for PDA response and comments. Quality and regulatory documents related to compliance, GMP, supply chain, quality systems, and content and format of CMC submission dossiers are also generally accepted for commenting. Health authority publications outside this scope are generally not considered for comment unless there are special circumstances warranting a response. RAQAB has defined documents related to clinical trial sponsorship, investigational drug treatments, labeling and medical error prevention as out of scope for PDA commenting. PDA generally focuses on regulations and guidance relating to drug products, both small and large molecule, however, draft documents related to combination products, vaccines and veterinary products may be considered for comment if they are within the scope areas noted above. Refer to **Figure 1** for an outline of the steps PDA takes when choosing to comment.

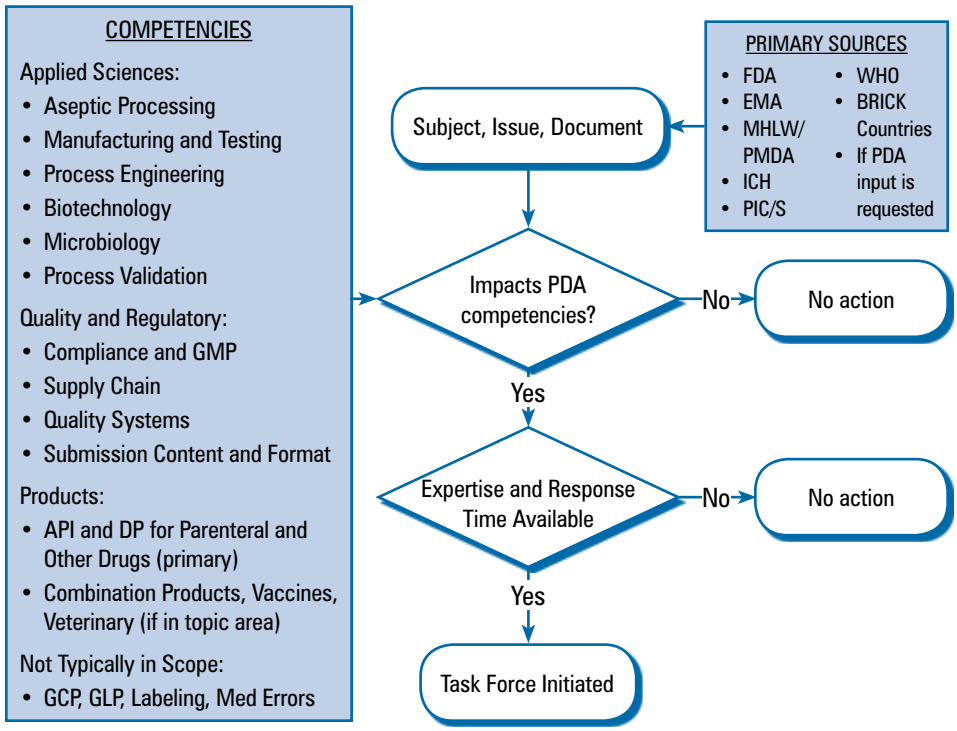
The primary sources of the documents on which PDA comments are the U.S. FDA, EMA, Japanese Ministry of Health, Labour and Welfare/PMDA, ICH, PIC/S and WHO. In 2013, PDA developed a process to submit comments to publications originating in "BRICK" countries (Brazil, Russia, India, China and Korea). Because these documents are generally published in a language other than English, additional time and translation steps are needed to complete these comments. PDA is actively looking for publications from these regions that fit within PDA's scope.

Once a proposed document is found to be within PDA's technical scope, the following criteria are considered in making a decision to form a task force and begin the commenting process.

- Relevance to and impact on PDA's core competencies and mission, (e.g., parenteral products and quality-related regulations and guidance)
- Scope and impact of the issuing regulatory authority (e.g., EMA and FDA will generally be of higher impact than other national authorities.)
- The amount of time available to complete the commenting process (In general, 60 days from the time the document is submitted to PDA is the minimum required. Expedited timelines are possible depending on the nature of the document and the engagement of the commenting team.)
- The need for translation of PDA's responses into a local language before the submission (in some cases, the brevity of timelines or lack of available subject matter experts prevent PDA from preparing comments or require an expedited process.)

