People • Science • Regulation

PDA Letter

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ROADMAP to EXTERNAL MANUFACTURING PARTNERSHIPS

A Guide to Effective Lifecycle Management

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Calling All Active PDA Members. Vote Now.

Online voting is now open for the 2014 PDA Board of Directors Election

PDA members, online voting opened September 11 for the 2014 PDA Board of Directors Election. Take a moment and vote for your candidates of choice.

All PDA members in good standing as of midnight on August 30, 2013 are eligible to vote. Voting closes at 11:59 p.m. EST on November 15, 2013. All votes cast after this date and time will not be accepted.

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

Thank you for being a valued PDA member and voting.

Instructions for Voting:

- Go to www.pda.org/vote
- Log into the system using your PDA Member ID and last name.
- Please read the instructions for each question carefully.
- Review the choices for each position then select a candidate for that position.
- When you complete your ballot, review your selection and then check the participant consent box and click on the "SUBMIT" button.
- You have now completed the voting process
- You can view and print your receipt or just exit the PDA eBallot System.

Thank you for your participation in this important election process.

Upcoming Laboratory and Classroom Training for Pharmaceutical and Biopharmaceutical Professionals

NOVEMBER 2013

Fundamentals of an Environmental Monitoring Program - *New Course*
November 11-12 | Bethesda, Maryland
www.pda.org/environmental2013

Advanced Technologies for Virus Detection in the Evaluation of Biologicals Course Series
November 12 | Bethesda, Maryland
www.pda.org/viralcourses2013

- Virus Contamination in Biomanufacturing: Risk Mitigation, Preparedness and Response – *New Course* (November 12)
- An Introduction to the Advanced Molecular Methods for Virus Detection – *New Course* (November 12)

Validation of Dry Heat Processes Used for Depyrogenation and Sterilization - *New Course*
November 13-15 | Bethesda, Maryland
www.pda.org/valdryheat

Biosimilars – Understanding the CMC Challenges of Meeting 'Similarity' - *New Course*
November 15 | Bethesda, Maryland
www.pda.org/biosimilars

Quality Systems for Aseptic Processing
November 18-22 | Bethesda, Maryland
www.pda.org/qualitysystems2013

DECEMBER 2013

Aseptic Processing for Senior Management - *New Course*
December 4-6 | Bethesda, Maryland
www.pda.org/apmanagement

Risk-Based Qualification of Sterile Drug Product Manufacturing Systems
December 9-12 | Bethesda, Maryland
www.pda.org/riskbased2013

2013 PDA Pharmaceutical Quality Metrics Conference Training Course
December 11 | Bethesda, Maryland
www.pda.org/metricscourse

Fundamentals of Aseptic Processing – *New Course*
December 16-20 | Bethesda, Maryland
www.pda.org/apfundamentals

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 Art Illustrated by Katja Yount

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

officers

Cast Your Ballots for PDA Officers and Directors*

Martin VanTrieste – Chair Elect

Martin VanTrieste is the Senior Vice President of Quality at Amgen. He is responsible for all aspects of quality assurance, quality control, compliance, operational excellence, environment, health and safety, along with training at Amgen.

Prior to joining Amgen, VanTrieste was with Bayer HealthCare's Biological Products Division as vice president of Worldwide Quality and Abbott Laboratories as the Vice President of Quality Assurance for the Hospital Products Division. While at Abbott, VanTrieste held various positions in Quality, Operations, and Research and Development. He started his career at Abbott in 1983 after obtaining his Pharmacy degree from Temple University School of Pharmacy.

VanTrieste has been actively involved with various professional and trade organizations, including United States Pharmacopeia (USP), Pharmaceutical Quality Research Institute (PQRI), Pharmaceutical Research and Manufacturers of America (PhRMA), and AdvaMed, and he has been a member of the Board of Directors of the Parenteral Drug Associations (PDA). He is the founder and first Chairman of Rx-360 and is currently on their Board of Directors. Rx-360 is a nonprofit international supply chain organization that will enhance patient safety by increasing the security and quality of all parts of the supply chain. Phar-

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Michael Sadowski – Secretary

Michael "Mike" Sadowski is the Director, Sterile Product Manufacture Support at Baxter Healthcare Corporation in Round Lake, Ill. He is responsible for international sterility assurance programs in support of pharmaceutical products and medical devices. Sadowski has over 20 years of experience with drug and device sterilization with a variety of sterilization methods including moist heat, ethylene oxide, radiation and aseptic processing.

In addition to participation on the task force that revised *Technical Report No. 1: Validation of Moist Heat Sterilization Processes: Cycle Design, Development, Qualification and Ongoing Control,* he was the Chairman of the task force for the revision of *Technical Report No. 30: Parametric Release of Pharmaceutical and Medical Device Products Terminally Sterilized by Moist Heat,* and has served on the PDA Board of Directors since 2008. Sadowski is a faculty member of the PDA Training and Research Institute (TRI) where he enjoys sharing his knowledge of the sterilization sciences. He is a published author and has given presentations and training sessions on moist heat sterilization and parametric release to industry and regulatory sterilization professionals across the globe. He received his BS degree in Microbiology from Purdue University in West Lafayette, Ind.

It has truly been a great privilege and valuable experience for me to serve the PDA membership during my second term as Director, and I am hon-

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Becky Devine – Treasurer

Rebecca "Becky" Devine, PhD is an independent regulatory consultant with over 30 years of experience in the regulation of biological products. She began consulting in 1999 after leaving the U.S. Food and Drug Administration (FDA). She joined the FDA in 1979 as a Microbiologist, and held various positions in the Center for Biologics Evaluation and Research (CBER) throughout her 20-year FDA career.

From April 1994 until June 1999, she was the Associate Director for Policy at CBER. In that position, she was responsible for the development and implementation of all regulations, policy and guidance for CBER regulated products. Throughout her CBER tenure and recent consulting career, she has been involved in the review of license applications, inspections, and quality control of vaccine, therapeutic, and biotechnology derived biological products.

Devine earned her BS and PhD degrees in microbiology from the University of Maryland in 1977 and 1986, respectively. She is currently an active member of PDA serving as Treasurer of the Board of Directors, and is a member of the PDA Biotechnology Advisory Board. Prior to serving as Treasurer, she was the Secretary of the PDA Board of Directors.

For the past two years, I have been pleased to be serving on the PDA

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Joyce Bloomfield – Director

Joyce Bloomfield has spent her professional career committed to providing safe products to pharmaceutical customers. From her beginning in 1991 as an FDA investigator and then Compliance Officer for the Center for Drug Evaluation and Research to becoming the Executive Director of Divisional Quality and Compliance management at Merck, Bloomfield's dedication to quality and compliance has always been at the forefront of her work.

In her current role as Executive Director, she has direct responsibility for Divisional Quality and Compliance services, including MMD's quality management system, divisional GMP auditing, labeling services, validation (computer, process, and cleaning) and pharmaceutical stability and quality standards. Aside from her current position, she has held positions as a Senior Consultant with PAREXEL Consulting and quality assurance executive positions in Cardinal Health's Sterile Drug Manufacturing business unit and Corporate Quality Compliance.

During her two decades in quality and compliance, Bloomfield has worked to teach the value, intent and application of GMPs as an enabler to establish and maintain high global quality and compliance standards. She holds a BA degree from Murray State University. She is a certified Medical Technologist of the American Society of Clinical Pathology.

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E.J. Brandreth – Director

E.J. Brandreth is the Senior Vice President of Quality and Regulatory Affairs at Ajinomoto Althea Technologies, specializing in biotech processing and aseptic filling. He has over 30 years in life sciences including small molecules, devices and a wide variety of pivotal biotechnology products, and he has been an active PDA member for over 18 years. Brandreth designed process validation programs and managed PAI inspections for five successful CBER/EMA product launches, and supported dozens of IND projects. He was VP of Quality for Favrille, overseeing a personalized CHO antibody process, and he was the Sr. Director of Quality for BioMarin where he helped build the commercial orphan drug facility and launched Aldurazyme and Naglazyme. During the inception of IDEC Pharmaceuticals, he held various management positions in QA, validation and regulatory affairs, and was a core team member for the development and launch of Rituxan and Zevalin. He is an author of *Technical Report No. 42: Process Validation of Protein Manufacturing*, and was the Co-Chair for *Technical Report No.14: Validation of Column-Based Chromatography Processes for the Purification of Proteins*. He is the Chairman of the PDA Biotech Advisory Board, he is a frequent industry conference presenter and moderator, and he is a member of the PDA PCMO and Portfolio

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Veronique Davoust – Director

Véronique Davoust has over 20 years' experience in the pharmaceutical industry, both in regulatory affairs and manufacturing, for Pfizer. In her current position, she is responsible for the monitoring and analysis of European emerging regulations and guidelines, especially focusing on GMPs and registration of the quality section of the Marketing Authorization dossier throughout the product life cycle, as well as on global topics such as serialization.

Furthermore, she ensures the communication and implementation of the guidelines and regulations within the firm, and the coordination of responses to proposed regulatory documents to the competent authorities.

Davoust has been an active member of the PDA for more than 15 years. She was a member of the Board of Directors from 2007 to 2010, and co-chaired the Paradigm Change in Manufacturing Operations℠ (PCMO℠) project since its creation in 2008. She contributed to *Technical Report No 54: Implementation of Quality Risk Management for Pharmaceutical and Biotechnology Manufacturing Operations.*

Davoust recently joined the PDA Regulatory Affairs and Quality Advisory Board and is a frequent lecturer at PDA conferences and meetings. For example, she chaired the PDA/EMA 2009 conference and

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Jette Christensen – Director

Jette Christensen is Aseptic Scientific Director at Novo Nordisk A/S in the Diabetes Finish Product section. Christensen sets directions and gives support within cleanroom design, classification and qualification, aseptic production including training in aseptic behavior and production microbiology. She exercises a global view on manufacturing processes, authority requirements and culture, and works with sites located in Denmark, France, the United States, Brazil and China.

Christensen has been PDA member since 1998 and has been involved in several activities. She has been a member of the Board of Directors for the last three years and a member of the Science Advisory Board since 2011. In the period of 2006–2012, she was a member, co-chair and chair for several of PDA's pharmaceutical microbiology conferences in Europe and in the United States. She is currently co-chair for the PDA task force working with mapping and comparing GMP requirements for aseptic production and a member of the task force revising *Technical Report No. 13: Fundamentals of an Environmental Monitoring Program.* She has presented at several PDA conferences.

In 1986, she received a master's degree in Food Science from the University of Copenhagen, Denmark.

Being a part of the Board of Directors for the last three years has been very interesting, and it is has been a great pleasure working together with the

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Edwin Rivera Martinez – Director

Edwin Rivera Martinez is Vice President, U.S. Quality Liaison, Global Quality, for Sanofi. Martinez has over 36 years of diverse experience in the pharmaceutical industry. He has held technical and managerial positions with the FDA, and a pharmaceutical consulting company.

It is an honor to be nominated to the PDA Board of Directors. While at the FDA, I worked with the PDA on several precedent setting topics, such as the rollout of the ICH Q7 Good Manufacturing Practice Guidance for Active Pharmaceuticals *and the* PDA/FDA Supply Chain Security Conferences/Workshops *starting in 2008. I'm grateful to be involved with this remarkable organization and have immensely enjoyed working with the excellent staff, volunteer, and leadership.*

Morten Munk – Director

Morten Munk is cofounder of CMC Biologics A/S, and Vice President, Business Development at CMC Biologics, located in Denmark. He has more than 25 years of industry experience in biopharmaceutical development and manufacturing.

Munk has expertise in downstream process development, facility design, single-use systems, process validation and regulatory affairs. He has presented on scientifically subjects at four to eight international conferences per year. He has been active in PDA and has been a Co-Chair for the task force behind the technical report on single-use systems and a member of the organizing committee for the *PDA Annual Meeting.*

Prior to founding CMC Biologics in 2001, Munk was a member of the Board of Directors and held a position as Principal Scientist at Novo Nordisk A/S.

I am honored to be nominated to the PDA Board, even though I represent a relative small company and a small country—Denmark.

I know this background might make it more difficult to be elected, but I hope for the best, as it would be a privilege to support the further positive development of PDA, by using my more than 25 years' experience in the biopharmaceutical industry, where I have worked and lived in both United States and Europe, as other regions in the world I've visited.

Over the past 10 years of my involvement with PDA, I have developed a

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Susan Schniepp – Director

Susan Schniepp is currently the Vice President of Quality and Regulatory Affairs for Allergy Laboratories, a contract manufacturing organization for sterile injectables and allergenic extracts. She has 33 years of industry experience in quality control and quality assurance and has worked for Abbott, Hospira and Searle. During her career she has had responsibilities for audits, complaints, labeling, investigations, compendial affairs, and other quality systems. As an active member of PDA, Schniepp has been on the PDA Board of Directors from 2010–2013, and a member of the P*DA/FDA Joint Regulatory Conference* since 2001, chairing the conference in 2007 and 2010, and co-chairing from 2011–2013. In addition, she is the chair of RAQAB and a member of the Membership Committee. She has presented at many PDA venues and written articles for the PDA Newsletter on a variety of quality topics. Sue was the recipient of the PDA Gordon R. Personeus Award in 2009, PDA Distinguished Service Award in 2008 and PDA Distinguished Author Award in 2007.

