Science • Technology • Quality • Regulatory • Community

PDA Letter

Volume XLV • Issue #9

www.pda.org/pdaletter

October 2009

In This Issue:

PDA℠ Parenteral Drug Association

Connecting People, Science and Regulation®

Long-Time Member & Volunteer, Richard Johnson, is PDA's New President

On September 8, 2009, **Richard Johnson** assumed the role of PDA's President.

"We are extremely pleased to announce that Richard M. Johnson will serve as president of PDA. On behalf of the PDA community, we welcome him and look forward to working together to assure the Association grows in its mission to develop scientifically sound, practical technical information and resources to advance science for the pharmaceutical and biopharmaceutical industries," said **John Shabushnig,** Chair of the Board of PDA.

"It is an honor to be appointed President of the Parenteral Drug Association. I have been active with PDA for many years, and know first-hand the value that the organization has brought me in terms of technical information, networking and opportunities to participate in the advancement of pharmaceutical technologies. PDA has been my primary resource for remaining current with new technologies and regulations. I am committed to ensuring that PDA maintains the high quality of information, resources and services it provides both to its current members and to new participants from the global PDA community," said Johnson.

Richard has over 30 years of experience in pharmaceuticals and medical devices in global operations, working for Abbott Laboratories, Fort Dodge Animal Health, Alcon Laboratories and most recently as a consultant. During these assignments, he had responsibilities for the start-up and compliance of the manufacture of sterile products, active pharmaceutical ingredients and solid, liquid and vaccine products in the United States, Europe, Latin America and Asia. Since 2006, he has provided consulting services globally. Richard holds both an MS and BS in Biological Sciences from Marshall University.

Richard is an active member in PDA, serving at various time on the Scientific Advisory Board, the Regulatory Affairs & Quality Committee, the Aseptic Processing, GMP and Glass Defects Task Forces and the Sterile Processing and Ophthalmic Interest Groups. He also has been active in PDA conferences and has published commentary articles in the *PDA Journal of Pharmaceutical Science and Technology.* In addition to his PDA activities, Richard has served as co-chair of the U.S. Sub-TAG to ISO/TC 198 (Aseptic Processing) and served on the Product Quality Research Institute (PQRI) Aseptic Processing Task Force.

He was a key leader in PDA's effort to work with the U.S. FDA to develop a revised

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These sponsorship and exhibiting packages are marketing opportunities you can't afford to miss!

The Parenteral Drug Association (PDA) presents Sponsorship Opportunities at the

2010 PDA Annual Meeting

MANUFACTURING EXCELLENCE

March 15-19, 2010
Gaylord Palms Resort and Convention Center
Orlando, Florida
www.pda.org/annual2010

Reach your target audience. Drive your company's success. Gain on-site exposure in front of government regulatory experts and highly-qualified, upper-level professionals with purchasing power in the pharmaceutical and biopharmaceutical industry. Thousands attend PDA events to stay abreast of new regulations, trends, technologies and more.

Connect and make new contacts with representatives from government agencies and industry professionals. Let this event help you improve your business performance, products, knowledge and sales. Use the valuable contacts gained at this meeting to gather new leads and gain key sources of information and support.

Potential clients attend the *2010 PDA Annual Meeting* to:

- Get updates on new trends and regulatory initiatives
- Network with experts in the bio/pharmaceutical industry
- Gather facts on innovative products and services

The *2010 PDA Annual Meeting* offers you numerous exciting sponsorship opportunities, including an exhibitor raffle drawing, refreshment breaks, long exhibit hours and more to showcase your company's talents and products.

Sponsorship opportunities include:

- Fun Run/Walk
- 4th Annual PDA Golf Tournament
- Opening Night Reception
- ~~Hotel Keys~~ *SOLD*
- Tote Bags
- ~~Memory Sticks~~ *SOLD*
- And more!

To learn more, please visit **www.pda.org/annual2010** or contact Nahid Kiani at (301) 656-5900 ext. 128 or at kiani@pda.org.

PDA™
Parenteral Drug Association

THE PDA TRAINING AND RESEARCH INSTITUTE (PDA TRI)

NOVEMBER TRAINING SCHEDULE

Contamination Control
2-5, 2009 | PDA's Training Facility | Bethesda, Maryland
This course is intended to give you a complete understanding of what is involved in developing a complete contamination control program. Topics covered will include control of components entering controlled areas, environmental monitoring (both viable and non-viable), personnel monitoring, gowning, cleaning and disinfection validation, testing and system implementation.

Selection and Implementation of Advanced Aseptic Processing Technologies
16-17, 2009 | Caribe Hilton San Juan | San Juan, Puerto Rico
This course will focus on advanced aseptic processing technologies. Isolator and RABS Design and Engineering, including design issues, background room classification, materials transfer and air systems will be discussed.

Application of Disposables in Biopharmaceutics
18-19, 2009 | PDA's Training Facility | Bethesda, Maryland
This course combines lecture and hands-on training in handling disposable components for biopharmaceutical processes. Following the route of generic manufacturing chains, participants will learn how individual unit operations are introduced for implementation of disposable or single-use alternatives.

San Francisco Course Series!
2-4, 2009

The PDA Training and Research Institute is coming to San Francisco this November! Nine courses taught by our expert instructors will be offered over this two-day curriculum.

2, 2009 **- cGMP Manufacturing of Human Cell-Based Therapeutic Products**
This course presentation will focus on cGMP requirements for cell-based therapeutic products, including manufacturing, documentation, process development and sourcing of human cells and tissue.

2, 2009 **- Effective Investigations and Corrective Actions** *New Course*
This course evaluates the current GMP requirement to investigate failure and looks at how companies' current methods of performing investigations are and are not meeting the regulatory requirements and improving operations.

2-3, 2009 **- Role of the Quality Professional in the 21st Century**
This course will not only describe the role of quality professionals, its importance and relationship to other groups in the company, but also provide opportunities to learn and practice the skills needed in small groups.

3, 2009 **- Quality Control and Quality Assurance of Cell-Based Therapeutic Products**
This course presentation will focus on cGMP requirements for cell-based therapeutic products, including manufacturing, documentation, process development and sourcing of human cells and tissue.

3, 2009 **- Global Harmonized Drug GMPs – Closer Than You Think** *New Course*
This course reviews current international development in the harmonization of GMPs and of GMP inspections, and where they are likely headed in the next 5-10 years.

3-4, 2009 **- Design Control**
Participants will be introduced to the applicable design control concepts such as those found in ISO 9001:2000 Quality Management System Requirements, ISO 13485 Quality Management Systems – Medical Devices – Requirements and the US Food and Drug Administration's Quality System Requirements (QSR).

4, 2009 **- Clean Room Design, Contamination Control and Environmental Monitoring for Controlled Environments** *New Course*
This lecture will provide the attendees with a comprehensive understanding of clean room design.

4, 2009 **- Biopharmaceutical ICH Q10 for Senior Management**
This course will help senior management to develop a cost-effective, risk-managed Q10 strategy for moving their biotech products through clinical development and into market approval.

4, 2009 **- GMPs for Manufacturers of Sterile and/or Biotechnology Products** *New Course*
This course is designed as an intermediate level course for supervisors and managers who need to understand the theoretical and practical background for the successful manufacture of sterile pharmaceutical and biotechnology products.

Learn from top industry experts in PDA's state-of-the-art training facility that resembles an actual manufacturing site, or catch us on the road hosting a PDA TRI course series!

To register for any of these training courses please visit www.pdatraining.org.

www.pdatraining.org

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Cover art:

This issue, we carry over artwork we developed for the announcement that Bob Myers was retiring and the search for a new president was on. We use it again here to symbolize the end of the search.