When a decision is made to accept a document for comment, PDA establishes a task force generally overseen by RAQAB.

Figure 1 PDA Decision to Comment



The Biotechnology Advisory Board or the Science Advisory Board may be designated as the lead advisory board when the nature of the regulatory document is highly technical or scientific. In this case both the lead advisory board and the RAQAB will ballot on the final comments. Each task force includes at least one representative from the lead advisory board. The remaining members of a commenting task force can be any PDA members with appropriate expertise and commitment to meet the deadlines. It is important to have task force members representing a broad perspective geographically and scientifically so that the resulting comments truly represent a consensus opinion. In cases where very specific expertise is required, even nonmembers may be invited to participate.

Anyone with interest in participating on a commenting task force should note that in a Volunteer Interest Profile submitted to **Jonathan Hill,** the PDA Volunteer Coordinator, at volunteer@pda.org.

Because PDA regulatory comments are official positions of the organization, each one is formally balloted through the RAQAB and then through the Board of Directors. At each ballot stage, board members have an opportunity to provide feedback and request revisions to the comments.

The PDA regulatory commenting process continues to be the starting point of important dialogue between the association and health authorities. In 2013, PDA comments related to FDA's request for quality metrics opened up the door to more discussion with the FDA and eventually resulted in the *2013 PDA Pharmaceutical Quality Metrics Conference* and subsequent Points to Consider document. **[Editor's Note:** See the cover story for the February 2014 *PDA Letter*.**]** PDA's comments on the EMA's shared facilities draft guideline led to PDA being invited to participate in an EMA interested parties meeting on the topic, also in 2013. These are just two examples of how PDA's regulatory commenting contributes to the PDA mission of connecting people, science and regulation©.

PDA members at large, chapters, interest groups and members of other Advisory Boards are welcome to submit publications for potential comment to the following:

Sue Schniepp, RAQAB Chair (sschniepp@allergylabs.com)

Jeff Broadfoot, RAQAB Vice Chair (jbroadfo@Cangene.com)

Denyse Baker, PDA staff liaison to RAQAB, (baker@pda.org)

2014 PDA ANNUAL MEETING

Qualifying Disinfection for Critical Environments and Cleanrooms

Dave Rottjakob, ATS Labs

Obtaining the highest confidence that aseptic cleanrooms and other critical manufacturing/quality control (QC) environments are properly disinfected is paramount in assuring the production of safe and effective pharmaceutical products or medical devices. The microbiological safety of these products is primarily determined by the quality of raw materials used, the integrity of the manufacturing process, and the effectiveness of the disinfection procedures performed in the facility. It is for this reason that the U.S. FDA requires that manufacturers of pharmaceutical and other critical products qualify the disinfection agents and procedures used in these clean environments.

Disinfection in the pharmaceutical, controlled cleanroom space refers to the killing, inactivation, removal or reduction of contaminating microorganisms to levels considered safe per industry standards and regulations. The effectiveness of these disinfectants and procedures is determined by conducting qualification studies in a laboratory setting, which simulate the use procedures and utilize the disinfectants, contaminants and surfaces found within the facility. These qualifications are critical to assuring microbial control in the environment.

How are Disinfection Qualification Studies Regulated?

The success of disinfection procedures used in an aseptic manufacturing environment and the qualification of such processes to complying with GMP's are not detailed in a simple guidance document. Although there is no harmonized protocol addressing the regulatory requirements associated with disinfection qualification studies, there are several approaches, principles and methodologies outlined in a variety of published sources. Such sources include USP chapters <1072> and <797>, ISO /DIS 14698-(1-3), ASTM E2614 and FDA's *Guidance for Industry: Sterile Drug Products Produced by Aseptic Processing—Current Good Manufacturing Practice.*

When Should Disinfection Qualification Studies be Conducted?

The ideal time to conduct a disinfection qualification study is at the construction of the manufacturing/cleanroom facility, prior to operation, when disinfection processes and products are being considered. At a minimum, a qualification should be performed prior to starting full scale GMP manufacturing operations and prior to a regulatory audit. ➤

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How is a Disinfection Qualification Study Executed?

In general, disinfectant efficacy evaluations are made using either suspension-based methods or coupon/surface-based methods.