It is an honor to be considered for the PDA Board of Directors. PDA is a unique organization because it accomplishes what it claims to do: connect people, science and regulation. It is refreshing to be part of an organization that accepts and values individual contributions and cooperative team efforts to achieve a common goal. I have been involved with a number of activities for PDA and have recognized their value

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Glenn Wright – Director

Glenn Wright is currently Sr. Director, Project Management, Technical Services/Manufacturing Science at Eli Lilly and Company focusing on the global integration of Lilly's Insulin Technical Agenda. He has over 20 years of experience in the pharmaceutical industry in areas from development through commercial manufacturing, both for biologic and traditional small molecule products. Prior to his current assignment Mr. Wright served as the Sr. Director of Quality (Italy), Director Manufacturing Science and Technology (USA), Director Global Regulatory Affairs, as well as in various other QA and QC management and technical position at Eli Lilly and Company, Amgen Inc. and Pfizer Inc. Mr. Wright received a Bachelors and Masters' degree in Microbiology from Southern Illinois University. He has and continues to be a very active member of PDA having served previously on the PDA Board of Directors (1998-2003), PDA Science Advisory Board, PDA Program Advisory Board, as well as countless conference planning committees and task forces.

In 1998 he received a distinguished service award from the PDA's Southern California chapter in appreciation for his efforts in founding and serving as the chapter's first president. He is currently a member of the PDA Board of Directors, PDA Science Advisory Board, and Editorial Review Board for BioQuality. Mr. Wright has received numerous PDA recognition awards including the prestigious **Frederick J. Carleton** Award in 2005 for his outstanding contributions to the PDA Board of Directors as well as the wider organization.

For me, PDA has and continues to be an organization of great importance that is built on the strength of its membership. Not only does it allow each of us the opportunity to connect, discuss, debate, and work together to find solutions to the challenges facing our industry. It also maintains our industry, providing the critical training needed for both the new and the experienced industry member, allowing us to keep in step with an every changing environment.

Ever since attending my first PDA meeting some 24 years ago in Washington, I have always believed that PDA is a unique and special global organization with the noble mission of increasing and sharing knowledge. After having had the opportunity to have lived and worked outside of the

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* 2013 PDA Board of Directors Elections

PDA members have the opportunity to choose volunteer leadership for 2014. There is the opportunity to select three officers and four board members who will take seats on the PDA Board of Directors in an election that runs from September 11-November 15. Members in good standing can vote online from the PDA website and at conferences that will be held between those dates in the United States and Europe. The open seats are for the following officers: Chair-elect, Treasurer and Secretary. Eight people are running to fill four director seats.

Vote online: www.pda.org/vote

Polls open Sept. 11, 2013 and close Nov. 15, 2013

You will need your member ID and password

Open to PDA members in good standing b Aug. 30, 2013.

Martin VanTrieste continued from page 6

maVoice in 2012 named VanTrieste as one of the 100 most inspiring people in the pharmaceutical industry and called him "a man with a mission."

I am honored to have the opportunity to be part of the Board of Directors of the PDA once again. It is through the collective expertise, collaboration and commitment to ongoing science education that this organization has been able to attain global recognition as a leading provider of technical and regulatory information.

Our pharmaceutical and biotech community has come to rely on us as a sound scientific resource and we should all be proud of that. I know I am. As our industry continues to evolve and we are faced with new challenges, we too must adapt to continue to offer the best thinking to help navigate these issues. I am confident with the support of our valued membership, committed staff and dedicated volunteers we will be able to do that. Thank you.

Rebecca Devine continued from page 6

Board as Treasurer. During this time I have worked to put in place some important policies related to the audit committee and investment controls. I would like to continue moving these and other initiatives forward. Therefore, I am happy to be nominated to serve a second term as PDA Treasurer.

In addition to continuing to support the audit committee, I am excited to be able to help advance initiatives in place under the PDA Strategic Plan. Having served on the Biotechnology Advisory Board for many years, and as a member of the PDA Board of Directors, I am looking forward to making sure there is a continued robust focus on biotechnology initiatives of PDA.

PDA as an organization is very strong and is an important contributor to advancing the interaction of science and regulation, and is an excellent opportunity for networking. Most importantly, PDA continues to focus its efforts on assuring the membership is served in areas that are important for our industry. I would feel privileged to continue to support these efforts. As Treasurer, I will support the hard-working PDA staff and leaders of the organization, and will work hard to assure that the financial health of the PDA remains strong. Assuring the financial strength allows PDA to provide the member benefits that are the hallmark of the organization. I look forward to working on these goals.

Michael Sadowski continued from page 6

ored to be nominated as the Secretary for the PDA Board of Directors. Despite economic times that have been challenging, PDA continues to grow ever stronger with an unmatched quality of products and services that further distinguishes the superior value that PDA brings to our membership.

As I reflect back on the growing successes of PDA over the past few years, it is clear to me that passion is one of the defining attributes that I see uniquely ingrained across the PDA community that differentiates PDA from all other organizations. The PDA staff, leadership, volunteers and members all share the same strong passion for science in the endeavor to drive the application of best demonstrated scientific approach to advance regulatory expectation and enhance our businesses for the ultimate benefit of our patients.

As we consider the future, the application of scientific principle will always be at the core of the PDA strategy supporting both our mission and vision. Our passion for science will continue to set us apart from other organizations and strengthen our leadership position as the foremost provider of best practice for the industry. I feel very fortunate and truly appreciate the opportunity to fulfill my passion for science while contributing to the future successes of PDA.

The next candidates are running for one of four seats on the board. They are listed in alphabetical order.

Joyce Bloomfield continued from page 6

Outside her work, she loves golfing, boating, fishing, dancing, traveling, camping, gardening, trips to the beach, reading, and most of all, spending time with her daughter and family.

My personal mission is to do all that I can to contribute to the advancement of medicine and its availability to the world's population. That is why I volunteer for PDA and why I am running for the board. I have been an active Science Advisory Board Member since 2010 and member of PDA since 2007.

My service to PDA includes co-chair of the Program Planning Committee for the 2013 PDA/FDA Joint Regulatory Conference, *co-chair of the 2012 aseptic conference Program Planning Committee, member of the* 2012 PDA/FDA Joint Regulatory Conference *Program Planning Committee, and co-chair of the 2011 glass quality conference Program Planning Committee. I was a keynote speaker at the* 2013 PDA Annual Meeting, *an active member of the 2011 Business Case for Quality Pharmaceutical task force, and industry presenter on harmonizing quality systems at the* 2011 PDA/FDA Joint Regulatory Conference. *During my volunteer work with PDA, I have been fortunate to have reviewed many technical reports through the Science Advisory Board and I have been on the book proposal committee.*

I dream of the possibilities in science and technology and thrive on driving advancement to realize innovation through sharing of knowledge and experience. It is an honor to be nominated for the PDA Board of Directors and I am grateful to have this opportunity to further serve the membership.

E.J. Brandreth continued from page 7

Steering Committees. He is also an active member of the BIOCOM FDA Committee, a regional biotech advocacy institute. He holds a MBA from University of Phoenix and a BA in Biology from University of California, San Diego.

I am truly honored to receive this nomination, and I wish to thank the PDA for this significant recognition. Working in the biotech industry for the past few decades, I recognized very early that the challenges for process control and regulatory approval were numerous and poorly defined, and it was through my participation in PDA that I was able to learn far more than what was available in guidelines and literature. My early participation in PDA interest groups, technical reports and conference sessions furthered my education of the pharmaceutical industry. The unprecedented network of pharmaceutical industry experts that PDA provides has been absolutely essential in addressing the endless surprises and challenges which emerge with new, cutting-edge technologies, and their passion for good science and clear guidance helps make this such a rewarding organization. PDA has the vision to be proactive and stay ahead of industry trends, and the staff and structure within PDA are flexible enough to assure that members receive the most current information possible. PDA provides the foundation of knowledge and experience the industry relies on for guidance, whether it is through references to technical reports and PDA Journal articles, or within conference workshops and interest groups, and I welcome any opportunity to give back to PDA whenever possible. I am very excited about the opportunity to serve on the Board, and I am dedicated to helping PDA be as beneficial and fulfilling as possible for the members, staff and numerous volunteers, who collectively create the engaging and positive culture of the organization.

Veronique Davoust continued from page 7

was a speaker at the PDA's *Current and Emerging EU Regulations and Inspection Trends* conference Dublin, Ireland in July 2013.

She just completed a one-year secondment at the European Federation of Pharmaceutical Industries and Associations (EFPIA) based in Brussels, Belgium, supporting the Technical and Development Operations committee.

Davoust is a pharmacist and earned a Doctorate in Pharmacy at the University of Rouen in Normandie, France.

As a PDA member, by participating in conferences and reading the publications, I recognize the high value and the great support offered by the organization. PDA's high scientific and technical level is recognized worldwide.

I have been fortunate to be in the planning committee for the PDA/EMA Joint Conference *at its creation in 2006 and continued to work diligently on the subsequent ones. I am also co-chairing the Paradigm Change in Manufacturing Operations℠ (PCMO℠) Initiative, the goal of which is to drive the establishment of "best practice" documents and training events to aid the pharmaceutical manufacturers to implement ICH Q8, Q9 and Q10.*

The more I am involved with PDA, the more I appreciate the interaction with other PDA members, their great expertise, and the open discussions for exchanging scientific and regulatory information. PDA has demonstrated to be an excellent and effective forum for networking and sharing valuable experience with colleagues from the pharmaceutical industry, thus making PDA a scientific partner of choice for regulators, especially in the United States and Europe, for establishing sound regulations and guidance.

Therefore, it is a pleasure, and a real honor, to be nominated for a mandate at the PDA Board of Directors and I look forward to contributing even more actively to the success and strength of PDA by enhancing further PDA's activities in influencing regulations in the Quality/GMP arena, encouraging members' input to these developments and leveraging internal and external communication. Again, I am thankful to be part of this great organization and to work with such fine staff, volunteers, members and leaders, and I am excited to have the opportunity to help further enhance PDA position as the premier organization for connecting science, regulation and people."

Jette Christensen continued from page 7

director group, PDA staff and members. It is an honor once again to be nominated for the Board.

PDA's mission, vision and strategy are really worth working for.

PDA is the leading global provider of science and technology information and education for the pharmaceutical and biopharmaceutical community. Especially the technical reports are highly valued by our members. I therefore highly support the new set up for preparing technical reports, drastically shortening the period from establishment of the task force to publishing of the final report, as I feel it represents a major improvement in PDA's service to its members.

PDA connects people, science and regulation with great success, but of course we can always do better. If elected, I will continue working on strengthening this relation to benefit for both PDA members and regulatory agencies.

The pharmaceutical and biopharmaceutical world develops, and PDA must continue supporting this development by choosing the right strategies and focusing on the right themes and issues, and it is my wish to contribute by serving on the Board of Directors.

If we jointly work for preparing scientifically sound and practical technical information, and jointly work for an even better cooperation between regulatory agencies and industry, PDA will continue to create substantial value to its members.

Morten Munk continued from page 8

strong network and knowledge base from my membership. I'm dedicated to driving the PDA mission of defining issues scientifically, deriving technically sound and practical solutions, and at the same time always meeting the highest quality standards.

PDA offers several valuable resources, including technical reports. I am pleased to have had taken part in the development of numerous technical reports, including being co-chair, together with Bob Repetto from Pfizer, for the upcoming technical report on single-use systems, along with an excellent team of experts from the PDA network. This work has included organizing and presenting at several successful conferences, featuring this emerging technology.

Organizing high-quality conferences, meetings and training events, are also valuable and educational outcomes of PDA's activities. As a PDA board member, I will do my best to continue the proud traditions of PDA and the organization's constant strive to improve and expand its offering to members.

Susan Schniepp continued from page 8

in advancing my knowledge base and allowing me to attain my career goals. I believe the organization helps people grow and achieve career success in a positive manner. In addition to creating a creative and nurturing environment for its members, PDA also has its pulse on the scientific advancements and regulatory activities that play such an important part in our industry. PDA technical reports are some of the most quoted and respected scientific documents used by the industry. It is because I believe in the activities and goals of the PDA that I wish to continue to serve on the Board of Directors so I can contribute in helping PDA maintain its uniqueness while being a leader in addressing scientific and regulatory advances so critical to the industry.