Coming Next Issue:

Hot topics from the PDA/FDA and PDA/EMEA Conferences

PDA Training and Research Institute
EDUCATION • TRAINING • APPLIED RESEARCH

SAN FRANCISCO COURSE SERIES

November 2-4, 2009

Solidify your Career and Improve Performance with Pharmaceutical and Biopharmaceutical Training Straight from Industry Experts!

- Effective Investigations and Corrective Actions – *New Course!*
- cGMP Manufacturing of Human Cell-Based Therapeutic Products
- Role of the Quality Professional in the 21st Century – *New Course!*
- Global Harmonized Drug GMPs – closer than you think – *New Course!*
- Quality Control and Quality Assurance of Cell-Based Therapeutic Products
- Design Control
- FDA cGMPs for Manufacturers of Sterile and/or Biotechnology Products – *New Course!*
- Biopharmaceutical ICH Q10 for Senior Management
- Clean Room Design, Contamination Control, and Environmental Monitoring for Controlled Environments – *New Course!*

www.pdatraining.org/sanfrancisco

PDA Parenteral Drug Association
Connecting People, Science and Regulation®

2009 PDA Workshop on

Validation of Aseptic Processes

This workshop is designed to give an overview on the most critical aspects when planning and performing any Validation of an Aseptic Process. It will include sessions on industry best practices developed with knowledge of FDA and EU regulations, representing solid approaches to validation studies. Benchmark your practices with experts present and bring home tools and actual experience to apply immediately to your job. Attend this workshop and understand the current practice and future direction when validating aseptic processes. Presentations will cover topics such as facility design, filtration, microbiological process control,media fill studies, regulatory requirements, and much more.

1-2 December 2009
Milan, Italy
Workshop

See the complete program at:
www.pda.org/europe

Register by 16 Oct 2009 and SAVE!

SAVE THE DATE FOR THE

2010 PDA/FDA Joint Regulatory Conference

September 13-15, 2010 | Renaissance Hotel | Washington, D.C.

The date is set and the planning is well underway for the ***2010 PDA/FDA Joint Regulatory Conference***. To get you ready we have set up an "Advanced Notification System." This notification system is quick and easy. Just visit http://tiny.cc/kFDxx, give us some basic information and we will send you a quick e-mail letting you know when the 2010 agenda is posted and the conference website is open.

Year after year, your colleagues at FDA provide updates on the current state of affairs impacting the development of global regulatory strategies, while industry professionals from today's leading pharmaceutical companies present case studies on how they employ global strategies in their daily processes.

Immediately following the conference, the PDA Training and Research (PDA TRI) will host a course series.

Here are the courses that we have confirmed for 2010:

- A Former FDA Investigator's Perspective on Conducting Effective Deviation Investigations, Root Cause Investigations, Corrective and Preventive Actions (CAPA) – *new course!*
  Instructor: **Jeff Yuen**, President and CEO, *Jeff Yuen & Associates Inc.*
- Establishing and Operating and Effective GMP Auditing Program
  Instructor: **Robert Dana,** Sr. Vice President of Regulatory Affairs and Training Research Institute, *PDA*
- Essentials of US and EU GMPs for Manufacturers of Active Pharmaceutical Ingredients
  Instructor: **Michael Anisfeld,** President, *Globepharm Consulting Inc.*
- Making the Grade with the FDA
  Instructor: **Barbara van der Schalie**, Clinical Training Manager, *SAIC-Frederick, Inc.*
- The Quality System: Design, Implementation, Evaluation and Management of Processes
  Instructor: **Robert Kieffer,** *RGK Consulting*

So, we are getting ready and we hope that you are as well. Again, visit **http://tiny.cc/kFDxx** to receive an Advanced Notification on *the* premiere event of 2010!

If you have any questions we would like to hear from you.

PLEASE CONTACT:

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E-mail: neal@pda.org

Editor's Message

An issue dedicated to PDA

The *PDA Letter* staff has been dedicated to presenting a hot topic on the cover of each issue ever since we redesigned the publication in 2004. But, due to the significant news PDA has had over the last several months, we've had no choice but to use two of the last three covers for major PDA announcements. You might remember that the July/August cover was dedicated to news about the 63-year-old PDA Journal. This month, nothing can be more important than the announcement of a new executive, and that is exactly what we dedicate the cover to. We are sure the membership will read with great interest about new PDA President **Richard Johnson,** and the selection process that unfolded this year.

The cover story doesn't end the space dedicated to PDA this issue. Inside, we have an expanded "News and Notes" section with messages from PDA Chair **John Shabushnig,** new President **Richard Johnson** and a farewell by **Bob Myers.** I hope readers take the time to read each of the messages, which have been carefully crafted and well-delivered. Also, we correct a serious omission—the hiring of new CFO Craig Elliott last June. I don't know how we forgot about Craig the last two issues, but the News and Notes article we have on him this month hopefully makes up for the error.

The Science and Technology Snapshot includes an Advisory Board Watch, which continues to track the efforts of PDA's advisory boards to align the activities, never more important than in the current period of financial strain facing our members and the Association itself.

All of this is not to say that this issue does not have pertinent and interesting non-PDA news in it. The feature article is our first report from the recently completed **2009 PDA/FDA Joint Regulatory Conference.** The article highlights key points made about avoiding or preventing glass breakage and defects during a session sponsored by the Prefilled Syringes Interest Group. Look for expanded coverage of that meeting and the upcoming **PDA/EMEA conference** in the November/December issue.

The regulatory briefs page isn't so brief this month as the U.S. FDA was particularly active in August and September. Another highlight of this issue is an article on the systems approach for designing a training process and implementing training requirements in the "TRI • Education" section.

Finally, **tell us what you think** of the Letter. Email me at morris@pda.org. We love getting feedback from readers and will even publish your note in an upcoming issue.

PDA Letter

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CHAIR'S MESSAGE

New Journal, President and Initiative

John G. Shabushnig, PhD

[Editor's Note: ***The following are John Shabushnig's opening remarks at the 2009 PDA/FDA Joint Regulatory Conference.*****]**

I am pleased to welcome you to the *2009 PDA/FDA Joint Regulatory Conference.* It is really great to see so many friends and colleagues, old faces as well as many new faces. This is always a great conference to meet and talk with people whom I haven't seen for some time. Again, it is wonderful to be here; it is wonderful to see you here.

I would like to give my thanks and the thanks of the PDA Board of Directors to the program committee and the staff for organizing this meeting. Looking through the agenda; I think it is an excellent one. We have some great speakers here, and I am personally very interested in the topics that will be discussed.

I want to take just a minute to touch on a couple of topics. The first one is the PCMO project, which is the Paradigm Change in Manufacturing Operations. Some of you may be familiar with this particular project. I want to quickly talk about the objective, which is to use the expertise within our membership to drive the establishment of best practice and/or training events to aid pharmaceutical manufacturers. I underline manufacturers because it is focused on manufacturing, either at the investigational or the commercial stage. Again, my emphasis is on implementation, because the key here is to take these best practices through implementation. The theory is interesting, but until it is implemented, we all don't see the value, we being manufacturers and our customers. So we really want to focus on that implementation phase for ICH Q8, Q9, Q10—the Q trio.

Looking at the product life cycle, and I think many of you have seen this before, the PCMO is not the gears that you see here, not even the oil that is being applied to the gears, but I see it as a framework and an area in which PDA can help keep those gears tightly engaged so that this machine runs smoothly. I think PDA has a lot to offer in that area, and I hope you agree, because we are also going to ask for your help. If you'd like to learn more about PCMO, please visit the PDA booth, there is a PCMO booth here at this meeting, or you can go to the PDA website—there is a specific PCMO section within the PDA website **[www.pda.org/pcmo].** Or if you'd like to write and get more information, there is a specific email for the PCMO **(pcmo@pda.org).** I would encourage you to learn and also to volunteer, because I think in the long run, it will help all of us as an industry and ultimately the patients that we serve.