Suspension-Based Testing

Suspension methods evaluate the reduction of a known organism population inoculated directly into a sample of the liquid disinfectant. Following a predetermined contact time, samples of the inoculated substance are removed, neutralized and evaluated for survivors as compared to an untreated control suspension to provide initial efficacy results.

Coupon-Based Testing

In contrast to suspension-based tests, coupon or surface-based testing is more rigorous and involves the creation of a dried organism film onto 2×2 coupons of each surface type encountered in the manufacturing environment. In the study, the coupons containing the dried organism films are exposed with the disinfectant in a simulated-use procedure. Following a pre-determined contact time, each surface is neutralized and the surviving organisms are enumerated in a quantitative fashion for comparison to untreated surfaces. Survivors found on the treated coupons are compared to survivors recovered on the untreated control coupons to determine the log10 reductions. The level of reduction observed can then be used to assess the success of the disinfection procedure.

Overview of Study Execution

The overall coupon-based testing process is generally executed in six steps:

Inoculation: Each surface coupon is inoculated with a test organism.

Drying: Inoculated coupons are placed into an incubator to allow the test organism to dry as a film.

Treatment: Once dried, each coupon is exposed to the disinfectant by simulating product application.

Neutralization: Following careful monitoring of the exposure, each coupon is transferred to a preselected solution designed to neutralize the disinfectant and elute, or rinse off, any surviving test organisms.

Quantitative Recovery: The solution is quantitatively evaluated to enumerate the number of survivors onto an appropriate agar plate medium.

Analysis: After incubation, the recovery plates are enumerated and the study controls evaluated to assure study validity and calculate log reductions.

Untreated, inoculated, coupons are similarly enumerated to determine the starting level of test organism on each surface type prior to treatment. Appropriate controls should be included with the study to assess the sterility of the materials used in testing and to confirm the adequacy of the neutralization techniques used.

Conclusion

Properly designed, consistently executed disinfection procedures are critical to the production of safe and effective biopharmaceuticals, medical devices and other products. Qualification of these disinfection procedures is required by regulatory agencies as outlined in guidance documented and demonstrated in various warning letters provided by the FDA. Manufacturers ensure the successful design and execution of a disinfection qualification study. Careful review of the data collected in these qualification studies will help facilities monitor potential deficiencies in their disinfection program ultimately ensuring a safer product for the end user or patient.

[Editor's Note: ATS Labs will be exhibiting at Booth #209 at the *2014 PDA Annual Meeting*.**]**

About the Author

Dave Rottjakob is Director of Business Development and over sees antimicrobial efficacy and disinfection qualification study design at ATS Labs.

Knowledge Management: Integral to the Quality System

Igor Gorsky, ValSource, and Program Committee Member

2014 PDA Knowledge Management Workshop • Bethesda, Md. • May 19–22 • www.pda.org/km2014

Knowledge management is an enabler of the pharmaceutical quality system which allows us to continuously learn about our products and our processes. In the past, we would develop our products, design processes to manufacture them and continue producing them in a static mode assuming that the process shall consistently produce the same output. Processes shift, however, due to a number of reasons, such as changes to raw materials, age of equipment, new personnel's learning curve, etc.

Unfortunately, most manufacturers do not realize this potential for a shift, and therefore, instead of consistent production we see a rise in deviations and rejected products which sometimes result in drug shortages. All of this could be avoided if we would embark on the journey where we would continuously learn and optimize our processes. Knowledge management enables us to optimize our processes, thus providing for effective and efficient manufacturing.

The 2014 PDA Knowledge Management Workshop–Enabler for ICH Q8–Q11, QRM and Continued Process Verification should help you with guidance on this journey. The presenters will share the techniques and methods of effective knowledge management systems. A number of productive tools and approaches which allow for a continuous learning and optimization environments shall also be presented.

In addition, the workshop will show you how to optimally utilize these knowledge management tools in the Continued Verification stage of process validation to prevent deviations and reduce or eliminate occurrences rejected product.

These are only few among many other subjects that are covered by the workshop, which was carefully designed by the task force that is preparing the technical report on knowledge management. Additionally, this workshop shall use a working group roundtable format to provide for sharing of knowledge management expertise and experiences. This should help attendees to gauge the standings of their manufacturing environments on the journey towards continued learning and optimization.