Glenn Wright continued from page 8

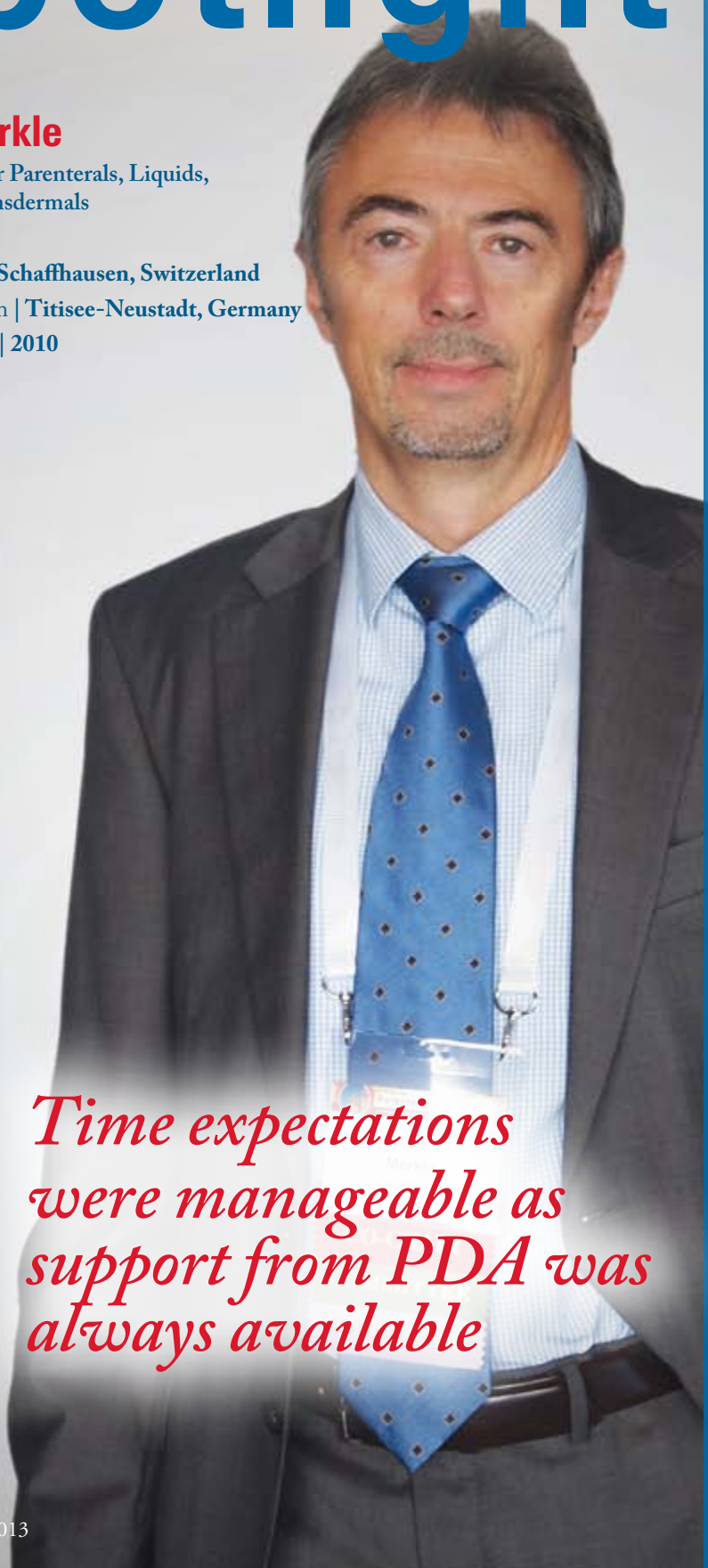
US for many years, I see it even more clearly as I have experience, first hand, the work of PDA across Europe, Asia, and the rest of the world.

I have, and continue to enjoy being an active member of PDA, sharing in its noble mission, and working to find the answers to today's tough questions. Continuing to serving on the PDA board of directors would allow me the opportunity to ensure we continue in our mission. Shaping PDA's future to equal the success of its past, always focusing on the science and the needs of each of the members.

PDA Volunteer Spotlight

Stefan Merkle

- Senior Director Parenterals, Liquids, Creams & Transdermals
- *Cilag AG*
- Current City | **Schaffhausen, Switzerland**
- Originally From | **Titisee-Neustadt, Germany**
- Member Since | **2010**



Time expectations were manageable as support from PDA was always available

If you could invite any three people to dinner who would you choose?

Dinner with President Obama, former Pope Benedict and the Dalai Lama would probably make for an entertaining evening.

What is the one book everyone should read?

I would recommend that everyone read more than one book.

What do you see as an upcoming trend within the industry?

The trend for personalized medicine will not only revolutionize manufacturing but also the distribution of pharmaceuticals.

How do you manage work/life balance?

I would not say I manage it, rather I deal with it.

Did you have a mentor in your life? And if so, what was the best advice he or she gave you?

My father told me to do things as good as they can be done. This is what I try to adhere to.

Okay, so I've just joined PDA. What should I do next?

Actively participate in areas you are familiar with and broaden your network and expertise.

Please discuss opportunities you have been involved with at PDA.

I have introduced two of my previous co-workers to leading PDA interest groups.

In a follow up to the question above, I notice that you were co-chair of the parenterals meeting in 2012? Can you explain to someone who has never volunteered, the value to your career you got out of doing this?

This was an opportunity to introduce industry trends into an attractive meeting program and, together with the other team members, identify relevant contributions and interesting speakers. Time expectations were manageable as support from PDA was always available. Some new relationships were built up, which increased my professional network

EMD MILLIPORE

There is more to drug safety than meets the eye.

Microbial Testing by EMD Millipore.

EMD Millipore offers more than a complete range of high quality microbiology testing solutions for the pharmaceutical industry. It's a comprehensive approach providing regulatory expertise, substantial service, and trust. For that one invaluable result: safe products.

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  - Viable and non-viable air monitoring
  - Surface and personnel monitoring
- **Traditional and rapid microbial detection**
  - Bioburden
  - Mycoplasma
  - Pyrogen
- **Sterility assurance**
  - Sterility testing
  - Media Fill

www.emdmillipore.com/biomonitoring

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chapter update

Canada Chapter Explores Logistics Concerns

Sabrina Ullah, SNC-Lavalin Pharma, and Antonella Maggio, Pharmascience

The PDA Canada Chapter welcomed PDA President **Richard Johnson** to the chapter's May 29 event on supply chain logistics. His opening address not only highlighted the many benefits of becoming a PDA member, but also PDA's upcoming priorities.

Following his presentation, **Brian Pedersen**, VP, Airfreight Logistics, KUEHNE + NAGEL, shared real-life experience in regards to pharmaceutical product shipping, including solutions to manage cold chain needs, shipment monitoring processes to ensure product remains within the temperature requirements and comprehensive risk management strategies to minimize any disruption within the supply chain.

Next, **Jason Dacosta,** General Manager, Postal Affairs and Specialized Markets, Air Canada Cargo**,** presented an airline's perspective on best practices for shipping temperature sensitive cargo by air.

Sarah Skuce, Drug GMP Compliance Specialist, Health Canada, then explored guidelines for temperature-controlled drug products during storage and transportation. She explained how these regulatory requirements help maintain the safety, quality and efficacy of drug products available on the Canadian market.

Concluding the event, **Jean Bedard,** President, Infitrak, discussed methods to achieve compliance for cold chain products. The pharmaceutical cold chain concept implies all necessary means to maintain therapeutic products in the specified manufacturer's temperature limits during all the logistics and distribution process. Cold chain compliance and gap analysis is the very first step to evaluate the compliance of operations and logistics in regard to the regulatory context.

The chapter chose the topic of supply chain logistics based on a survey of attendees at a previous chapter event. The Canada Chapter plans to continue offering affordable events featuring enlightening topics of interest to members.

This event was sponsored by Air Canada Cargo and Lesirg Consultants.

[Editor's Note: For pictures of Canada Chapter events, please visit www.pda.org/canada/photos.**]**

PDA India Chapter Hosts Inaugural Convention

Ivy Louis, Vienni Training and Consulting

Earlier this year, PDA President **Richard Johnson** exchanged emails with us, the leaders for the India Chapter, about hosting an inaugural convention for June 4 and 6. That email sent all of us in a tizzy! So much to do and so little time! This was a prestigious occasion and all of us knew it would set a benchmark for everything that followed. If pulling rabbits out of a hat is a magical feat, then having to run this event was no different—and it seemed even more when the dates for the convention were proposed!

The clock had started to tick and so began a flurry of activities. We started scouting for hotels, planning the details of the event, sending invitations and seeking service providers.

The fever bug peaked in mid-April once we finalized the schedule for the inaugural convention. It was a thrill to conceptualize, execute and revel in this high stakes assignment. It also brought all of us in the chapter together, in so many ways, enabling us to share concerns and work out resolutions.

The day of the convention saw mixed emotions. One was relief that there was no more planning required. The other was anxiety as to what would unfurl that day. Throughout the convention, attendees exchanged ideas on biodecontamination, water systems, isolators and aseptic processing—always a popular topic!

(l-r) B.L. Meena, General, Drugs Control Administration; Richard Johnson, PDA; Sanjay Singh, President PDA India Chapter; Sanjit Lamba, President-Elect, PDA India Chapter

Naturally, providence and near misses were also the order of the day. From missing names to spilled oil, confetti not spraying out in the optimal amount to unburst balloons—everything was taken with a pinch (nee—a dish) of salt, while we galloped on with plans for subsequent programs.

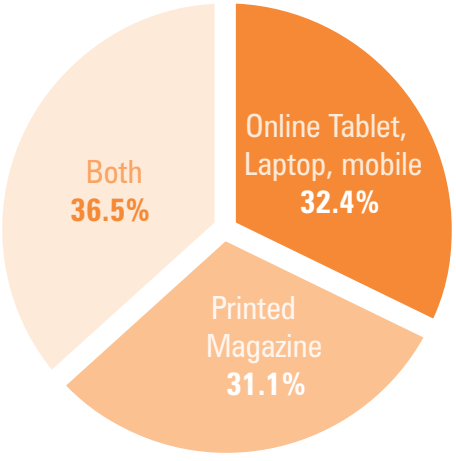
Now with volunteers signing on, membership in the India Chapter has swelled by 42%!

Life at the PDA India Chapter is never going to be the same again!

PDA Pulse

PDA Members Prefer Both Print and Online Versions of the *PDA Letter*

PDA recently asked members how they'd prefer to receive the *PDA Letter*. There is a close tie between those who would prefer just an online version and those who prefer just a hard copy. Yet another third would prefer to receive both formats.



Session 3: Process/Manufacturing

(l-r) Nuno Neves, PhD, 3B's Research Group; Mark Angelino, bluebird bio; Julian Kay, GlaxoSmithKline

Session 2: Raw Materials

(l-r) Jaana Vesterinen, Fimea; Valerie Pimpaneau, PhD, Voisin Consulting Life Sciences

Session 2: Raw Materials (cont'd)

(l-r) Margarida Menezes Ferreira, PhD, Infarmed; Paula Salmikangas, PhD, Fimea; Dagmar Blöcker, CellGenix; Jean Stanton, Janssen Pharamceuticals

Wilfried Dalemans, PhD, TiGenix, emphasizes a point to PDA President Richard Johnson.

Conference co-chair Giovanni Migliaccio, PhD, Istituto Superiore di Sanità, speaks during a Q&A session.

The Parenteral Drug Association presents...

2013 PDA Europe

The Universe of Pre-filled Syringes and Injection Devices

Providing Value and Compliance

Track 1 New Developments Related to Pre-filled Syringes/ Parenteral Drug Delivery

Moderators: Arno Fries, *Gerresheimer*
Ian Thompson, *Ypsomed*

The interface between the primary drug container and the injection device, particularly for safety systems or self-injection devices, demands new innovations in terms of materials, tolerances and innovative solutions. Most importantly, these new innovations must be robust and reliable and well accepted by the Health Care Professionals and patients who use them. In this session, you will hear about work performed on understanding and improving the pre-filled syringe interface and how pharmaceutical companies have tackled these issues for recently developed and launched devices.

Track 2 New Developments of Pre-filled Syringes as a Key Enabler of Drug Development Path

Moderators: Nicolas Morais, *BD Medical – Pharmaceutical Services*
Thomas Schönknecht, *SCHOTT*

Pre-fillable syringes are the container of choice for a broad variety of therapeutic classes. Many new drug formulations are highly sensitive, increasing the risk of interactions between the drug substance and the primary container system. This has led to the development of specific treatments and production processes in the container industry. The session provides insights into the latest technologies implemented for pre-filled syringes and cartridges to ensure continued safety and efficacy of the drug throughout its shelf life. This session will also introduce an example of drug life cycle management through successive launches. Another key driver in the market is medication safety, especially in hospitals. The use of polymer containers, together with pump systems, is also addressed during the session.

Track 3 Formulation Challenges in the Development of Drug Devices

Moderator: Mariana Dimitrova, *Biogen Idec*

The need to deliver highly concentrated clinical doses and continuous requirements for improved drug delivery have increased in recent years the demand for large volume injectors, novel delivery devices and innovative formulation solutions. As an emerging parenteral drug delivery technology, large volume injectors have growing appeal for the biopharmaceutical companies offering less frequent dosing and improved patient convenience. This session will focus on studies illustrating formulation challenges in the development of drug devices for protein therapeutics, biosimilars and vaccines and will illustrate creative solutions developed for the delivery of large clinical doses, overcoming interfacial incompatibilities, as well as resolving challenges with injection forces during subcutaneous administration.

Track 4 Optimized Pre-filled Syringe Filling – Process and Simulation Models

Moderator: Frank Bamberg, *F. Hoffmann-La Roche*

Understanding complex and sophisticated fill/finish processes is key for both pre-filled syringe suppliers and equipment manufacturers. And, regulatory bodies are increasing their demands for 'zero defect' operations to further increase patient safety. This session takes a closer look at these challenges and how to deal with them. The speakers will discuss topics such as: how to predict leachables in pre-filled syringes; and advanced CCI test methods. Furthermore presenters will review how to process interchangeable primary containers on the same filling line and present a case study on how to fill cytotoxic drugs.

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President Takes PDA Message Across the Globe

Richard M. Johnson, PDA President

This late spring and summer has been a busy travel period for me, spreading the word about PDA and meeting members across the globe. I would like to share with you some of the highlights of these trips.

India

I was fortunate to be a participant in the inaugural events for our new chapter in India. Our new chapter leaders, **Sanjay Singh**, President; **Sanjit Lamba**, President-Elect; **Ivy Louis,** Treasurer; and **Vishal Sharma,** Secretary, were great hosts and organizers.

During the first week of June all day events were held in Hyderabad and Mumbai. The programs included several speakers, and were well attended by members and future members in India. We were honored by the participation of **B.L. Meena,** Director General, Drugs Control Administration, Andhra Pradesh, **Farhana Khan,** Assistant Director (Medicines), U.S. FDA, and **Peter Baker,** Office of International Program, FDA India Office.