If you have not looked at the new e-Journal site, I would encourage you to visit. Earlier this year, we converted to an e-Journal simply by providing links to PDF versions of the Journal, but we now have gone to a full interactive website for the PDA Journal. This is a wonderful website. Not only is it easy to navigate through the current journal to look for articles, you can download electronic copies, making it easy to take with you. I think we all spend enough time on airplanes or other transportation—it is very convenient to have this electronic alternative rather than big stacks of paper. Now you also have access to not only the current year of the Journal, but past years, through a searchable database. So you have a great reference—a reference that I use quite frequently and I find very helpful. Again, I would encourage you to take advantage of this new member benefit.

I want to thank our sponsors. First, our Gold Sponsors, bioMerieux and Sparta Systems and our Bronze Sponsor, ValSource. Without our sponsors, it would be very difficult to put on meetings like this. I also want to thank our Passport Sponsors and our media and advertising sponsors. We appreciate the support of all of our sponsors.

This has been a very exciting year. As many of you know, **Bob Myers,** our past president, retired this year. Bob's many contributions to PDA, both his long volunteer service and his time as president of the association will be celebrated later during this conference. ➤

His retirement prompted a search for our next president, and the list that you see shows our search committee. I want to thank the members of the search committee for their hard work this year in identifying our next president. We went through a very extensive process of vetting those people who had submitted resumes who had expressed an interest in the position of president, and I was encouraged by the breadth and depth of expertise of candidates both within our association and from outside. After a thorough search and many hours of interviews, I am pleased to announce that we have selected **Richard Johnson** to be our next president. I have known Richard for many years. He has been a volunteer within the PDA for many years. I think he brings a wide range of experience to PDA, and I am very much looking forward to working with Richard as the new president of PDA. It is truly my pleasure to introduce Richard to you, and I would encourage you to take the opportunity to meet and get to know Richard better. I know he is interested in your thoughts and opinions about PDA.

PDA President Search Committee

The following PDA volunteers served on the committee to find PDA's new president.

John Shabushnig, Pfizer
Rebecca Devine, Consultant
Maik Jornitz, Sartorius Stedim Biotech
Tim Marten, retired
Nikki Mehringer, Eli Lilly and Company
Bob Myers, retired
Martin VanTrieste, Amgen
Anders Vinther, Genentech

PDA Thanks All of the 2009 PDA/FDA Sponsors

Gold: Sparta Systems • **Bronze:** Valsource

Passport: American Stelmi Corporation; bioMerieux; Bioscience International, Inc.; Commissioning Agent, Inc.; Mass & Peither AG GMP-Publishing; Regulatory Compliance Associates, Inc.; Working Words

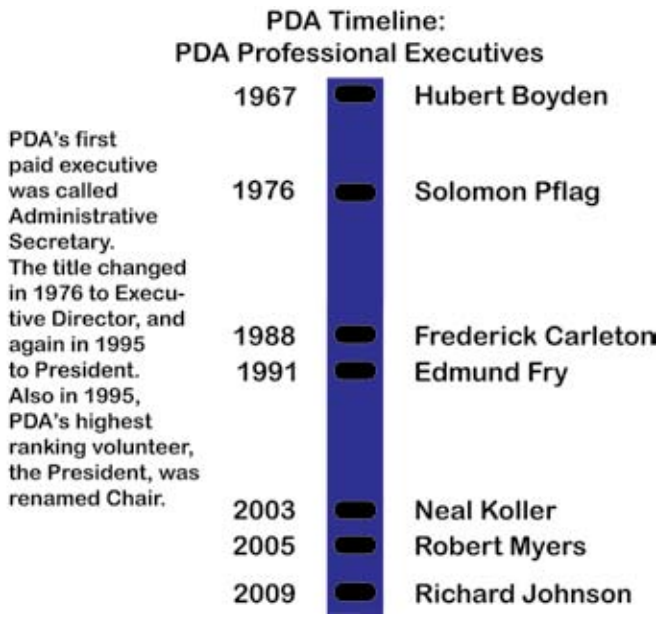
Media: Bioprocess International; Pharmaceutical Technology

Long-Time Member & Volunteer, Richard Johnson, is PDA's New President, continued from cover

guidance on aseptic processing of sterile pharmaceutical products earlier this decade. The result of PDA's efforts was the formation of a working group in the FDA-supported PQRI. This group produced a number of recommendations to the FDA, many of which were ultimately incorporated into the final guidance published in 2004.

"PDA is a primary source of technical and quality guidance for the pharmaceutical industry, and has the deserved reputation for representation of the industry in discussion of the key regulatory issues. As President, I will work to ensure that PDA continues this legacy of development of technical guidance and advocacy of science-based regulation. We also must deal with a global environment where international understanding must be achieved, different perspectives must be recognized and common goals must be advanced. PDA must offer members access to current issues and the opportunity to actively participate in the development of policy, and I would work to make the organization responsive to these needs."

The search for a new president began when former President **Robert Myers** announced his intention to retire in late 2008. PDA created a presidential search committee, comprised of members of the Board of Directors and Association members-at-large, to conduct the search process. There was a strong response to the call for applications made in early 2009, with candidates for the position interviewed, first by phone and then in person by the search committee and senior members of the Association's staff. Based on the feedback from these interviews, the Board of Directors unanimously endorsed Richard to be the next president.



PRESIDENT'S MESSAGE

Greetings to PDA and Delegates at PDA/FDA

Richard M. Johnson

[Editor's Note: ***The following are Richard Johnson's opening remarks at the 2009 PDA/FDA Joint Regulatory Conference, just one week after he started as PDA's President. Next month, Richard will outline some of his goals as PDA's new President.***]

Thank you John. It has been an interesting week. It is definitely an honor to be able to stand here before you as a representative of this outstanding organization. For many years, I have been proud to serve as a member of PDA. I have been an active participant, and through some of those activities, I have gotten to know many of you.

For those of you that I haven't had the opportunity to meet, I would encourage you to please stop me in the hallway, or look for me on the PDA website and send me an email or call me.

It is also very humbling to be here as president. There is quite a tradition in PDA, and certainly I feel very strongly that it is my role to continue that proud tradition. Since that announcement went out, I have received best wishes from many of you and thank you very much. With your support I look forward to continuing to work with you in the future.

I am very excited about the challenges that we face as an Association going forward, and I am committed to continuing the tradition of PDA.

The challenges that we face are quite many, just like many of your organizations, but our commitment to our mission is equally clear. And so we will be continuing to live up to that mission as we go forward. With your support and participation, we are going to continue "Connecting People, Science and Regulation."

So with that, I just want to say, thank you.

Craig Elliott Joins PDA as CFO

No stranger to the pharmaceutical industry or PDA, **Craig Elliott** joined PDA as Chief Finance Officer.

Craig first became a part of PDA when he worked for Genentech in 2007 after he was asked by Past-Chair **Vince Anicetti** to be on the Auditing Committee, of which he later became the chair.

Before he came to PDA, Craig held a myriad of jobs that embraced his financial and scientific background. After obtaining a BS in Microbiology and Chemistry, Craig started his career at a Merck manufacturing plant in Elkton, Virginia. Besides holding various positions with Merck in microbiology, analytical chemistry and quality assurance, Craig earned his MBA from James Madison University. The pursuit of his MBA reflected his passion for business. "From the time I was old enough to ride a bike, I was venturing into little businesses. I delivered papers, provided lawn service, and even sold Christmas cards and wrapping paper."