It is most definitely going to be a truly exciting event. You should attend as knowledge management is one of the hottest subjects in our industry today.

Volunteer Opportunities at PDA

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- PDA Executive Officers
- Director
- Scientific Advisory Board
- Biotechnology Advisory Board
- Regulatory Affairs and Quality Advisory Board
- PDA Committee Chair/Co-Chair
- Task Force Co-Chair

- Author/Contributor to the *PDA Letter*
- Author/Contributor to the *PDA Journal*
- Poster Presenter
- Attend Chapter Committee/Planning Meetings
- Technical Report Peer Reviewer

- Speaker
- Chapter Leader
- Task Force Member
- TRI Instructor
- Interest Group Leader

PDA Committees:

- Program Planning Committee
- Membership Committee
- PDA Letter Committee
- Education Committee
- Audit Committee

- PDA Membership
- Attend Global PDA Meetings
- Attend Chapter Events
- Survey Reviewer
- Interest Group Member
- Attend TRI Courses

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Is Your Packaging System Qualified?

Roger Asselta, Genesis Packaging and Program Committee member

2014 PDA Packaging Conference • Washington, D.C. • May 20–23 • www.pda.org/packaging2014

Can your company effectively address the present and future regulatory outlook on packaging systems? Is your company aware of how these regulatory demands affect relationships with suppliers?

Ultimately, regulatory packaging concerns reflect the fact that selection of appropriate packaging components and systems throughout the manufacture, storage and distribution channels is central to ensuring the pharmaceutical product is protected until delivery to the patient. The demands on packaging materials and delivery systems continue to be challenged through the advancement of novel medicines and the expectation for effective caregiving measured by patient outcomes.

The program for the *2014 PDA Packaging Conference* is filling up with a series of very interesting and relevant presentations that address many of the current issues and concerns with parenteral packaging systems.

The conference provides a look to what is unfolding in the industry including regulatory guidance, changes to compendia and new views to the relationships with packaging component suppliers. The talks will be given by some of the most recognized leaders in parenteral packaging as well as some very knowledgeable newcomers. The presenters come from the U.S. FDA, the pharma industry, packaging suppliers and advisory groups

This conference has evolved from the successful *PDA/FDA Glass Packaging Conferences* held over the last three years. Those conferences well addressed specific issues with glass packaging. This year's conference has broadened in scope to cover all aspects of parenteral packaging systems. There will be presentations on materials of construction, packaging components and complete container/closure systems. Among others the sessions will include: regulatory perspectives, quality and supplier relationships, container/closure integrity, package serialization/track and trace, packaging concerns with compounding pharmacies, and the latest innovations in the pharmaceutical packaging science and technology.

The committee and the PDA staff have worked hard to bring together a very exciting program. We hope you will take the opportunity to join us as it is presented this May.

Regulatory Briefs

Regulatory briefs are compiled by PDA member volunteers and staff directly from official government/compendial releases. Links to additional information and documentation are available at www.pda.org/regulatorynews.

North America

Secure Supply Chain Pilot Program Open

In late February, the U.S. FDA officially initiated its two-year Secure Supply Chain Pilot Program. The Agency selected 13 companies to participate in this program; these companies will be allowed to receive expedited entry for importation of up to five selected drug products into the United States. The Agency will use this program to evaluate resource savings efforts that focus less on low-risk drugs coming into the country, and instead emphasize surveillance on importations of high-risk drug products.

Europe

EMA Launches Drug Shortages Catalog

As part of a short-term action to address drug shortages in the European Union, EMA launched a public catalog of drug shortages on its website. The Agency announced that any drug that's in shortage in more than one member state would be listed. The catalog would be similar to the U.S. FDA's list of drug shortages on its website. The EMA catalog is part of the Agency's 13-point plan to address drug shortages.

The catalog can be accessed here: tinyurl.com/p6twspj.

The Changing Landscape of Release Testing for Sterile Drug Products continued from page 32

About the Experts

Robert Tomaselli has over 33 years Quality Assurance and Process Development experience in the Medical Device and Diagnostics, Biotechnology, and Pharmaceutical (small and large molecule) industries.

Jeffrey Weber has been with Pfizer Kalamazoo for 13 years, starting in R&D developing methods for trace metal analysis and process trouble shooting. He has an extensive background in analytical chemistry developing new methods and applications.