During the visit I was also able to meet separately with Meena as well as **Mahesh Zagade,** Commissioner Food and Drug Administration, Maharasthra State, who were supportive of PDA's initiatives in India.

[Editor's Note: For an account of this event from the India Chapter, see story on p. 15**.]**

Chicago

I attended the *2013 PDA Aseptic Processing-Sterilization Conference* in Chicago June 20–21, and was pleased at how this conference is growing. There were excellent presentations and interaction, and I was please to catch up with former colleagues from the Midwest.

Italy

I immediately left Chicago to attend the PDA Europe's *Advanced Therapy Medicinal Products* conference in Florence, Italy. The conference was very interesting, and highlighted cutting edge new therapies. The PDA Italy Chapter (**Walter De Matteo,** President**; Vincenzo Tarantino,** Vice President; **Massimo Golia,** Secretary; and **Gaetano Fiorentino;** Treasurer) was very supportive and hosted not only a spectacular dinner for the attendees overlooking the city but also hosted a special dinner for the PDA Board of Directors. Never was Italian hospitality so well demonstrated.

Ireland

After a brief interlude with my family, it was back across the Atlantic for the *Emerging EU Regulations and Inspection Trends* conference held in cooperation with the Irish Medicines Board in Dublin, Ireland. This was a very interesting meeting, with topics ranging from the new Falsified Medicines Directive and GDPs to a spirited discussion on EU GMP Annex 1 on sterilization filtration. Immediately prior to the meeting, we were able to meet with members of the Irish Medicines Board to discuss key upcoming activities of both IMB and PDA. We also met with the PDA Ireland Chapter leaders **Alice Redmond,** President; **Ann McGee,** Treasurer; and **Anne Greene,** Secretary, and discussed opportunities to better support the chapter.

Australia

Next I traveled to Melbourne to attend a meeting of the PDA Australian Chapter. Chapter leaders **Greg Jordan,** President; **Kim Waters,** President-Elect; **Paul Kerr,** Treasurer; **Anna Corke,** Secretary; and **Ano Xidias,** Past President, made me feel welcome. I was able to take the roadshow to two local companies and talk about PDA before almost 100 people, as well as present to attendees at a chapter meeting. The highlight of that meeting was presenting long service pins to several of our Australian members.

Singapore

Greg Jordan and I traveled to Singapore and met with members interested in initiating a chapter in Singapore. The energy and enthusiasm they displayed makes our inauguration of a new chapter just a matter of time. It was inspiring to learn that we have a long history and active chapters in this region, who are extending the PDA message around the world.

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PDA Chair Recommends Escaping Comfort Zone to Achieve Success

Rebecca Stauffer, PDA

WHEN he began his career in 1991 as a scientist for Novo Nordisk in his native Denmark, **Anders Vinther,** PhD, probably never imagined that in 2013 he'd be working in the United States as VP of the Quality Biologics Operating Unit for Genentech and chair of the PDA Board of Directors.

A 20-year member of PDA, Vinther says he owes his move to the United States and subsequent career change through his involvement with the Association. At the same time, his willingness to take risks and look ahead has also helped him achieve notable milestones.

"Your next job should always be one where you are slightly out of your comfort zone because that's the way you grow," he advises. "When you have been in a role long enough to learn and add significant value to the department in the company, one should think about what is the next thing where you can stretch yourself a little bit."

By making a career move overseas, Vinther has indeed stretched himself, particularly by immersing himself into a different culture. He even had to hone his communication style.

"One of the things that we are known for in Scandinavia is that we are very direct, so if there are things we feel are non-functioning, I was used to saying 'I don't think this works, we need to look at it and fix it,'" he remembers. "I learned that here in California, instead, we talk about 'opportunities for improvement.'"

He also notes that work hours are different between the United States and Europe, pointing out that in the United States. he has experienced 24/7 availability. But "I would never wear a Hawaiian

shirt to work in Denmark…it happens in my current job," he laughs.

For those in the industry looking to make a cross-cultural move, Vinther recommends taking into account the culture of the new location. He cites sports terminology as an example.

"Be mindful of where is it you're moving to and make sure that you show respect," he says. "I don't impose my own culture if that's not appropriate. And there's actually one extra thing that I noticed—there's a lot of expressions in the business world that come from sports—'it's a home run,' 'hit it out the ballpark,' 'touchdown,' and other things. For most Europeans that is not language you understand because it's not the same sports. You've got other sports here than we do in Europe so when you use terminology sometimes people just don't know what you're talking about."

Still, regardless if you move to another country or the company across the street, Vinther cautions against neglecting your core values and work ethos.

"No matter whether it's within a country or it's from country to country, you've got to remember your own identity," he says.

So how does Vinther recommend moving ahead internationally when it comes to your career?

Networking, he states firmly.

"When you network, you start to make really good friends and you learn about other companies, other cultures, and other ways of looking at things. " he says. "And I'll tell you that I would not have my current job today if it wasn't because of my networking at PDA."

"PDA does connect People, Science and Regulation—our tagline. That's exactly what we do. And that's one of the wonderful things about PDA," he stresses.

At PDA, Vinther has served in numerous volunteer roles on conference committees and task forces to Board of Director roles.

While Vinther has taken several leaps in his career, he urges employees to avoid jumping ship in the face of challenges.

"My own view is that you should not leave a job until you feel you've given back what the company has invested in you," he says. "Be open about where you would like to go but don't say 'I want to try and do something else' because then you're not seen as being a stable employee…then you're one who jumps around from job to job and you don't want to be seen that way."

Just like Vinther probably never imagined at the start of his career that more than 20 years later he'd be a vice president working for a multinational company abroad, who knows where you'll be 20 years from now. Vinther's experience with networking and volunteering shows that significant change can come by aggressively moving outside one's comfort zone. By taking such initiative, maybe 20 years from now, you'll be working overseas wearing a Hawaiian shirt as well!

snapshot

Microbiology Technical Reports Offer New Best Practices

Josh Eaton and Jahanvi (Janie) Miller, PDA

While previewing the upcoming *PDA 8th Annual Global Conference on Pharmaceutical Microbiology* (see story on p. 42), the *PDA Letter* took a look at some upcoming and recently published microbiology-related technical reports. Below are descriptions of five technical reports that should be of interest to pharmaceutical microbiologists.

- *Technical Report No. 62: Recommended Practices for Manual Aseptic Processes,* which was just published in July, outlines methods and approaches for control and evaluation of aseptic processing operations for drug products, using all or partial manual procedures. This technical report is applicable to personnel in the following operations: vaccine preparation, cell culture, gene therapy, investigational new drug (IND/IMP) manufacturing, clinical and commercial manufacturing.
- *Technical Report No. 33 (Revised): Evaluation, Validation and Implementation of New Microbiological Testing Methods* will provide guidance for the successful evaluation, validation and implementation of alternative and rapid microbiological methods needed by the pharmaceutical, biotechnology and medical device industries to assure product quality. If all goes well, this technical report will be published in early September.
- *Technical Report No. 13 (Revised): Fundamentals of an Environmental Monitoring Program* will identify microbiological and particulate control concepts and principles as they relate to the manufacture of pharmaceutical products, and other designated controlled environments. At this time, the report is currently under review by the Science Advisory Board.
- *Exclusion of Objectionable Microorganisms From Pharmaceutical and OTC Drug Products, Medical Devices and Cosmetics,* is also currently in development. In the second quarter of 2013, the technical report team began conducting an extensive survey of companies, both inside and outside of PDA's membership, to determine best practices for developing a framework for mitigating the risks objectionable microorganisms pose during nonsterile drug product development (see story on p. 32 for further information about nonsterile product development). This technical report should be available sometime in 2014.
- And finally, a technical report team is currently working on a presently untitled report on bacterial endotoxins. This report is projected to be published in early 2014.

Tech *Trends*

Industry Seeks Sterility Test Answers for PET Drugs

Eric Webster, PETNET Solutions

New U.S. FDA rules on GMP's for Positron Emission Tomography (PET) drugs became effective Dec. 12, 2011. Since the regulations went into effect, two questions have arisen within industry pertaining to the accuracy of sterility testing. First, does the radiation from the drug product prevent microbial growth during the sterility test? And second, is the small sample size used for PET sterility testing sufficient for the size of the batch? Both questions were answered in posters presented at the *2013 PDA Annual Meeting* and at the *International Symposium on Radiopharmaceutical Sciences* provided by PETNET Solutions.

To assess the first question, Sodium Fluoride F 18 injection was manufactured to the highest strength (radioactive concentration) used during routine manufacturing. Typically, the sterility samples are removed from the final product vial and injected into sterility test media within 15 minutes from the end of manufacturing. This is when the drug product has the highest amount of radioactivity. The combination of the radioactive drug that is injected into the sterility media and the radioactive field from the final product vial may inhibit microbial growth, which could lead to false negative sterility test results. Sterility media was inoculated with 10-100 or-

Continued at bottom left page 41

In *Print*

Suggestions for Developing Load Patterns for Continuous Tunnels

The following was excerpted from section 6.4.1 of PDA Technical Report No. 3 (Revised 2013): Validation of Dry Heat Processes Used for Depyrogenation and Sterilization. *The technical report was available for free member download through August 31, and is now available for purchase at www.pda.org/bookstore.*

The worst case load should be determined on the basis of load mass, configuration or other parameters. Process parameters should then be developed to achieve the required conditions of time and temperature for the load. Load items should be placed into the tunnel so they remain upright, thus requiring placement on the belt in a "tight" load, so that items that may be disturbed will be held upright by the neighboring items. To maintain this load, either the belt speed must

Continued at bottom right page 41

Journal *Preview*

September–October Issue Looks at Leachables and Extractables

This issue includes several articles on PQRI's extractables leachables research. **Daniel L. Norwood, Lee M. Nagao,** and **Cheryl L. M. Stults** offer commentary on leachable and extractables thresholds for inhaled drugs while **Diane Paskiet**, et al. review the Product Quality Research Institute's initiatives in this area. **Dennis Jenke,** et al. offer research on characterizing extractables for packaging systems.

Editorial

Govind Rao, "Waiter, There Is a Fly in My Soup!"

PQRI Special Section

Commentary

Daniel L. Norwood, et al., "Perspectives on the PQRI Extractables and Leachables "Safety Thresholds and Best Practices" Recommendations for Inhalation Drug Products"

Review

Diane Paskiet, et al., "The Product Quality Research Institute (PQRI) Leachables and Extractables Working Group Initiatives for Parenteral and Ophthalmic Drug Product (PODP)"

Research

Dennis Jenke, et al., "Extractables Characterization for Five Materials of Construction Representative of Packaging Systems Used for Parenteral and Ophthalmic Drug Products"

Regular Section

Research

Patrick J. McCormick, et al., "Evaluation of a Rapid Microbiological Method with a Mixed Culture Biofilm Model"

Harry Yang, "Setting Specifications of Correlated Quality Attributes through Multivariate Statistical Modelling"

Changfeng Ge, et al., "Application of the Finite Elemental Analysis to Modeling Temperature Change of the Vaccine in an Insulated Packaging Container during Transport"

Commentary

Annalaura Carducci, et al., "The Application of Quality Risk Management to the Bacterial Endotoxins Test: Use of Hazard Analysis and Critical Control Points"

Expanded Microbiologist Role in Process Design, Operations?

Walter Morris, PDA

When a company drafts contracts, it usually turns to its lawyers. When they change employment policies, it turns to human resource experts (who can also be lawyers). When it wants to raise funds, it taps the expertise of investment bankers. When it wants to lower its tax burden, it turns to the accountants.

So, how come many pharmaceutical companies fail to involve their microbiologists in the design and operation of its processes for the manufacture of sterile drugs?

This question was posed by two speakers at the *PDA 2013 Aseptic Processing-Sterilization Conference* held June 20–21 in Chicago, Ill.

Bob Seltzer, Sr. Manager, Acorda Therapeutics, and **Thomas Arista,** Field Investigator, U.S. FDA, both suggested pharmaceutical companies are ill-served by keeping their microbiologists locked up in the laboratory.

It was noted during the discussions that no microbiologists were on hand at the New England Compounding Center, the company behind the 2012 fungal meningitis outbreak in the United States. While industrial pharmaceutical production is immensely more advanced and safer, Seltzer asserted that involvement of microbiologists either as operators or supervisors or both in aseptic and other sterile processes would help industrial manufacturers reduce batch failures, product recalls and severe inspection findings.

Seltzer said microbiologist should serve an integral role of the cleanroom filling operations in aseptic processing and wherever there are critical control points in sterile manufacturing. "Wherever there is a critical control point in the process flow for a sterile drug product," he said, "a microbiologist should be intimately part of it, if not responsible for or accountable for that piece of the process."

As for operators, "We should have qualified, schooled cleanroom operators, schooled in microbiology," said Seltzer. He noted that you can find this in countries like Brazil, which makes them attractive places to manufacture sterile products.

Microbiologists are inherently strong risk managers, Seltzer explained. "That is brought out in ISO 13408, which provides a rundown of risk management that a person actually must have skills in to work in an aseptic processing area, including:

- Knowing the origins of contamination sources
- Knowing routes of contamination
- Understanding the ability of microorganisms to cross a segregation barrier
- Performing contamination detection and removal

Arista advised companies to "exploit the technical expertise and knowledge [of microbiologists] to the benefit of the organization." Calling it "applied microbiology," the FDAer said companies can use microbiologists to do other things besides typical laboratory work. The microbiologist would be the obvious "empirical tool" for companies in aseptic processing.