Craig started his finance career at Covance Laboratories in Vienna Virginia, where he eventually assumed responsibility as the Sr. Manager of Covance's Genetic Toxicology business unit. Next, he moved to Genentech in San Francisco, California, where he ultimately landed in the Corporate Financial Planning and Analysis group.

At PDA, Craig plans to work with new President **Richard Johnson** and the Board of Directors to make sure that the Association is financially stable and has the resources and reserves needed to not only survive the economic recession, but to emerge from it stronger and better positioned than ever before. Craig said that it was imperative that PDA's financial foundation is strong and secure to enable a continued and enhanced value to members in the years to come. He said that he also looks forward to continued growth from PDA Europe. "2009 is PDA Europe's second full year in operation and I am looking forward to another great year."

BOB'S FAREWELL

Thanks for Your Support

[Editor's Note: ***At the 2009 PDA/FDA Joint Regulatory Conference, Bob Myers was recognized for his many years of service to the Association, including the last four years as PDA President. He prepared these remarks following the meeting for the*** **PDA Letter.]**

Having just retired as President of the PDA, I wanted to offer some comments on our accomplishments and thank all those who have made the past four years among the most rewarding of my life.

PDA is a great organization, and I truly believe that our byline "Connecting People, Science and Regulation" is truly inspirational. I think that we have fulfilled the spirit of our mission and have at the same time increased our prestige and scientific credibility in the global pharmaceutical and regulatory community. We have developed many new consensus scientific documents in conjunction with global regulators and manufacturers. We have established new forums for idea exchange in Europe and Asia and have strengthened our programs in the United States. We have created a unique, world-class sterile product training facility (TRI) which serves the training needs of both the industry and the regulatory inspectors. As PDA continues to grow and thrive, I am sure that it will be involved in creating similar facilities around the world for training and research into applied sterilization science and new process systems. I consider these achievements to be among the most important of my now 35 plus year career in the pharmaceutical and biopharmaceutical business.

I want to thank all of the PDA members and partners for their support in creating the successes we have accomplished over the last four years. The PDA staff is truly professional and is fully dedicated to the success of every PDA program and PDA publication. Our 11,000 members and scientists are the best subject matter experts in the world and are the key to our success in the creation and publication of consensus scientific standards. Our regulatory partners are working with us to help communicate their objectives to the global industry in a constructive way. Lastly, PDA's efforts could not be achieved without the help of the many sponsors and exhibitors who support the work we do. The organization is strong as a result of our combined leadership, experience and hard work, and I am satisfied to be leaving PDA knowing that the organization is held in high esteem globally.

One of the strongest parts of the organization is the volunteer members who devote so much time in the guidance, planning and execution of the PDA events and activities. Our volunteer Board of Directors is extremely hard working and dedicated, and our organization is in very good hands with their oversight. Their constant support has made my last four years very fulfilling and allowed me to focus on the priorities that we all agreed were in the best interest of the organization.

Finally, I would like wish **Richard Johnson** much success in his role as PDA's new President. I am sure he will receive the same level of support that I have received, and he knows our industry and the PDA very well. I know you will give your full support to him and the PDA staff in continuing to maintain this organization as the premier sterile science and regulatory organization in the world.

Again, thank you all for your support over the past four years.

Bob and wife Carol enjoy a view of the Colorado River during a recent trip to the Grand Canyon

Science & Technology *Snapshot*

ABs Look At Managing PDA Professional & Volunteer Resources at September Joint Strategy Meeting

Richard Levy, PhD, PDA

We live in challenging times, yet PDA's community of scientists, technicians, regulatory experts and regulators are busier than ever, as are the professional staff at PDA. The inexorable march towards new manufacturing, quality and regulatory paradigms has shined a brighter spotlight on our Association with the expectation that we will come together to help the industry find more cost effective pathways to the new paradigms

To be responsive to these contradictory trends, the leaders of PDA's major Advisory Boards began meeting in 2009 to ensure that the Association has a strategy for connecting all the dots and aligning each PDA product (technical reports, workshops and conferences, trainings, etc.) with the most important initiatives in which our members are involved.

Program Advisory Board Chair **John Geigert** used this space in the June 2009 *PDA Letter* to discuss the first joint-AB meeting last April, and I'm pleased to use this column to update you on the second joint-AB meeting, which occurred at the *2009 PDA/FDA Joint Regulatory Conference* in September.

At this meeting, each AB chair presented a brief overview of their group's activity, and it is clear from the discussions that PDA has entered a period in which its members are very active and productive. The conference, workshop and TRI training schedules for next year are loaded with events of primary importance to our members. Equally impressive was the number of technical report projects currently wending through the PDA peer-review process. During the meeting, we determined that 40 technical report projects are currently sanctioned by the Biotechnology, Science Advisory Boards and Regularly Affairs and Quality Committee (BioAB, SAB and RAQC respectively), and 20 more in the discussion phase. If it is our goal to publish them all within three years, the Association would need to develop and publish about 20 per year.

This realization prompted us to discuss the crux of the matter: How can PDA produce so much with current levels of volunteer and professional capital and continue to deliver quality products and value to the overall membership? And the answer was, it would be difficult. For one, a full plate of activity on all fronts makes it difficult to be responsive to changing developments. A hot new technical report project can get buried behind a number of existing projects in the publication queue, some of which might not be as critical as they were at inception. A regulatory action might spur the need for a workshop or conference, but a full calendar might prevent the Association from sponsoring it.

This challenging situation is forcing PDA to prioritize projects according to their importance to the overall membership and the prospect that the project will generate a return on investment so PDA can continue to serve its members in the future. The advisory board leaders came to the realization that they need to work together and manage the risk and reward—comparable to portfolio management—to vet all project proposals.

In the end, it was agreed that these joint-advisory board meetings have been effective in breaking down the barriers between the various volunteer groups so that there is a mutual understanding of PDA's current project commitments *and* resource constraints. In the end, the group agreed that a smaller committee will be formed to develop a portfolio management strategy to govern all of PDA's scientific, technical and regulatory activities in the future.

Overall, the two joint-AB meetings were very productive and helpful, and exemplify the care for and dedication to the Association that our members have. I look forward to the continuation of this dialogue.

Technical Report/White Paper *Watch*

In Production: Coming soon! PDA is preparing to publish a regulatory white paper entitled **"Using an Interactive Voice Response System or Interactive Web Response Technology to Manage Investigational Medicinal Product Retest Dates in lieu of Placing Retest Dates on Labels"**

In Board Review: *Following technical editing, TRs are reviewed by PDA's advisory boards. If/when approved, the PDA Board of Directors makes the final decision to publish or not publish the document as an official PDA TR.*

- **Last Mile: Guidance for Good Distribution Practices for Pharmaceutical Products to the End User**

Journal *Preview*

New Editor Govind Rao Introduces Himself to PDA

Volume 63, No. 5 (September/October) of the *PDA Journal of Pharmaceutical Science and Technology* is now available online. This issue represents new Editor Govind Rao's inaugural one. In outlining his vision of the Journal, he writes: "The PDA Journal is unique. We are here not just to present the best science at the business and regulatory interface, but also to serve our members current needs and anticipate future technologies that will impact all of us."

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New Inspection Techniques For Aseptic Processing

The following is excerpted from the chapter, "New Inspection Techniques For Aseptic Processing" by James Veale, Lighthouse Instruments. The chapter appears in the recently published PDA/DHI book, Practical Aseptic Processing: Fill and Finish, Volume I, *edited by Jack Lysfjord. References have been removed for this excerpt.*

Aseptic manufacturing processes have evolved over a long period of time and are capable of producing high quality parenteral products. Continued innovation in aseptic processing techniques will ensure that the quality and production yields of sterile products continue to improve over time. Contributing to our understanding and evolution of aseptic manufacturing processes are new advanced test and measurement technologies. In particular, nondestructive in-process analytical methods now exist that provide real-time data for monitoring and controlling aseptic manufacturing processes. These test and measurement technologies offer unprecedented insight into the various stages of aseptic processing showing where processes are under control and also where processes are at a greater risk for going out of control. This scientific knowledge is invaluable to those persons responsible for maintaining and improving manufacturing processes.