The Changing Drug Supply Chain Regulatory Umbrella

Rafik H. Bishara, PhD, Chair, PDA Pharmaceutical Cold Chain Interest Group

2014 PDA/FDA Pharmaceutical Supply Chain Conference • Washington, D.C. • June 3–6 • www.pda.org/supplychain2014

Nearly three years ago, the U.S. Food and Drug Administration Safety and Innovation Act (FDASIA) became law. This broad legislative package includes a number of initiatives aimed at improving the managed review process, enhancing continuity of drug supply, and bringing greater transparency to U.S. FDA decision-making processes. The Agency is in the midst of implementing FDASIA with several initiatives such as the one for pharmaceutical quality metrics.

Another major effort is underway among regulatory authorities in the Pacific Rim countries, including the U.S. FDA and Health Canada, to converge regulatory standards and requirements for supply chain security. Known as the APEC Roadmap for Global Medical Product Quality and Supply Chain Integrity, it is a five-year plan that aims to include stakeholder input.

If you need to stay abreast of these and other regulatory initiatives that impact pharmaceutical supply chain, come to the *2014 PDA/FDA Pharmaceutical Supply Chain Conference* in June which also includes educational support from Rx-360. This year's theme is "Expanding Your Quality System (Q10) for a Robust, Reliable and Secure Supply Chain."

We have planned plenary and concurrent sessions covering many interesting topics including:

- The pharmaceutical supply chain: illicit acts and the impacted patient
- The impact of globalization of the biopharmaceutical supply chain
- Learning from other industries—case studies and lessons learned
- End-to-end temperature control
- Supply chain security: cargo theft
- Q&A—An open dialog between audience, industry leaders and experts
- The Drug Quality and Security Act
- Tools to deal with multitier supplier challenges facing the biopharmaceutical supply chain
- FDA'S Secure Supply Chain Pilot Program
- Benchmarking to accelerate learning and adopting best practices
- Overview of worldwide legislation, regulation and guidance—What does it all mean?

Ursula Busse, PhD, Novartis

2014 PDA ANNUAL MEETING

Annual Meeting Embraces Innovations, New Opportunities

The *PDA Annual Meeting* is one of PDA's signature meetings, attracting participants from around the world every year and featuring the largest exhibit hall of any PDA event. After the first event in 1951, the Annual Meeting was PDA's biggest fall event for many years, held in Philadelphia and then Washington, D.C. A decade ago, PDA decided to hold its Annual Meetings in the spring, and since 2002, they occur in different regions of the United States every year.

The *PDA Annual Meeting* reflects current trends and challenges in our industry, and offers the perfect blend of industry updates, educational topics and technical advances. Meeting content emphasizes innovative approaches to meeting the challenges raised by new product categories, manufacturing designs, and global regulatory and patient expectations—including presentations on new industry topics.

I have been engaged as a volunteer in Annual Meeting planning committees for many years. The committee is composed of highly qualified industry leaders who are knowledgeable about the challenges our industry faces. Besides the great teamwork experience and the satisfaction of seeing ideas taken to completion in the form of successful meetings, my involvement also allowed me to stay informed of new scientific, technological and regulatory developments.

Annual Meetings are planned almost a year in advance. Potential topics and themes of interest are brainstormed, and a general program is laid down in a face-to-face meeting shortly after the previous Annual Meeting. In this phase, participants' session evaluations are critical to selecting topics and potential speakers. Over the course of the following months, the planning committee lays down the details of the meeting and finalizes the agenda through monthly and biweekly conference calls, while PDA staff coordinates activities and prepares meeting logistics.

The conference offers daily plenary sessions that address universal themes of interest to all segments of our business. Specific topics of current interest are covered in a series of parallel sessions with a focus on case studies. Presentations explore opportunities, but also challenges with the implementation of new technologies. Participants can start the day by attending one of several interactive breakfast sessions on a variety of topics, and end the day by attending one of several highly interactive PDA interest group sessions covering a broad range of science and manufacturing technology. The agenda is structured to give participants many opportunities to talk with the speakers, encourage interactive panel discussions and provide ample time for questions, answers and discussion during and after each session.