Arista listed a number of critical factors for which input from a microbiologist would be valuable:

1. The microorganisms that are unique to your facility and manufacturing operations
2. The personnel and material flow
3. Airflow pattern evaluations
4. Observation of your aseptic filling operations
5. The EM sample site selection process

When conducting inspections, Arista likes to ask firms, "With respect to quality controls to prevent the ingress of microbiological and nonviable particulate contamination, do you folks include microbiologists in evaluating the aforementioned considerations proactively?" If the company says "no," Arista said he then asks, "Why not?"

Seltzer wrapped up his talk with the following advice for companies: "The cost of microbiology credentials moving into the cleanroom operations is repaid many times over."

About the Experts

Thomas J. Arista has been with the FDA for 34 years as a Microbiologist and Pharmaceutical Investigator. He is a National Expert Pharmaceutical and Biotechnology Field Investigator for FDA's Office of Regulatory Affairs.

Bob Seltzer is currently a Senior Manager – Quality GMP for Acorda Therapeutics, Inc. He has 27 years in R&D, process development, quality assurance, compliance, and audit management roles for biopharmaceuticals and medical devices.

Attention Microbiologists!

You can stay ahead of the microbial curve by attending PDA's *8th Annual Global Conference on Pharmaceutical Microbiology.* To learn more, visit www.pda.org/microbiology2013 and check out our preview article on page 42.

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2013 PDA UPCOMING EVENTS

SEPTEMBER EVENTS

16-18
2013 PDA/FDA Joint Regulatory Conference
Washington, DC
www.pda.org/pdafda2013

18-19
2013 PDA/FDA Improving Investigations Workshop
Washington, DC
www.pda.org/investigations2013

19
PDA UK Chapter Single Use Workshop
Billingham, UK
www.pda.org/UKSingle

19-20
2013 PDA/FDA Joint Regulatory Conference Course Series
Washington, DC
www.pda.org/pdafdacourses2013

23
Selection Considerations for Manufacturing Freeze Dryers Workshop
Düsseldorf, Germany
https://europe.pda.org/WSFreezeDrying2013

24-25
Pharmaceutical Freeze Drying Technology
Düsseldorf, Germany
https://europe.pda.org/FreezeDry2013

25-26
PDA Ireland Chapter: Capturing Opportunity through Innovation and Excellence
Dublin, Ireland
www.pda.org/Irelandopp

26
ICH Q9: Application of a Risk-based Approach to Freeze Drying Processes Training Course
Düsseldorf, Germany
https://europe.pda.org/ICHQ92013

26
PDA Southern California Chapter 2013 Educational Event: Implementing ICH Q10
San Diego/Los Angeles, California
www.pda.org/socalichq10

26-27
Development of a Freeze Drying Process Training Course
Düsseldorf, Germany
https://europe.pda.org/TCFreezeDrying2013

30-3 October
2013 Lyophilization Week
Bethesda, MD
www.pda.org/lyophilizationweek

OCTOBER

1-2
Fundamentals of Cleaning and Disinfectant Programs for Aseptic Manufacturing Facilities Training Course
Bethesda, MD
www.pda.org/disinfection

7
PDA Missouri Valley Chapter: Current Trends in Environmental Monitoring
St. Charles, MO
www.pda.org/missouriEM

7-8
2013 PDA Visual Inspection Forum
Bethesda, MD
www.pda.org/visualinspection2013

7-8
2013 PDA Analytical Methods Development & Validation Workshop
Baltimore, MD
www.pda.org/amd2013

8-9
Pharmaceutical Cold Chain Integrity
Berlin, Germany
https://europe.pda.org/ColdChain2013

9-10
An Introduction to Visual Inspection Training Course
Bethesda, MD
www.pda.org/visualinspectionlab2

10-11
PDA Good Temperature-Controlled Management Practices Training Course
Berlin, Germany
https://Europe.pda.org/TCColdChain2013

www.pda.org

For an updated PDA calendar of events please visit www.pda.org/calendar.

Save these dates!

EVENTS

14-18
2013 Aseptic Processing Training Program – Session 5
(Week 2, November 4-8)
Bethesda, MD
www.pda.org/2013aseptic

21-23
PDA 8th Annual Global Conference on Pharmaceutical Microbiology
Bethesda, MD
www.pda.org/microbiology2013

23-24
Single-Use Systems for Manufacturing of Parenteral Products Training Course
Bethesda, MD
www.pda.org/singleusemanf2013

24-25
PDA 8th Annual Global Conference on Pharmaceutical Microbiology Course Series
Bethesda, MD
www.pda.org/microcourses2013

28-1 November
2013 Filtration Week
Bethesda, MD
www.pda.org/filtrationweek2013

29-31
Validation of Biotechnology-related Cleaning Processes Training Course
Bethesda, MD
www.pda.org/biotechcleaning

NOVEMBER EVENTS

4
Pre-Conference Workshop: Polymer as a Container Material for Pre-filled Syringes
Basel, Switzerland
https://europe.pda.org/WSUPS2013

4
Combination Products Interest Group Meeting
Basel, Switzerland
https://europe.pda.org/IGUPS2013

5-6
The Universe of Pre-filled Syringes and Injection Devices
Basel, Switzerland
https://europe.pda.org/UPS2013

7
Glass – The Packaging Material for Parenterals Training Course
Basel, Switzerland
https://europe.pda.org/TCGlas2013

7-8
Development of a Pre-filled Syringe Training Course
Basel, Switzerland
https://europe.pda.org/TCUPS2013

7-8
Development and Technical Requirements for Combination Injection Products Training Course
Basel, Switzerland
https://europe.pda.org/ComProd2013

11-12
Fundamentals of an Environmental Monitoring Program Training Course
Bethesda, MD
www.pda.org/environmental2013

12
PDA/FDA Advanced Technologies for Virus Detection in the Evaluation of Biologicals Conference Course Series
Bethesda, MD
www.pda.org/viralcourses2013

13-14
PDA/FDA Advanced Technologies for Virus Detection in the Evaluation of Biologicals Conference
Bethesda, MD
www.pda.org/virusdetection2013

13-15
Validation of Dry Heat Processes Used for Depyrogenation and Sterilization Training Course
Bethesda, MD
www.pda.org/valdryheat

15
Biosimilars – Understanding the CMC Challenges of Meeting 'Similarity' Training Course
Bethesda, MD
www.pda.org/biosimilars

18-22
Quality Systems for Aseptic Processing Training Course
Bethesda, MD
www.pda.org/qualitysystems

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

True partnerships build upon aligned principles, focused on people, fit, trust, culture and accountability. This tenet should carry throughout the life of a partnership. Ultimate success is determined by the partnership's ability to provide uninterrupted supply of quality product to the patient. Established identity, empowerment and governance of the team, along with leadership support, are key factors in achieving success. Refer to **Table 1** for an outline of the four steps of the EMP lifecycle: identify, establish, maintain and discontinue.

Table 1: The Four Steps of the EMP Lifecycle

1) Identify	2) Establish	3) Maintain	4) Discontinue
• Search	• Relationship Foundation	• Commercial Production	• Product Retirement
• Assess	• Technology Transfer	• Relationship Management	• Partnership Retirement
• Audit	• Knowledge Development	• Change Management	
• Select	• Process Qualification		
	• Registration		

Change is inevitable, so plan for it!

1) Identifiy

Identification of an EMP is the most important element of creating lasting and successful relationships. Develop an EMP search team composed of cross-functional representation (quality assurance, supply chain, process development, business-development, etc.) to ensure a balanced approach. Overall timing from identification to selection is roughly three to five months, depending upon the complexity of the process and number of EMP candidates under evaluation.

Consolidate known data around the product prior to an official EMP search team kick off. This should include development work, analytical methodology, equipment requirements, technical capabilities, program timeline, and any other pertinent information. It is crucial to work from a complete set of information.

Identifying potential partners for consideration involves searching industry databases and the internet, obtaining referrals or contracting consultants to screen for viable EMPs. The initial work identifies companies that have the capabilities you require based upon published information and Requests for Information (RFI). Requesting presentations by the first round of EMP candidates helps to develop a deeper understanding of their capabilities for consideration. The team should target three to five EMP candidates for initial evaluation.

Utilize publicly available selection tools or create one tailored to the project needs. The selection tool should include not only the process Scope of Work (SOW), cost, capabilities and timing, but also the quality philosophy of the EMP candidate along with regulatory history. Established criteria with weighting rankings (higher value to the most important attributes) allow for clearer comparison.

Once the viable EMP candidates have been identified, the search team then progresses to the Request for Proposal (RFP) stage, quality site audits and final selection. The RFP includes the collection of detailed information about the product and process under consideration. EMP candidates are then compared using a delineated SOW that serves as the basis of comparison. The SOW combined with other important attributes, such as cultural fit, quality philosophy and capabilities for today and the future should make up the assessment tool. After the final viable EMP candidates have been identified, you should progress to site quality audits before making a final selection. It should be understood that leadership endorsement and support are critical for long-term success.

2) Establish

After selecting an EMP, the relationship foundation needs to be built with structured governance. Sufficient time is required for contract development (development supply agreement, commercial or master supply agreement, quality agreement, etc.) as it provides the aligned vision on how you will work together in the future, and typically involves numerous iterations. It is worth noting that you, the application owner, have ultimate responsibility for the product and should have a responsible person held accountable for the performance of the partnership. That does not alleviate any of the EMP's responsibility. The EMP must have sound rationale and supporting documentation in place for established processes, qualification of systems, and statements of impact for nonconformance events. Expectations must be clearly defined within relevant agreements.

Technology transfer is necessary to establish the process and methodologies. A key tenet of technology transfer is knowledge management; the deliverable may be an established process, test methods, or other technology shown to be repeatable and capable of consistently meeting established acceptance criteria. Knowledge databases need to be developed and shared across partnerships. Information contained within the knowledge database should evolve as the process is developed and better characterized. Shared internet portals are a great tool for this purpose (e.g., SharePoint or eRoom).

A process map is a useful way to represent the overall plan with stage gates requiring steering committee (or other governing bodies) visibility and defined decision points when significant investment is required—process qualification is an example. Defined activities should include things like small-scale work such as sterilizing filter validation, material compatibility for product contact materials, initial Leachables and Extractables (L&E) evaluations, and lyophilization cycle development. Engineering runs are required to demonstrate that the process behaves similarly at production scale as it did at small scale —this is the time to address and resolve any unexpected differences. Successful engineering runs will provide a level of confidence before committing resources to clinical or commercial production. This is a cost of doing business, but also an opportunity to generate characterization data and complete initial process validation studies—capitalize on the opportunity!

Refer to **Figure 1** on the top of page 30 for an example of a process map.

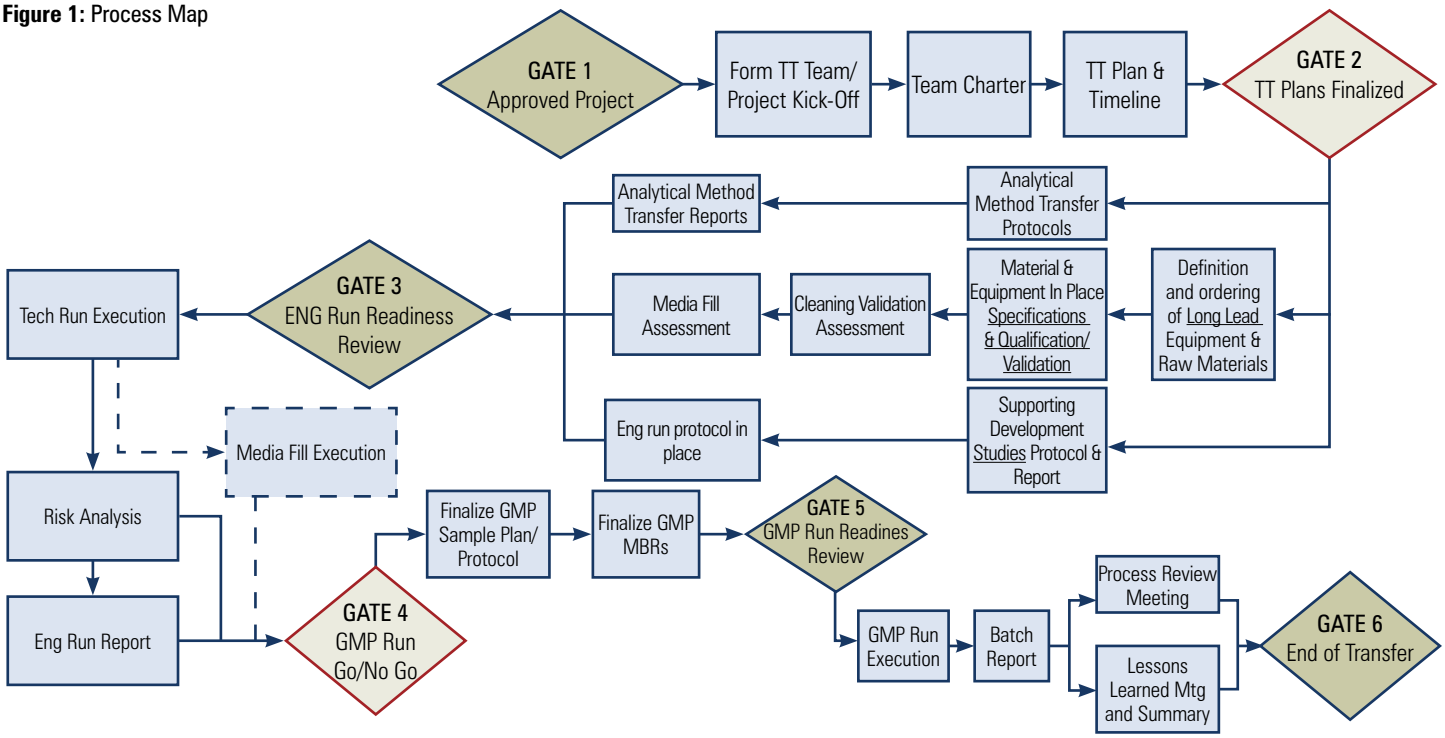
[Editor's Note: For an expanded view of this graphic, see the online version of this article at www.pda.org/pdaletter.**]**

Once the process is established and clinical applications completed, you should continue to produce product as required to support trials, gain real time stability data, and build your knowledge database. Use this opportunity to develop characterization data in support of pro-

Article at a Glance

- External partnerships are shaped by common principles
- Management is the key to successful technology transfer
- Transparency is essential for successful partnerships

Figure 1: Process Map



cess criticality and further refine the control strategy.