Aseptic manufacturing capacity is growing rapidly due to the growth in large molecule formulations. These biopharmaceuticals are for the most part liquid or lyophilized and require specialized technology and complicated processes for their manufacture. The growth in sterile products brings challenges as well as opportunities to the industry in terms of developing and implementing in-process monitoring and control strategies that minimize the risk of product defects.

The objective here is not to review all the available in-process analytical and inspection methods currently used in aseptic processing. It is to describe one relatively new inspection method in detail and discuss several important applications. The method is nondestructive headspace analysis and the applications relate to sterile fill and finish operations.

The ability to measure headspace gas composition and pressure rapidly and nondestructively allows manufacturers to monitor a number of quality parameters such as oxygen content, moisture content and container closure integrity (CCI) simultaneously. Historically these quality parameters were monitored off-line using multiple destructive technologies or in-line using technologies that suffer from limited dynamic range and high false reject rates. ➤

New nondestructive headspace inspection technologies are reducing the number of false rejects, allowing a larger percentage of product to be tested and reducing the amount of rework due to process upsets. These process improvements are increasing production yields and increasing our understanding of where risk exists in sterile manufacturing. Directly monitoring quality parameters of every manufactured sterile product before release to the market, as opposed to the current model of testing a statistically insignificant number of samples from a batch, will also improve our understanding of current manufacturing processes and lead to improvements in product quality.

In principle, in-process analytical methods should operate at speeds comparable with the manufacturing speed and perform measurements nondestructively. For example, oxygen sensitive sterile liquid pharmaceutical products are compounded and filled into vials and ampoules at rates of 10,000 containers per hour. This high speed presents a challenge to personnel responsible for assuring product quality. Off-line process monitoring of head-space oxygen occurs only at periodic intervals, typically 3–10 containers per hour, which can lead to significant production losses and potential customer complaints if process upsets occur between tests. The rationale for testing only 0.03–0.1% of manufactured product is that a validated process which runs continuously should have consistent performance. Workflow is, however, periodically interrupted as a result of jams, line speed variations and operator error. Process upsets increase the probability for manufacturing significant amounts of out-of-specification product.

Another example is moisture monitoring of freeze-dried product using Karl Fisher analysis. Typically 20–200 samples from batches of 20,000 are analyzed for residual moisture content. Again the rationale for testing <1% of manufactured product is that a validated process should produce uniform in-specification product. Data presented later in this chapter show that, even after extensive lyophilization cycle development, a significant number of vials in a batch could be out-of-specification for moisture content due to process defects (e.g., stopper seating and shelf position). A last example is leak detection of lyophilized product packaged under vacuum. The vast majority of lyophilized product packages are not tested in process for container closure integrity. The reasons are a lack of available in-process analytical methods and a generally held belief that once a package is developed and has shown CCI in laboratory tests then in-process testing is not needed. The increasing number of product recalls in recent years related to package integrity defects indicates that package defects often occur in-process and a need exists for new test and measurement technologies to understand where and why defects occur and to remove defective packages from fill and finish lines.

In general, new test and measurement technology will provide more detailed knowledge of aseptic processes and will help to locate where quality defects are occurring. This will in turn allow improvements to be made that minimize the amount of rework, reduce customer complaints and reduce the risk of recall.

This chapter aims to review the relevant regulatory guidance documents in the context of nondestructive headspace analysis, describe how the technology operates and provide examples of applications for oxygen, moisture and leak detection. It will hopefully be a working guide to help engineers, scientists and managers understand how nondestructive headspace gas analysis can contribute to a better understanding of sterile manufacturing processes, maintain consistently high quality and minimize the number of product defects.

Key points

Laser headspace inspection of sterile products and processes enables:

- Science-based understanding of sterile manufacturing processes and product defects
- Rapid test and measurement for process optimization and control
- Finished product inspection for guaranteeing product quality

Case Study

In the case study described here, two batches of freeze dried product were manufactured using two different lyophilization cycles. Each batch contained 1600–10 cc clear tubing vials (a total of 3200 lyophilized samples). At the end of secondary drying, each vial was stoppered under 800 mbar of nitrogen. The chamber was vented to atmosphere, and the vials were removed and crimped.

Results

The headspace moisture in all samples from each batch were measured using the laser absorption method described in the section on "Moisture Performance Data and Method Validation." Results of the headspace moisture analysis of product manufactured using the initial lyo cycle are shown in Figures 15.26–15.27. The results are plotted in two ways. Figure 15.26 displays the headspace moisture values of all samples from all trays plotted from low to high values. This moisture distribution gives insight into the efficiency of the lyo cycle as a whole. The high moisture tail in this distribution indicates a significant portion of samples did not dry efficiently and contain elevated levels of water. In addition, the moisture distribution as a whole has a significant slope indicating non-homogenous drying across the shelves.

Figure 15.27 displays the headspace moisture value as a function of tray position. For each tray the average, standard deviation, maximum and minimum moisture values are reported. It is clear from this graph and the statistics that the drying efficiency for this lyo cycle is dependent on location within the freeze dryer. For example, average headspace moisture values and the standard deviation across tray 2 were much lower than samples in tray 4.

The lyophlization cycle was modified and a second set of 1600 vials was produced. Results of the headspace moisture analysis on product manufactured using the modified lyo cycle are shown

in Figures 15.28–15.29. The overall headspace moisture values are lower indicating on average dryer product. Headspace moisture as a function of tray position (Figure 15.29) shows more consistent drying across the freeze dryer shelf. The overall moisture distribution plotted in Figure 15.28 clearly shows that the modified freeze drying cycle has produced more consistent, homogenous and dryer product. This distribution is now much flatter than the moisture distribution in Figure 15.26.

The outliers produced in each cycle offer some interesting insight. The sample with the highest moisture content in the first cycle (Figure 15.26) was in tray 4 and had a moisture value of 4.88 mbar. In the second cycle where average moisture values dropped by 44% compared to the first cycle, the sample with the highest moisture content (Figure 15.28) was in tray 6 and had a moisture value of 7.96 mbar, a factor of 1.6 times higher. This seems to indicate that outliers are random and somewhat independent of the cycle. Only 100% inspection could find these outliers and keep them from entering the market. In set 2 there are still a significant number of vials (six out of 1898) that have moisture content at a factor of two or more above the average. The potency of these out-of-specification products will certainly degrade over the product shelf-life.

Conclusions

Headspace gas analysis can characterize freeze drying cycles and provide insight to freeze dryer dependent drying effects. The technique can also provide 100% inspection capabilities for identifying out-of-specification product. The total time for the moisture analysis of the two batches described above (~3200 samples) was approximately nine hours using a manual benchtop system. Automated systems could inspect this number of vials in minutes. The results above indicate a need for advanced measurement technologies to control the freeze drying process and inspect individual containers for moisture content.

Key point

Laser headspace inspection can rapidly determine moisture content of lyophilized product. Nondestructive moisture analysis enables high speed 100% inspection. Automated systems can simultaneously inspect packages for moisture content and seal integrity.

Conclusion

This chapter provides a detailed and thorough review of frequency modulation spectroscopy as it applies to the inspection of sterile products. The promise of this and other nondestructive laser based test and measurement technologies is their ability to provide real-time scientific insight about aseptic processes. Increasing our understanding of aseptic processes will in turn allow for better control of processes and further improve the quality of parenteral products.