The program is complemented by an exhibit that showcases suppliers on the newest technologies and services. Posters presenting the latest in studies and concepts related to sterile product are displayed around the exhibit hall. After the conference, participants can benefit from PDA's Training and Research Institute's highly valuable training courses, or attend a workshop on current topics of interest.

PDA's Annual Meetings are a unique opportunity to network with friends, colleagues, regulators and industry leaders from around the world, whether during networking breaks or evening social events, or during the annual run/walk event and the golf tournament that take place on the Sunday preceding the meeting. The Annual Meeting also provides opportunities for PDA to recognize selected volunteers for their special contributions to the success of PDA in a special awards ceremony.

This year, PDA will host its 63rd Annual Meeting in San Antonio, Texas, April 7–9. The conference will be held at the JW Marriott San Antonio Hill Country Resort and Spa, under the general theme of "Biopharmaceutical and Sterile Pharmaceutical Manufacturing – Embracing Innovation to Meet Global Challenges." As the co-chair of this meeting, and on behalf of PDA and the program planning committee, I am pleased to say that we have again succeeded in developing a highly interesting meeting agenda. It's now up to you to discover it, by attending and contributing to another successful *PDA Annual Meeting*.

Last but not least: if this article has stimulated your interest in volunteering on the program planning committee, please do not hesitate to contact PDA's SVP of Programs and Registration Services **Wanda Neal** at neal@pda.org.

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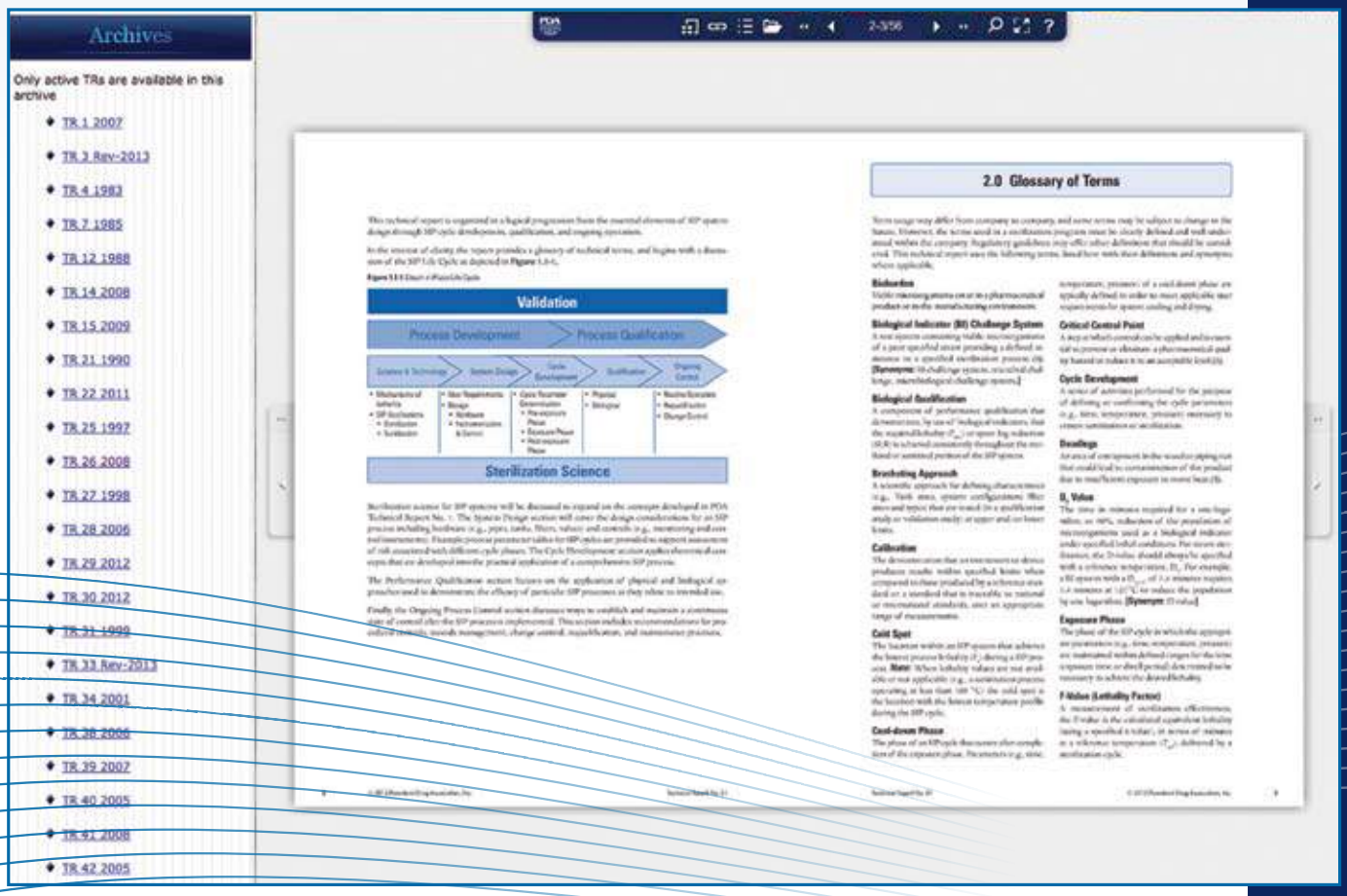