Process Performance Qualification (PPQ) and Registration are the final steps to provide medicines to the market. It has been a long road to this point, and now it is time to fine tune the demonstration package included in the registration application. The demonstration package, from a CMC perspective, should include such items as equipment qualifications, sterility assurance evaluation, product characterization, product stability and process qualification. This data, typically captured within the Common Technical Document, is submitted to the health authorities where market authorization is sought. A well-developed process and submission package should result in market authorization.

3) Maintain

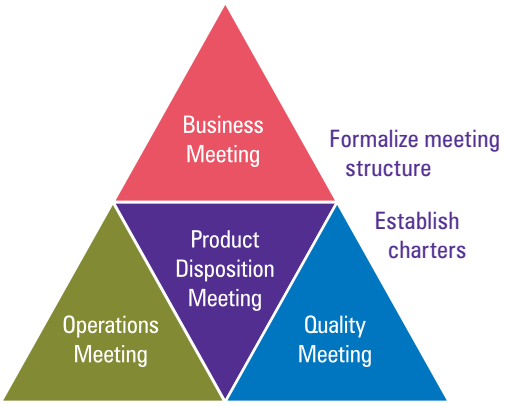
Now that the process is established and registered, it is time to maintain supply, manage change, continue to build upon the knowledge database and reinforce the relationship management model.

Key Performance Indicators (KPIs) measure performance over time, such as batch success rate, right first time, and turnaround time. Specialized partnerships need to determine the attributes that are indicative of performance for measurement and evaluation. KPIs should be reviewed regularly during business and quality meetings to target areas for improvement and concur on implementation plans.

Change is inevitable, so plan for it! How will changes be communicated? What forum will be used to evaluate proposed changes to determine appropriate implementation plans? Change management is one element of the control strategy that needs to be in place to cover monitoring of process performance and product quality.

Continuous process verification work will add to the knowledge database, which includes Out of Trend (OOT) or Out of Specification (OOS) results, process change evaluations, and statistical process monitoring and analysis. As process experience is gained, the control strategy should be revisited periodically and discussed in the appropriate forum.

Figure 2: Meeting Forums Model



Reinforce the relationship management model. Are meeting forums appropriate to support the operations and business management? Has team membership requirements changed? What is the scope and goal of the meeting, and how frequently should the team meet?

Remember, similar to developing a product, maintaining a partnership takes effort and dedication. Work done in the front-end will pay dividends later.

4) Discontinue

It sounds easy enough. Once a decision is made to discontinue a product or an EMP partnership, stop production and terminate the agreement, right? Not quite. A plan needs to be developed, executed and confirmed whereby the product, and/or EMP partnership, can be discontinued. Regulatory submission files are then amended and all documentation reconciled with appropriate archival. Aligning the plan and rationale with the EMP is important.

Continued on page 47

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Micro Contamination Prevention Remains Big Concern for Manufacturers of Nonsterile Products

Rebecca Stauffer, PDA

The microbiological control of finished nonsterile products remains a prime concern among pharmaceutical manufacturers. The paucity of regulatory guidance does not help. In 2011, **Erik Greb** wrote: "So far, no regulatory authority has set formal microbial-control standards for the manufacture of nonsterile dosage forms" ***(1).***

The *PDA Letter* reached out to the following experts to learn more about these issues: **Julie Barlasov,** Laboratory Manager, Perritt Laboratoroies, **John Metcalfe,** PhD, Sr. Review Microbiologist, U.S. FDA, **Scott Sutton,** PhD, Principal, Microbiology Network, and **Anthony Cundell,** PhD, Sr. Principal Scientist, Microbiology, Merck.

Barlasov is moderating a session of the upcoming *PDA 8th Annual Global Conference on Pharmaceutical Microbiology* ***(2).*** Metcalfe, Sutton and Cundell will present.

Barlasov told the *PDA Letter* she commonly finds the following problems with nonsterile processes: "contamination with Gram-negative rods that pose health concerns, no set guidelines for risk assessment, and confusion between objectionable organisms and USP-designated organisms."

Barlasov also believes poorly trained personnel is as an issue within the laboratory space. In her opinion, "New college graduates have *zero* concept of GMP."

Externally, Barlasov feels that communication between manufacturing personnel and management could be better, allowing for more effective knowledge transfer.

Regulations Not Clear

A larger concern according to Sutton is the lack of clarity in the regulations globally and the paucity of helpful guidance.

"There is significant confusion in interpretation of requirements surrounding 'objectionable organisms' within the industry. In addition, many companies react to issued 483 observations as if they are regulatory guidance—some 483 observations are quite frankly a bit confusing in this area.," he said. "And I think that's unfortunate. I think that it would be well served to have more clear guidance."

During the upcoming session, Metcalfe will discuss FDA's perspective on some of these issues. He will touch on microbial contamination prevention, which he told the *PDA Letter* "is dependent on appropriate equipment cleaning, disinfection and drying, and control of microbial contamination of raw materials, including water."

Metcalfe will also refer to 21 CFR 211.84(d)(6) requirements regarding objectionable microbiological contamination.

Outside of FDA, the U.S. Pharmacopoeia has recently released

draft chapter <1115>, which could serve as a source document on microbial control considerations during manufacturing. In fact, Sutton—who sits on USP's Microbiology Expert Commitee—intends to review the draft chapter in his talk at the upcoming conference.

"I am going to be relying heavily on the draft USP chapter as a source document, because that right now is the only thing we really have," Sutton said.

Barlasov agrees. "More standardization in the testing guidelines will create better control over environment and finished products from a microbial standpoint," she said. "Hopefully implementation of Chapter <1115> will bring us closer to this goal."

Subhead 1: Microbial Control and Stability Testing

Cundell plans to expand on the subject of testing in stability program in his presentation.

"I have been a strong and consistent advocate of the role of water activity determination to develop risk-based microbial testing programs," he said.

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Furthermore, Cundell advocates a risk-based approach as the co-chair of the PDA task force working on the objectionable microorganisms technical report.

"A risk-based approach will be taken," he said, "because a microorganism isolated from a product cannot be considered objectionable without considering product attributes, number of organisms as measured by colony-forming units, their potential pathogenicity, ability to grow in the product and the intended use of the product. Any decision needs to be made by the drug manufacturer in this context."

As far as the future of nonsterile manufacturing, Cundell foresees an expanded global response in this area, particularly in response to misaligned manufacturing processes due to mergers.

"Pharmaceutical companies are consolidating their manufacturing in the Americas, Europe and Asia-Pacific in response to over capacities, changes in product mixes and emerging pharmaceutical markets," he said. "As with many pharmaceutical microbiologists working in the United States, we need to operate in a global environment. In any one week I may be communicating with colleagues in diverse countries such as Puerto Rico, Brazil, Ireland, the Netherlands, India and Singapore."

In the end, nonsterile products pose a lot of challenges but offer unique opportunities for microbiologists.

"I'm of the opinion that the nonsterile side is far more interesting than the aseptic side. I mean, aseptic, or in terminal sterilization, it's black and white, right? Anything that's present in the final product is wrong," said Sutton. "But on the nonsterile side, we do have things that we need to think about. By definition, a nonsterile product is contaminated. There is a certain level of microbiological contamination that is acceptable. It's the question of how you determine the level, the concentration of microorganisms and how do you determine the types of microorganisms that are acceptable. This is where it becomes really, really interesting."

On the whole, Cundell sees a lot of significant changes in the field of pharmaceutical microbiology beyond nonsterile products.

"The biggest changes I see is in the implementation of MALDI TOF mass spectrometry for microbial identification, PCR for microbial screening and the new understanding of the role of microorganisms in the human body coming out of the Human Microbiome Project," he said. The latter will be covered in the opening keynote address at the conference.

All in all, Cundell believes it's "an exciting time to be a microbiologist!"

Reference

1. Greb. E. Feb. 16, 2011. Manufacturers Recalibrate Microbial Control for Nonsterile Drugs. *Pharmaceutical Technology.* www.pharmtech.com/pharmtech/Production+Lines/Manufacturers-Recalibrate-Microbial-Control-for-No/ArticleStandard/Article/detail/707389
2. Barlasov. J., Cundell, A., Metcalfe, J. and Sutton, S. "Microbiological Quality of Nonsterile Manufacturers." Presentation at the PDA 8th Annual Global Conference on Pharmaceutical Microbiology, Monday, Oct. 21, 2013, 1–3 p.m., Bethesda, MD, October 2013 www.pda.org/microbiology2013

About the Experts

Julie Barlasov has been the Laboratory Manager at Perritt Laboratories in Hightstown, N.J. for the past three years.

Anthony Cundell works for Merck Research Laboratories as a senior Principal Scientist, Analytical Sciences – Microbiology, in early phase drug development.

John Metcalfe began his career at CDER in Jan. 2003, where he works as a review microbiologist.

Scott Sutton operates a consultation and training company, the Microbiology Network (www.microbiologynetwork.com).

BIOPHARMACEUTICAL MANUFACTURING OUTSOURCING IN 2013

During the second quarter of 2013, BioPlan Associates published the company's *10th Annual Report and Survey of Biopharmaceutical Manufacturing Capacity and Production.* Ultimately, BioPlan surveyed 238 individuals at biopharmaceutical manufacturers and contract manufacturing organizations in 30 countries. The following are some highlights from the survey's section on outsourcing.

Analytical Testing Tops the Charts

In 2010, 61.4% were outsourcing some analytical testing activities. This increased by 46.7% in 2013 to 90.1%.

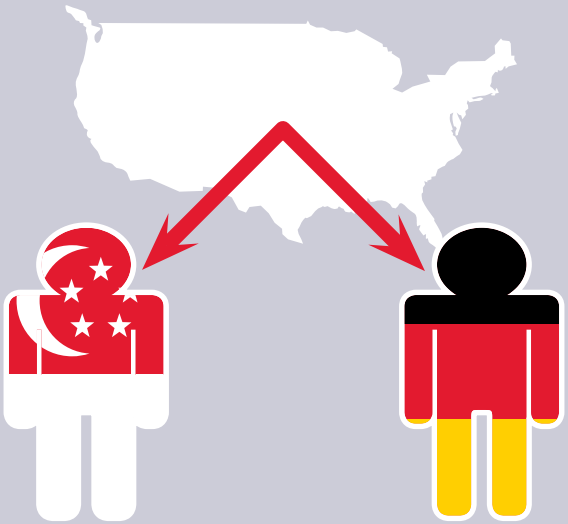
Nearly 26% of respondents also plan to outsource higher levels of analytical testing over the next two years—more than any other activity listed.

The top mistake clients make with CMOs?

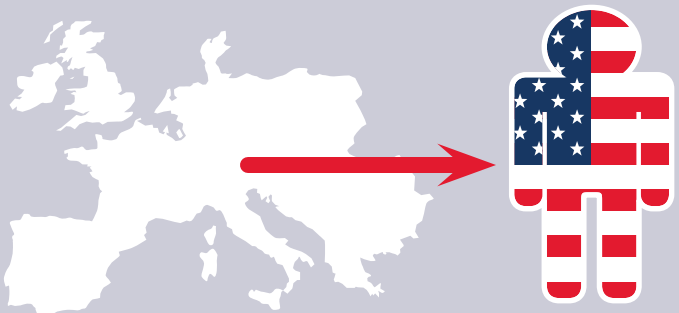
100%
said Clients do not communicate effectively

Outsourcing Destinations

Singapore and Germany were tied as the No. 1 outsourcing destination for U.S. companies.



The No. 1 outsourcing destination for European companies? The United States



Source

1. BioPlan Associates. *Tenth Annual Report and Survey of Biopharmaceutical Manufacturing Capacity and Production.* Rockville, MD: BioPlan Associates, Inc., 2013.

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snapshot

Interest Group *Corner*

Interest Groups Discuss Supply Chain Issues at Joint Meeting During Supply Chain Workshop

Rebecca Stauffer, PDA

One of PDA's most active cadre of members is involved in the he Supply Chain Management Interest Group (SCMIG) and Management of Outsourced Operations IG (MOOIG); the two groups have been holding joint sessions for several years. The latest addressed a variety of supply chain topics at the *2013 PDA/FDA Pharmaceutical Supply Chain Workshop* this past June. **Lucy Cabral,** Head, Global Supplier Quality Management, Genentech, and leader of the SCMIG, along with **Sue Schniepp,** VP, Quality and Regulatory Affairs, Allergy Laboratories, and coleader of the MOOIG, spoke about a number of key supply chain topics along with **Amelia Mutere,** Principal Technical Manager, Genentech.