Figure 15.26 Moisture distribution across an entire lot for cycle I. Data plotted from low to high

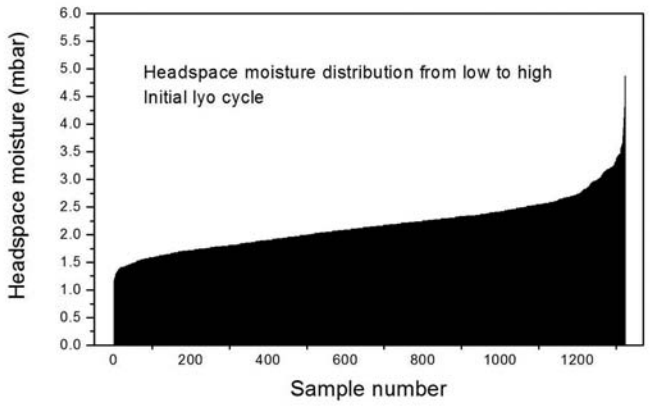


Figure 15.27 Moisture distribution across individual trays in a freeze dryer. The product was not dried in a particularly uniform manner

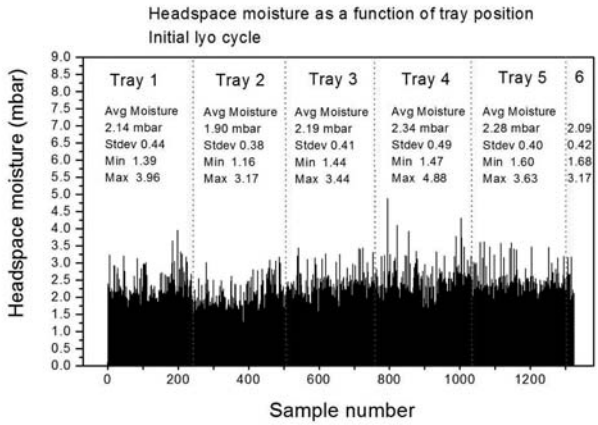


Figure 15.28 Moisture distribution across an entire lot for optimized cycle. Plotted from low to high

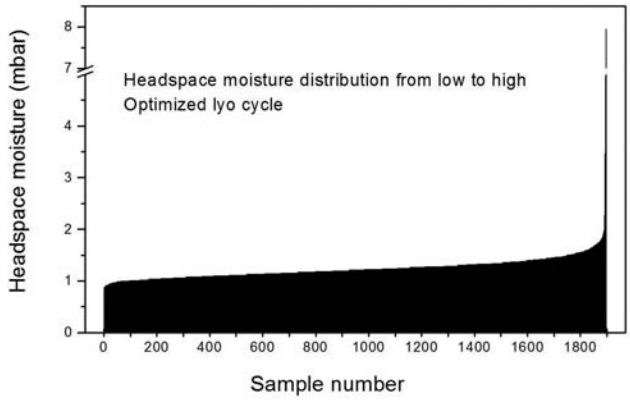
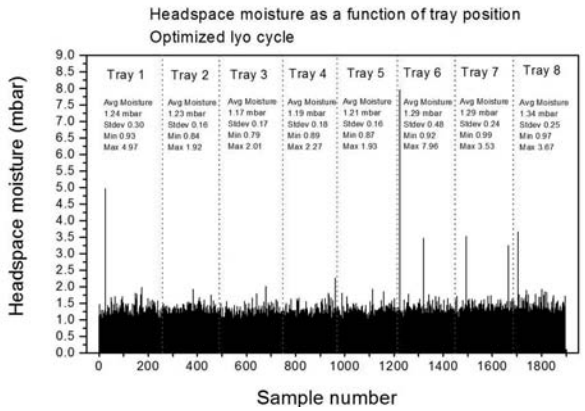


Figure 15.29 Moisture distribution across individual trays for an optimized lyophilizaton cycle



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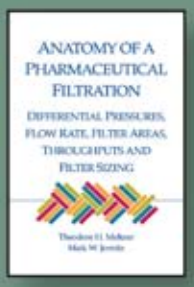
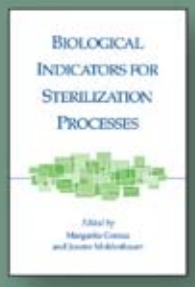


Theodore H. Meltzer and Maik W. Jornitz
(Item No. 17261)



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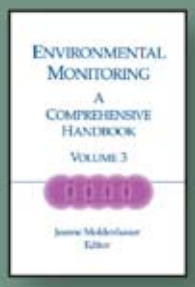

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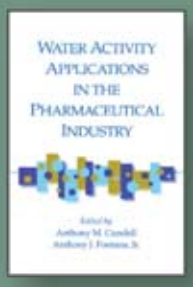

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Jack Lysfjord
Paul Pluta
Anthony M. Cundell, PhD and Anthony J. Fontana Jr., PhD

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   Item No. 17283, PDA Member $425, Nonmember $530
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Prefilled Syringes IG Discusses Breakage Solutions

Emily Hough and Walter Morris, PDA

Glass breakage, or more precisely, how to avoid it, was the topic of concern during a PDA Prefilled Syringes Interest Group breakfast discussion at the *2009 PDA/FDA Joint Regulatory Conference,* presaging a broader discussion of the challenges with glass at an upcoming PDA workshop in Venice on October 26.

Prefilled Interest Group leader **Thomas Schoenknecht,** PhD, Director, Drug Product & Device, Amgen, greeted session participants and explained how the IG's discussions have evolved. In the prior year, the IG considered industry requirements for primary packaging. This year, Schoenknecht said, the IG wanted to consider the regulatory perspective and how to reduce breakage and other problems.

"Glass is not stainless steal, glass is not plastic, whenever you handle glass, depending on secondary packaging, we have to appreciate its material, which is extremely stable and well prepared, but it is glass. Glass can get tension, glass can get bruises when you are handing it all over your production lines."

Shoenknecht gave way to a panel of five industry experts who gave brief presentations on glass breakage and possible solutions. One of the experts represented a larger purchaser of glass vials, and the other four represented suppliers. A discussion with IG participants followed their talks.

Eric Berg, Director, Supplier Quality, Amgen, launched directly into the heart of topic by asking the audience rhetorically: "A fundamental question is how do we make the problem of glass breakage go away?" He offered two "simple" solutions: "One, acknowledge that it is a problem and two, drive an action to make it go away."

In reality, there are no simple solutions. Berg noted that there has been some reconsideration of glass as a primary packaging material. "I think it is something for us to look at," he said.

As to why industry should pursue a zero-defect approach, Berg asked attendees to put themselves into the mindset of a consumer safety officer: "A consumer safety officer perspective might be that not one defect should make it into the hands of patients." Even if a glass defect did not prevent a patient from using a prefilled syringe product, the consumer safety officer might see other problems, including microbial contamination. Therefore, the Amgen official noted, regulators might say "there is a clear case for zero defects—not one broken glass article can make its way into the marketplace. I think we should think of that perspective as we consider solutions to what we are doing."

Solutions must be comprehensive and must involve the glass suppliers and users. "Glass is fragile, so every person that touches it could potentially render some vulnerability. Every USP truck, every warehouse, every pallet mover, every step along the way from the supplier to the manufacturer, and then in our processes as manufacturers for filling and further processing. We consider the entire spectrum of all the possibilities and make sure we understand and that the people who are touching the glass all along the way understand [that they] have a role in what we are delivering to our patients."

In the end, Berg agreed with the regulatory view about zero defects: "I would give my advocacy that we look at glass holistically, that we seek as an industry to work jointly with suppliers, that we see glass breakage as a problem, that we need to have a sense of urgency to drive solutions and see zero defects as a target. I think that that is key." Just as an airplane traveler would not accept "six sigma," demanding perfection upon every plane, a patient demands perfection, also.