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Parenteral Drug Association

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Unabashedly Proud of the *2014 Annual Meeting*

Our third issue of the year is usually reserved for spotlighting some of the great content to appear at the April *PDA Annual Meeting*. And this year, the content is so good, we couldn't restrain ourselves to just a few articles. Both the cover story, the second feature article and the Infographic all pertain to PDA's biggest science meeting of the year.

I'm very pleased that several speakers and other Annual Meeting participants were willing to take additional time to speak with us or to pen articles on their own in addition to that spent developing their presentations. I want to thank and list each speaker who contributed to this issue:

Carol Lampe
Barbara Potts
Byron Lambert
Robert Dream
John Geigert
Jeffrey Weber
Robert Tomaselli
Rahul Singhvi
Dave Rottjakob
Ursula Busse

Each of these articles are written in a way that gives the reader useful information, even if you decide you cannot attend the meeting. After reading them, however, I'm sure most will *want* to attend!

In addition, I applaud **Rebecca Stauffer** and **Katja Yount** for developing an Infographic that breaks down the meeting by science, regulation, association business and networking. If you are unsure what you will get by attending, this quick and easy guide can help you (see page 32).

PDA members and *PDA Letter* readers know that we do a lot with regulators and are involved in the regulatory commenting process. But just how does PDA come up with comments and suggestions? Well PDA's Sr. Regulatory Advisor **Denyse Baker** outlines the comprehensive process in this issue's Regulation Snapshot.

This issue also answers another important question, which many of us might not think about: Are you afraid to be Googled? This issue's Tools for Success outlines five steps to ensure you survive a Google search.

PDA Letter

The PDA Letter is published 10 times per year, exclusively for PDA members.

Subscriptions are not available.

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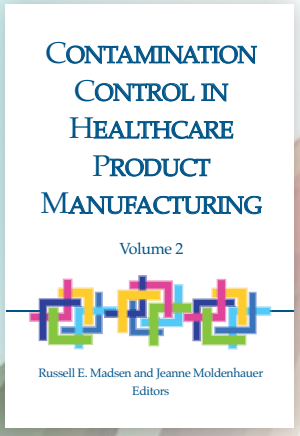

Item No. 17317

Contamination Control in Healthcare Product Manufacturing, Volume 2

Edited by Russell E. Madsen and Jeanne Moldenhauer

Volume 2 addresses some microbial control issues as well as other types of contamination.

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Topics covered in this volume include:

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- **Stephen Langille's** chapter discusses particulates present in injectable products
- **Kevin Lorcheim** covers the use of chlorine dioxide as a contamination control methodology
- **Miguel Nogueras's** chapter discusses the application of human factors in aseptic processing
- **Art Vellutato** extensively covers cleaning validation
- **Jeanne Moldenhauer** gives an overview of various contamination control sterilization processes
- **Mark Hunter, Michelle Luebke and Mark Pasmore** explain contamination risks and the patient
- **Jane Wyatt** offers a strategy for implementing contamination control in the Biotech industry
- **David Fletcher** considers contamination control in drug substance manufacture

These valuable chapters will provide a great deal of information in your arsenal for contamination control.

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