Not surprisingly, the first item of business included a discussion of the U.S. FDA's guidance on quality agreements for contract manufacturers, which had only been available a few weeks at that point.

"I thought it was actually straight forward and well-written," Schniepp said. "They do make it clear in some of their case studies too that both parties are responsible. I thought that came out really clear."

Along with U.S. regulations, the session touched on international supply chain issues, notably in Europe.

"EMA has published some written questions and answers on written confirmation requirements for APIs," Mutere said. "This is the Falsified Medicines Directive that comes into play next month. And Lucy and I have been talking about this a lot in our interest group but we haven't gotten a lot of best practices."

Moving on, the panel led a short discussion concerning the explosion of warning letters in recent years.

"Sterile products continue to be a highly scrutinized area," Mutere said. Next, there was discussion on the regulatory requirements for CMOs. Mutere noted that the quality of drugs manufactured by a CMO must meet the same level of quality as ones manufactured at a company's own facility.

At the end of the meeting, Schniepp and Cabral indicated the two interest groups will continue to hold joint meetings. Anyone interested in joining either interest group should contact PDA's Volunteer Coordinator **Megan Kuhman** at kuhman@pda.org.

About the Experts

Lucy Cabral has over seventeen years of management experience at Genentech in the quality assurance, compliance and quality control groups.

Amelia Mutere joined Genentech External Quality in 2009. In 2010, she moved to Associate Director of Americas Region, Supplier Quality.

Sue Schniepp is VP, Quality and Regulatory Affairs at Allergy Laboratories, a contract manufacturing organization for sterile injectables.

Hailey's Comments
KFDA Reorganization

Hailey (HeeYoung) Park, Ministry of Food and Drug Safety

It has been close to three years since the last installment of "Hailey's Comments" in the *PDA Letter*. I hope that everyone is doing well. In this issue, I would like to discuss ongoing changes at the regulatory level in South Korea.

On March 23, an amendment to the Government Organization Act went into effect. This Act upgraded the former Korean Food and Drug Administration (KFDA) to the Ministry of Food and Drug Safety (MFDS). Previously, food safety matters were handled by different ministries. This led to discussion about centralizing food and drug safety within one organization.

Thus, MFDS is responsible for issuing and submitting bills related to food and drug safety to the National Assembly. The former Korean Food and Drug Administration was an independent administration, not an affiliate of the Ministry of Health and Welfare.

The new Ministry of Food and Drug Safety is organized with a focus on policy development and management. The review departments of drug approval application and clinical protocol are located in the Ministry's headquarters. These departments specialize in the following: drug evaluation, biopharmaceuticals, herbal medicines and medical devices. These departments were transferred to the National Institute of Food and Drug Safety Evaluation during the reorganization. The responsibility of issuing product approval and controlling GMP/GCP inspections, however, remains the responsibility of the headquarters.

Many functions of policy implementation, except for evaluations, were transferred to regional food and drug administrations. The functions of drug approval and GMP on-site inspection specifically were transferred to these regional food and drug administrations. This was due to increases in both regulatory and industry employees in the Gyeonging and Daejeon regions

After this extensive reorganization, MFDS hopes to promote an exchange of ideas among staff. Ultimately, MFDS wants to leverage this exchange as part of the South Korean president's goal of securing food and drug safety.

[Editor's Note: Hailey "HeeYoung" Park spent a year with PDA as an intern in 2010.**]**

About the Author

HeeYoung "Hailey" Park is the Associate Deputy Director in the Pharmaceutical Policy Division, Ministry of Food and Drug Safety, South Korea. For the past 11 years she has worked in the areas of GMP inspection, drug registration and policy management, among other areas.

PDA Comments on Risk Identification in Shared Facilities

For the comments grid, visit www.pda.org/regulatorycomments

26 June 2013

European Commission
Health and Consumers Directorate –General, Brussels
sanco-pharmaceuticals-d6@ec.europa.eu

Ref: Guideline on setting health based exposure limits for use in risk identification in the manufacture of different medicinal products in shared facilities (EMA/CHMP/ CVMP/ SWP/169430/2012)

To the Health and Consumers Directorate-General:

PDA is pleased to provide comments on this guideline submitted for public consultation. PDA is a non-profit international professional association of more than 10,000 individual member scientists having an interest in the fields of pharmaceutical, biological, and device manufacturing and quality. Our review was completed by an international group of expert volunteers with experience in investigational medicinal products, regulatory affairs and GMP on behalf of our Regulatory Affairs and Quality Advisory Board.

PDA supports the concept of health based exposure limits and welcomes the guidance as advocating a risk based approach. PDA advocates flexible approaches for products currently manufactured in shared facilities to avoid interruption of supply of essential medicines. We also ask that the guideline make it clear that the approach described therein is not the only acceptable one. Any scientifically justified, toxicological, risk based approach with a documented rationale should be acceptable.

If you have any questions, please contact me.

With very best regards,

Georg Roessling, PhD
Senior VP, PDA Europe
Roessling@pda.org

cc: Richard Johnson, PDA, Rich Levy, PDA

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

U.S. FDA Adopts ICH ANDA Guidelines

The U.S. FDA has adopted International Conference on Harmonization (ICH) guidelines concerning requirements for ANDA stability testing. The ICH guidelines adopted cover stability testing of new drug substances, photostability testing new drug substances, stability testing for new dosage forms, bracketing and matrixing designs for stability testing of new drug substances, and evaluation of drug safety data.

Europe

EMA Official to Retire After 16 Years

The EMA has announced the retirement of **Patrick Le Courtois,** Head of Human Medicines Development and Evaluation. Le Courtois first joined EMA in 1997 and had been part of EMA's senior management team since 2001. He had been in his current position since 2009.

Asia-Pacific

China FDA Finalizes Reorganization

The consolidation of the China Food and Drug Administration, formerly the State Food and Drug Administration, has been finalized.

New pharma-related duties of the CFDA will include pharmacopoeia codification, drug manufacturing certification, GMP certification, drug supply certification and GSP certification. Local FDAs will handle reregistration of drugs, changing approval of class III medical device registrations and contract manufacturing applications.

Africa

South Africa Receives Observer Status with European Pharmacopoeia

On July 12, the European Pharmacopoeia Commission granted observer status to South Africa, bringing the number of observers to 29. With observer status, South Africa can participate in the Pharmacopoeia's scientific work and attend its meetings. Additionally, South Africa can work closely with the Pharmacopoeia on issues related to healthcare.

Tech Trends continued from page 23

ganisms listed in USP <71> prior to inoculation of the radioactive drug product. The sterility tubes were left in the radioactive field that was present from the final product vial until the radioactivity had decayed to background levels. The sterility test media was then incubated to determine if growth was still supported in the radioactive field. The results from the test indicated that the radioactive field that was present from the final product vial and the sterility test inoculations did not inhibit microbial growth.

To assess the second question, the entire volume of product in a single vial was subjected to sterility testing. Sodium Fluoride F 18 injection ([18F]NaF) was manufactured according to conditions described in a submitted ANDA. Approximately 96% of the batch volume was inoculated into two sterility test media. The sterility test media was then incubated for 14 days. No observable growth was observed after the incubation period.

We hope these two studies offer guidance to manufacturers of PET drugs. At the same time, we recognize the need for further studies in the area of PET sterility testing.

About the Author

Eric Webster has worked in PET Drug manufacturing for more than 11 years. He has had varying areas of expertise including cyclotron engineer and process development engineer. Eric's current role is Biomarker Development Manager for PETNET Solutions which oversees process development, validation and microbiological monitoring and trending.

In Print continued from page 23

be consistent with the washer speed, or if the belt speed is to remain constant, the width of the load must be varied.

In tunnels, exposure time is controlled by belt speed and setpoint temperature. The temperature of the glass is affected by exposure temperature, airflow, and the mass of glassware. Exposure temperature is maintained by a feedback control loop which controls temperature at a relatively constant steady state, but may vary as the load conditions change. For example, at start-up when glass first enters the tunnel, the introduction of cold containers may cause the tunnel temperature to drop. The severity of the drop is dependent on the response characteristics of the control system. Airflow should be regulated and relatively constant so not to impact temperature.

The relationship between the washing speed, drying/heating/cooling zone belt speed, and the filling speed should be established. The conveyor belt should be loaded in a uniform manner to provide reproducible thermal conditions within the heating zones. Irregular gaps in the components will produce non-standard but typically more effective thermal conditions. These situations may occur in production operation and are of no consequence; however they should be avoided during qualification studies. The process must provide components from the cooling zone into the aseptic area at a suitable temperature for filling.

Loads should be introduced into the heating zone in a manner representative of actual manufacturing.

Change is the Only Constant for Microbiologists

Renee Blosser, U.S. FDA, and Program Committee Member

PDA 8th Annual Global Conference on Pharmaceutical Microbiology • Bethesda, Md. • Oct. 21–25 • www.pda.org/microbiology2013

PDA's *8th Annual Global Conference on Pharmaceutical Microbiology* is fast approaching. This 3-day conference provides networking opportunities for microbiologists working in industry and regulatory.

The theme of this year's conference is *Staying Ahead of the Curve: Proactive Pharmaceutical Microbiology.* The landscape of microbiology is ever changing, and as microbiologists, our mission is to proactively adapt to that change. This year's conference features two keynote speakers who will discuss current and exciting endeavors in microbiology. **Karen Nelson,** PhD, President, J. Craig Venter Institute, will provide an update on the Human Microbiome Project. She will discuss the current initiative of identifying and characterizing the microorganisms that are found in both healthy and diseased humans. **Ian Critchley,** PhD, VP, Cerexa, will discuss his company's experience developing a new antimicrobial drug to combat the continually evolving challenge of antimicrobial resistance.

The third day will include a variety of presentations from the U.S. FDA, including a an "Ask the Regulators" panel discussion. As always, refreshment breaks provide a relaxed environment for networking and discussions surrounding the day's presentations. We look forward to seeing you in October!

Four courses will be offered after the conference by PDA's Training and Research Institute. The first course, "Investigating Microbial Data Deviations," will be held on Oct. 24.

The second course, "Microbiological Quality of Raw Materials and Components," also offered on Oct. 24,will delve into the renewed issue of microbial contamination of raw materials/components.

The third course, "Evaluation, Validation and Implementation of Alternative and Rapid MicrobiologicalTesting Methods" will be held Oct. 24–25. This course will provide attendees with an overview of the revised *PDA Technical Report No. 33.*

The fourth course, "Microbiological Risk Assessment of a Pharmaceutical Manufacturing Process" will be held on Oct. 25.

To learn more these courses, visit www.pda.org/microcourses2013.

Save the Date for the *2014 PDA Annual Meeting*

Ursula Busse, PhD, Novartis, and Jose Goin, PhD, Genentech

On behalf of the program planning committee, we would like to extend a warm invitation to the *2014 PDA Annual Meeting,* scheduled for next April at the J.W. Marriot in San Antonio, Texas.

The theme for the meeting is "Biopharmaceutical and Sterile Pharmaceutical Manufacturing – Embracing Innovation to Meet Global Challenges."

Manufacturing technologies are changing rapidly in response to new regulations, requirements and capabilities. The industry is changing at a fast pace by adapting these technologies as it evolves in the global economy.

The three main tracks of the meeting ("Biological Sciences," "Product Manufacturing" and "Quality Systems") will address many of the current challenges our industry faces. The planning committee has also designed a program with concurrent sessions that offer the perfect blend of industry updates, educational topics and technical advances. We will hear from experts in supply chain, environmental controls, new therapies, personalized medicines and biosimilars, along with many other important topics.

The conference will also include plenary talks on the future of manufacturing in our industry and global access of medicines to patients.

2014 PDA Annual Meeting • San Antonio, Texas • April 7–9 • www.pdaannualmeeting.org

Please be sure and mark your calendar now so you don't miss this unique opportunity. We look forward to seeing you in San Antonio next April. As the committee finalizes the details, please check www.pdaannualmeeting.org for updates.

PDA's Training and Research Institute (TRI) will be offering multiple courses, covering topics such as quality risk management, process validation, combination products, parametric release, biosimilars and more.

PDA to Explore Quality Metrics at December Conference

Program Planning Committee Co-Chair Steve Mendivil, Amgen

For a number of years pharmaceutical companies have been utilizing metrics and scorecards to help drive quality and business improvements with varying degrees of success. The *2013 PDA Pharmaceutical Quality Metrics Conference* will be an opportunity to hear from companies that have successfully implemented quality metrics and then discuss and share successful implementation tips.

PDA, with the U.S. FDA, is excited to add a regulatory perspective to this conference as part of an ongoing initiative to broaden the discussion about potential regulatory aspects of quality metrics.

The enactment of the Food and Drug Administration Safety and Innovation Act (FDASIA) last year also has potential implications for quality metrics. New FDA authorities under FDASIA include conducting risk-based inspections as well as the ability to collect records "in advance or in lieu of inspection."

FDA is assessing whether quality metrics might be helpful as an input into their Inspectional Risk-Based Model to determine both frequency of inspections and possible opportunities to reduce postapproval change reporting requirements. If there is value, the Agency may propose certain metrics be submitted.

FDA speakers will present their latest thinking on what they hope to achieve from quality metrics and will join in the dialogue in various breakout sessions. This is an opportunity for PDA members to help shape potential regulatory requirements for the future.

Come join us for timely and informative sessions as well as a TRI course on quality metrics this December.