Berg challenged the audience to consider what might be done to achieve zero defects and to think hard about alternatives to glass.

Berg found a partisan in **Justin Wright,** PhD, Manager, Bio-Analytical and Pharmaceutical Sciences, BD Medical, who stated, "Continuous improvement is not good enough anymore." During his presentation, called "Next Generation Automated PFS Production: A Holistic Approach to Quality by Design," Wright touted the use of sound design strategies to prevent defects.

"The shortest way to reach a high-quality container" is to be "process focused and not defect focused," Wright said. "You have to not only start with the raw materials, but you have to take that through all the way to the patient and think about what the impact is going to be."

This is made even more challenging by the moving "frontier of drugs," which is rendering traditionally compatible materials incompatible. "Whether it is cell-based therapy, interferon drugs or whatever it might be, the syringe or the vial that we generate today is probably not going to be good enough ten years from now. I think we've gotten comfortable for many years, 30 years, to strengthen the vials that we've known have worked, and they've worked really well. About 10 years ago we started to see an emergence of really complex molecules that just weren't compatible, and so we have to really think about what

are the right dimensions that we should build our containers by."

BD founded the "sensitive drug initiative," Wright said, "to go out into the pharmaceutical/biotech industry and understand the requirements—what are the end-user requirements, what are the processing requirements, what are the interaction requirements?...This is really the large net that we've cast to understand what are all those dimensions around drug products that are important to container design."

Christian Helbig, Manager Business Development, Schott North America, agreed with Wright about implementing quality into the design of the process. He discussed QbD in the context of vial design and composition. "The key is to really maintain the glass quality throughout the whole process." Helbig said that there is a tight control on the dimension and level of consistency in Schott's operation of glass manufacturing by way of temperature and flame control. "There is a focus on reducing the stress on the glass that is needed on the container at the same time to prevent that it will break throughout the process."

Helbig said that his company uses a camera system to increase the level of quality; it has been developed to detect critical defects. A mathematical model has also been implemented to reduce stress on the glass and to educate the customer base as to what glass can and cannot do.

Klaus Wuttke, Director of Operations, Gerresheimer Bunde, said that he was pleased by efforts of drug companies like Amgen to raise the quality expectations for glass products. More stringent demands are driving efforts at his firm to improve processes internally. The company is using a new machine outfitted with strategically placed cameras, which, combined with other controls, allows the measure of all geometric dimensions and accuracy of the burner temperatures, as well as detection of defects, damages and cracks.

Howard Drake, Vice President, Ompi of America, said that handling of glass must be optimized by avoiding glass-to-glass or glass-to-metal contact, but acknowledged that it is not easy to come by materials that are "ideally suited" for the handling of glass. Online measurement that pushes data in real time to the glass forming stations is one solution Drake's firm is using. This allows the firm to know that it is operating within parameters throughout processing. "It is very important that you have these things under tight control, fully automated within your systems both for temperature control as well as for the distribution and analysis of these working temperatures." He said that if you have a manual adjustment on the temperature, the ability to control accurate manufacturing conditions is linked to the skill level of the operators. Lack of control leads to cracks and breakage resulting from quality defects that might not be visible to the naked eye, like unevenness, thinness, concentrated loads or residual strain. Drake said decades-old process designs are part of the problem.

PDA has been heavily involved in advancing the science and standards for prefilled syringes by holding five large conferences on the subject since 2004. The sixth *Universe of Pre-filled Syringes and Injection Devices* takes place in Venice in late October in conjunction with the aforementioned workshop on glass. The conference will give updates to the relevant aspects of prefilled syringes and parenteral injections. It will cover technical issues from the development to manufacturing, quality and engineering, supplier issues, regulatory topics and inspections, handling and use of devices. To learn more about this, visit www.pda.org/europe.

Want to learn more about identifying glass defects?

Check out ***PDA Technical Report No. 43, Identification and Classification of Nonconformities in Molded and Tubular Glass Containers for Pharmaceutical Manufacturing,*** prepared by the PDA Glass Defects Task Force to provide consistent, standardized quality criteria for use by pharmaceutical companies for the visual inspection of incoming glass containers.

PDA's Technical Report No. 43 can be purchased at the PDA bookstore at www.pda.org/bookstore. PDA members receive a discount.

A follow-up technical report is being developed to expand TR-43 to include Ampoules, Syringes and Injection Devices for Pharmaceutical Manufacturing. If you are interested in reviewing the document, contact Iris Rice at rice@pda.org.

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 http://www.pda.org/regulatorynews.

Asia/Pacific

TGA Recognizes U.S. and EU Pharmacopeias per Amended Act

The British Pharmacopoeia must make room for the U.S. and EU Pharmacopeias as the "default standard" in Australia, according to the Therapeutic Goods Administration (TGA). The recently amended Therapeutic Goods Amendment (Medical Devices and Other Measures) Act 2009 amends the 1989 act in relation to the standards applying to medicines and other therapeutic goods that are not medical devices, and calls for the expansion of acceptable standards.

The amendment, which cleared Parliament on July 1, 2009, recognizes the European Pharmacopoeia and United States Pharmacopeia-National Formulary as acceptable standards alongside the British Pharmacopoeia. Until the amendment, the British Pharmacopoeia was the only standard recognized by the Act, in the absence of a standard determined by the Minister under section 10. The British Pharmacopoeia was informally referred to as the "default standard." Section 3 of the Amended Act now defines the "default standard" as any of the British Pharmacopoeia, European Pharmacopoeia, and United States Pharmacopeia-National Formulary.

Europe

Danish Medicines Agency Signs MOU with the SFDA to Develop Collaborative Framework

The Danish Medicines Agency has signed a memorandum of understanding with China's State Food and Drug Administration, P.R. China (SFDA). The agreement gives an opportunity for the two authorities to develop a framework of collaboration. By signing this agreement, Denmark is one of the first countries in the EU to formalize cooperation with China.

"The agreement is important because the industry uses more and more raw materials from China to manufacture medicines. At the same time, Danish pharmaceutical companies, which make up Denmark's biggest export industry, increasingly export to the Chinese market and place their manufacturing sites in China," explains Jytte Lyngvig, CEO of the Danish Medicines Agency.

The Danish-Chinese cooperation began when the Danish Minister for Health and Prevention, Jakob Axel Nielsen, visited China in December 2008.

EMEA & EU Authorities Provide Public Info on GMP Status

Starting on July 30, a new version of the EudraGMP database provides public access to Good Manufacturing Practice (GMP) related information about manufacturing, importation authorizations and GMP certificates. EudraGMP 2.0 can be accessed at http://eudragmp.emea.europa.eu.

The EudraGMP database, which covers both human and veterinary drugs, was initially launched in April 2007 to facilitate the exchange of information on GMP compliance among the competent regulatory authorities within the European medicines network, i.e., the EU Member States and Iceland, Liechtenstein and Norway. The database contains information on (1) manufacturing and importation authorizations issued by the national competent authorities within the network, and (2) GMP certificates issued by competent authorities following GMP inspections conducted either within the European Economic Area or in third countries.

Version 2.0 of the database will also contain Non-Compliance Statements. These statements will be issued in cases where the reporting inspection service is of the opinion that a manufacturer's noncompliance with GMP is so severe that regulatory action is required to remove a potential risk to public or animal health.

In a drive for more openness and transparency, the EMEA and the national competent authorities are giving general public access to the information contained in the database, with the exception of commercial and personal information considered confidential under the rules on access to EMEA documents. The information contained in the EudraGMP database will be completed and updated on an ongoing basis by the national competent authorities. For some national competent authorities, the publicly available information in the database is limited at this time. Due to the timing of national inspections and the fact that the normal inspection cycle is about 3 years, as well as different approaches to technical implementation of the database at a national level, public access will be phased in from July 2009 onwards, as individual national authorities become ready. The deadline for public access to data from all national authorities will be January 2011.