2013 PDA Pharmaceutical Quality Metrics Conference • Bethesda, Md. • Dec. 9–10 • www.pda.org/metrics2013

The PDA Training and Research Institute will be offering courses in conjunction with this conference. Please go to www.pda.org/courses for updates.

Check Out New Viral Detection Technology this Fall

Mark Plavsic, Genzyme Corporation, and Program Committee Member

PDA has been very active in the area of advancing technology for virus detection and virus clearance as well as educating members regarding the regulatory approaches and technical issues surrounding viral safety. Examples include *Technical Report No. 41: (Revised 2008) Viral Filtration* and *Technical Report No. 47: Preparation of Virus Spikes Used for Virus Clearance Studies.* These technical reports not only educate readers regarding these highly complex topics but they also define best practices. In addition, PDA conferences bring together experts and opinion leaders to present and discuss technologies and their impact on drug development. In 2011, the *PDA/FDA Adventitious Agents and Novel Cell Substrates* conference initiated discussions on using emerging advanced technologies for virus detection. This year, the *PDA/FDA Advanced Technologies for Virus Detection in the Evaluation of Biologicals Conference* will offer attendees the chance to discuss the use of novel virus detection technologies in biopharmaceutical applications, focusing on nucleic acid based methods such as next generation sequencing (deep sequencing, massively parallel sequencing, etc.).

The conference will commence with both regulatory and industry perspectives on currently used virus detection methods and the opportunity of using the advanced molecular methods for adventitious agent detection. These introductory talks will be followed by data-driven presentations on approaches taken by firsthand users to address some of the critical issues related to sample processing, virus standards and performance evaluation.

The second day will focus on bioinformatics, which is critical for the analysis of massively parallel sequencing data. Presentations will focus on data analysis pipelines and considerations for development of curated databases. In addition, a progress report of the efforts of a group comprised of industry and regulatory agency representatives to identify and address some of the critical gaps for using the new technologies will be presented.

The conference will end with an interactive panel of renowned experts from industry and regulatory agencies. The experts will discuss and take questions from the audience on approaches to address some of the critical issues related to sample processing and bioinformatics.

PDA/FDA Advanced Technologies for Virus Detection in the Evaluation of Biologicals Conference • Bethesda, Md. • Nov. 12–14 • www.pda.org/virusdetection2013

By attending this conference you will gain knowledge from industry and regulatory agencies, specifically related to:

- the potential applications of new methods in overall biosafety testing strategies
- how advanced virus detection technologies might complement and further enhance current testing methods
- the challenges in designing, evaluating, validating and implementing advanced technologies for virus detection in biologicals

On behalf of the program planning committee, we look forward seeing you this November!

Prior to the conference, PDA's Training and Research Institute (TRI) will be hosting two one-day courses on Nov. 12 to complement your learning at the conference. One course will cover virus contamination in biomanufacutring and the other will focus on advanced molecular methods for virus detection. To learn more about these courses, please visit www.pda.org/viralcourses2013.

TRI Offers Menu of Aseptic Processing Course Options

James Wamsley, PDA

PDA's Training and Research Institute (TRI) has responded to its audience and greatly expanded its course offerings related to aseptic processing. While our success has made us highly recognized as the place for aseptic processing training, our offerings on the topic were limited. Therefore, we have expanded our offerings in this subject area to give our constituents more opportunities for high-quality aseptic processing training.

We have now developed a curriculum featuring more than ten courses, either specifically focused on aseptic processing manufacturing or directly related. PDA offers these courses as classroom lectures in conjunction with our conferences, or as hands-on laboratory courses at our unique training facility in Bethesda, Md.

For those of you in the industry involved in the production of sterile products through aseptic processing, but don't need to cover all aspects, we have several courses to enhance your knowledge in specific subject areas. These courses will provide a greater understanding of how you fit into the larger picture, while also giving you the knowledge to do your job better and advance your career.

There is still an opportunity to register for these courses in 2013:

- "Fundamentals of Cleaning and Disinfectant Programs for Aseptic Manufacturing Facilities" (Oct. 1–2, Bethesda, Md.)
- "Single-Use Systems for Manufacturing of Parenteral Products" (Oct. 23–24, Bethesda, Md.)
- "Filters and Filtration in the Biopharmaceutical Industry - Basics Course" (Oct. 28–29, Bethesda, Md.)
- "Filters and Filtration in the Biopharmaceutical Industry - Advanced Course" (Oct. 30–Nov. 1, Bethesda, Md.)

Courses have also been developed and tailored to individuals of all levels within the industry. There are now courses for individuals who have just started in the industry, who have just started within the field of aseptic processing and for people with several years of experience who are now in senior management roles.

No matter where you are in your career, you can benefit from one of these courses this year:

- "GMPs for Manufacturers of Sterile and/or Biotechnology Products" (Sept. 19, Washington, D.C.)

- "2013 Aseptic Processing Training Program: Session 5" (Oct. 14–18 and Nov. 4–8, Bethesda, Md.)
- "Quality Systems for Aseptic Processing" (Nov. 18–22, Bethesda, Md.)
- "Aseptic Processing for Senior Management" (Dec. 4–6, Bethesda, Md.)
- "Fundamentals of Aseptic Processing: Session 2" (Dec. 16–20, Bethesda, Md.)

Earlier this year, we offered the lecture courses "Recommended Practices for Manual Aseptic Processing" and "Process Simulation Testing for Aseptically Filled Products" at the *2013 PDA Annual Meeting*. These courses are of special value to PDA members because they are based on our popular technical reports with the same titles. Be on the lookout for these courses at PDA conferences again in 2014! We are also working to develop a laboratory version of *Technical Report No. 62: Recommended Practices for Manual Aseptic Processes* that should debut in the first half of 2014.

PDA is continually working to provide you with the education you need to be successful. If you have benefited from a PDA course, or haven't found what you're looking for, we'd love to hear from you. Please contact us at TRI@pda.org.

Roadmap to External Manufacturing Partnerships continued from page 30

There are many reasons for discontinuation, including phasing out of product lines or changes in sponsor strategy to gain efficiencies to grow shareholder value. Whatever the reason, always be transparent with partners to maintain good relations.

The road to establishing and maintaining partnerships can be complex and often times overwhelming if it is not established with clear planning, aligned expectations, robust processes and a commitment to collaborative partnership management. **Benjamin Franklin** is quoted as saying, "By failing to prepare, you are preparing to fail." This certainly holds true in the outsourcing world.

Guiding Principles

Build realistic timelines and include risk analysis, along with phase appropriate planning as the process develops through clinical production into commercial—iterate and refine as needed. **Winston Churchill** captured this sentiment well, "Those who plan do better than those who do not plan even though they rarely stick to their plan."

Clearly define the mission of the partnership and establish an identity—emphasize the importance of each person's role and the end goal of serving the patient to enable them to get the treatment they need to lead better lives.

Establish partnerships with the intent to grow and develop over time, i.e., "invest" in the partnership.

Constantly reinforce the goal of providing medicines that are **safe,** of appropriate **quality** and in sufficient **supply** to meet the needs of the patient. Everyone plays a part!

[Editor's Note: For a list of recommended resources, please visit the online version of the article at www.pda.org/pdaletter.**]**

Figure 3: Execution of Closeout

Plan for Discontinuation	***Confirm Closeout***
• Change control	• All regulatory submissions amended
• Capital equipment recovery/write-off	• Capital equipment retrieved or written-off
• Plan for support of product in marketplace	• Material destroyed
• Regulator notifications	• Change control closed
• Cell bank destruction	• Contract terminated
• Drug material destruction	

About the Author

Paul Gauthier leads the technology transfer and clinical manufacturing group in Shire Pharmaceutical's rare disease business unit. He is responsible for the creation of business processes, search and establishment of external partnerships, technology transfer, clinical supply manufacturing, and leading process qualifications through to registration.

Steven Mendivil, Amgen

PDA Expanding Discourse With Global Regulators

PDA's Strategic Plan identifies four areas of focus: People, Science, Regulation and Business Management. My focus for a number of years has been on the "Regulation" part of the plan. PDA has developed a strong working relationship with the U.S. FDA, EMA and Japan's PMDA over the years. The *PDA/FDA Joint Regulatory Conference,* the *PDA/EMA Joint Regulatory Conference* and PDA Japan Chapter meetings have developed into premier conferences for presenting and discussing the latest trends and issues between industry and regulators. Part of the strategic plan is to develop strong working relationships with regulatory bodies in emerging markets.

PDA is making progress on a number of fronts. First, PDA's Regulatory Affairs Quality Advisory Board (RAQAB) has expanded its membership over the past few years, and now includes representatives from Brazil, Russia, China and South Korea in addition to representatives from the United States, European Union, Canada, Australia and Japan. These members keep the RAQAB up to date on developing requirements and trends in these emerging countries. This information is then shared with the membership through the *PDA Letter* and other forums. PDA is also expanding chapters beyond the United States, European Union, Australia and Japan to include South Korea, Taiwan and India with discussions underway in many emerging market countries.

PDA is a leader in developing a strong working partnership with PIC/S through PDA/PIC/S joint scientific workshops and trainings. Last year's workshop was viewed as a successful working model for future collaborations. We also jointly developed a PIC/S ICH Q7 training from industry and regulators. PIC/S stands for Pharmaceutical Inspection Co-operation Scheme, and has as its members various regulatory bodies from around the world with the goals of educating and alignment on GMP inspections. PIC/S currently has 43 different inspectorates that are official members and many more going through the "accession" process. PIC/S is an important organization to PDA as we look to understand and help align GMP requirements globally. As more countries develop their own GMPs and regulatory requirements, PIC/S is critical in understanding differences and similarities in requirements. While PIC/S has no legal status to change specific country requirements, it is important to accept the equivalence of GMPs, facilitate dialogue and understand the rationale behind different countries' requirements as the first steps toward global harmonization.

PDA is also targeting specific conferences in emerging markets in 2014 to facilitate the dialogue and understanding of country-specific requirements and how these fit into global requirements. PDA is using many different paths to understand and initiative the conversation on new regulatory requirements and interpretations as they develop around the world. In today's complex global environment, PDA is leading this effort on behalf of its members. Stay tuned for new chapters, conferences and workshops leading to stronger partnerships with various regulatory agencies around the world.

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Tell Us How We Are Doing!

We are in the middle of conducting the first of what will be a biannual readership survey for the *PDA Letter*. Since I joined PDA in 2003, we've worked very hard to turn the Letter into a true membership magazine for the members, with articles by the member. It all started in 2006 when we formed the first ever *PDA Letter* Editorial Committee (PLEC). Not only has this committee been very popular—growing from eight members to 16—we always receive an overwhelming response when opportunities to join arise. The PLEC does a fantastic job helping us identify topics for our features section, finding authors, contributing articles and vetting author submissions. In 2011, we moved the "People Department" to the front of the magazine to highlight the importance of our members.

Now, we are reaching out to all our readers for feedback on how we are doing. Moving forward, we want to make sure all the content in the Letter is appropriate, interesting, helpful and written to the level our members deserve. We also want to make sure members get the magazine in a format that is convenient to them.

We launched the survey in early August and have received a great response. The survey will be open through the end of September. I encourage everyone to participate!

www.surveymonkey.com/s/JBQWRF7

It is also that time of year to select your PDA volunteer leaders. The News and Notes section of this issue contains all the information you need for the 2013 PDA Officers and Directors election. Check it out and go online (www.pda.org) or find a voting booth at an upcoming PDA meeting to participate.

Finally, make sure you check out the *PDA Letter* Podcasts. The last one, posted in July, was "cGMPs Continue to Evolve as U.S. FDA Expands Regulatory Authorities Under FDASIA". In September, we are posting an interview with **Katja Kotter** of Vetter Pharma. An archive of all previous podcasts is also available.

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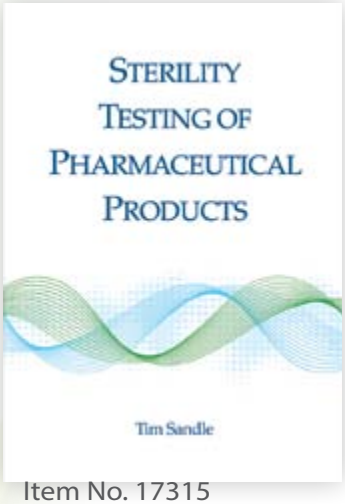

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Sterility Testing of Pharmaceutical Products

By Tim Sandle

Sterility is a hard factor to control, not least because of the ubiquity of microorganisms in the environment. Whilst pharmaceutical processes can be controlled and environments protected through the use of cleanrooms, contamination issues can arise. Examples could include a failed filter, a contaminated water supply, an incorrect cycle run on a sterilizer, and so forth.

In addition to these control failures comes the human factor for people are the primary sources of contamination within cleanrooms, representing the primary source of microbial carrying particles through the deposition of skin detritus into the air. People also need to touch objects, and poor hand or surface sanitization can also result in contamination transfer.

The central argument of the book is that control of the process and environmental control are considerably more important guarantors of sterility than the questionable comfort gained from a 'pass' result at the end of the incubation of a sterility test.

This book balances theoretical, and sometimes philosophical, discourses about the nature of sterility and the conceptual problems of microbial viability with sound practical guidance on how to validate the sterility test, problematic products as well as solutions on how to control the environment and review manufacturing process parameters, while navigating the regulatory minefield.

The aim of the book is to present the sterility test as a final product release test as seen in the past, the present and with a view towards the future and is aimed at quality assurance personnel, production staff, microbiologists, students and those with an interest in medicinal products.

www.pda.org/steriletest

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