Note: Dr. Francisco Peñaranda, EMEA Inspections Sector, will give a detailed report on the public version of EudraGMP on October 13 at the 2009 PDA/EMEA Conference in Berlin. For more information, go to www.pda.org/emea2009

International Harmonization

EMEA, U.S. FDA Launch GCP Collaborative Inspection Activities

The EMEA and the U.S. FDA have agreed to launch a joint initiative to collaborate on international Good Clinical Practice (GCP) inspection activities.

This initiative—per the confidentiality

arrangements between the European Commission, the EMEA and the FDA—includes the sharing of information on inspection planning, policy and outcomes, and the conduct of collaborative inspections.

The EMEA and the FDA will start their new initiative with an 18-month pilot phase on September 1, 2009.

Applicants interested in volunteering to participate in a collaborative inspection during the pilot phase can contact the European Medicines Agency or the FDA. Contact point for the EMEA is Dr. Ana Rodriguez, Inspections Sector, at GCP@emea.europa.eu.

ICH Q4B Annexes 9 and 10 Available for Comment

The U.S. FDA has announced the availability of draft guidances, Q4B E*valuation and Recommendation of Texts for Pharmacopoeial Use in the International Conference on Harmonisation Regions;* Annex 10 on Polyacrylamide Gel and Electrophoresis General Chapter and Q4B Evaluation and Recommendation of Pharmacopoeial Texts for Use in the ICH Regions; Annex 9: Tablet Friability General Chapter.

The draft guidances convey recognition of the three pharmacopoeial methods by the three ICH regulatory regions and provide specific information regarding the recognition. The draft guidances are intended to recognize the interchangeability between the local regional pharmacopoeias and avoid redundant testing in favor of a common testing strategy in each regulatory region.

Comments on the draft guidances should be submitted by October 13, 2009.

U.S. FDA Asking for Public Input in Preparation for ICH Meeting

The U.S. FDA has announced that a public meeting entitled, *Preparation for ICH Meetings in St. Louis, Missouri* will be held to provide information and receive comments on ICH and the upcoming meeting in St. Louis.

The purpose of the public meeting, which will be held October 14, 2009 in Rockville, MD, is to solicit public input prior to the next Steering Committee and Expert Working Group Meetings.

North America

U.S. FDA Extends Submissions Deadline for Biotechnology CMC Pilot

The U.S. FDA has announced an extension of the deadline for submitting requests to participate in a pilot program involving the submission of quality (chemistry, manufacturing, and controls) information for biotechnology products in an expanded change protocol consistent with the principles of quality-by-design and risk management in pharmaceutical manufacturing. Because the deadline for requests to participate in the pilot is being extended, FDA is also extending the application submission deadlines.

Submit written and electronic requests to participate in the pilot program by September 30, 2010. Submit investigational new drug applications and post-approval supplements by March 31, 2011.

Agency Program to Give Firms 15 Days to Respond to a 483

The U.S. FDA is initiating a program to establish a timeframe for the submission of post-inspection responses to FDA 483 inspectional observations for FDA's consideration in deciding whether or not to issue a warning letter. The Agency would like to see a response to FDA483's within 15 working days.

In the event FDA decides to issue a warning letter, if the firm's response to and FDA483 is received within 15 business days, the letter will acknowledge the response and provide comment as to FDA's perceived adequacy of the firm's response. If the firm's response is received more than 15 working days after the issuance of an FDA483, FDA will not comment on the response in the warning letter. Rather, they will evaluate the response to the FDA483 along with the response to the warning letter.

FDA indicates they are initiating the program as a means of supporting public health protection by facilitating the timely issuance of warning letters. It begins will begin on September 15, 2009 and will be evaluated after 18 months.

Key Regulatory Dates

Comments Due:

Oct. 13
U.S. FDA for ICH Q4B Annexes 9&10

Dec. 16
U.S. FDA Draft Guidance: Microbial Data for Systemic Antibacterial Drug Products—Development, Analysis and Presentation

Dec. 22
U.S. FDA rule on cGMPs for Combination Products

Deadline Extensions:

Sept. 30, 2010
Requests to participate in FDA Biotechnology CMC Pilot

Meetings:

Oct. 14- 15
PDA/EMEA Joint Conference

Oct. 14
FDA Meeting: *Preparation for ICH Meetings in St. Louis, Missouri*

U.S. FDA Seeks Comment on Draft Guidance on Microbial Data for Antibacterial Drugs

The U.S. FDA has announced that a draft guidance entitled, *Microbiological Data for Systemic Antibacterial Drug Products—Development, Analysis, and Presentation,* is available.

The draft guidance informs industry of FDA's current thinking regarding the types of microbiological studies, assessments, and clinical trials needed to support an investigational new drug application and a new drug application for a systemic antibacterial drug product.

Recommendations in this guidance cover microbiological considerations

in the three major areas of conducting general nonclinical studies; conducting animal and human

studies and clinical trials; and establishing and updating in vitro susceptibility test methods, quality control parameters, and interpretive criteria.

This guidance also recommends the content and format for presentation of microbiological data for antibacterial drug products in the Microbiology subsection of labeling.

Comments on the draft guidance should be submitted by December 16, 2009.

U.S. FDA Clarifies cGMP Requirements for Combo Products

The U.S. FDA has published a notice about a proposed rule which would codify the cGMP requirements for combination products.

This proposed rule is intended to promote the public health by clarifying which cGMP requirements apply when drugs, devices and biological products are combined to create a combination product. The proposed rule also sets forth a regulatory framework for firms to use when demonstrating compliance with cGMP requirements for single-entity and co-packaged combination products.

Submit comments on this rule by December 22.

Agency Guidance Targets Melamine Contamination

The U.S. FDA has announced the availability of a guidance entitled, *Pharmaceutical Components at Risk for Melamine Contamination.*

The guidance provides recommendations that are intended to help pharmaceutical manufacturers of finished products, repackers, other suppliers and pharmacists, who engage in drug compounding avoid the use of components that are at risk for melamine contamination.

Comments may be submitted by October 6, but the Agency has issued this guidance as a Level 1 guidance for immediate implementation and are not seeking comment before implementation.

Guidance on End-of-Phase Meetings Released by U.S. FDA

The U.S. FDA is announcing the availability of a guidance entitled, *End-of-Phase 2A Meetings.*

This guidance meets one of the performance goals agreed to under the September 27, 2007, reauthorization of the Prescription Drug User Fee Act (PDUFA IV).

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PDA TOOLS FOR SUCCESS

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

Create Your Own

Businesses seem to be waiting for government stimulus money to trickle down into their cash flow. Unfortunately, few people seem aware of the glacial slowness of big government. Rather than wait on the Fed, businesses can create their own stimulus plan.

While in this economy it's hard to increase sales, it's easy to focus on reducing costs. Every dollar saved goes straight to the bottom line. And employees love finding ways to simplify, streamline and optimize the business to better serve customers.

According to the July-August 2009 *Harvard Business Review* survey (*How Bleak is the Landscape?*):

- 27% of businesses are streamlining product or service offerings
- 34% are reengineering processes
- 37% are improving products, services or customer support

Shouldn't your business be using this opportunity to improve the value chain?

Stimulus 1
Simplify

Every business collects clutter over the years in offices, factory floors, inventory, product or service lines. Now is a perfect time to put employees to work on eliminating the flotsam and jetsam of the past. When the clutter is gone, it's easier to see where to focus on the next step: Streamlining.

Stimulus 2
Streamline

Far too many businesses make stuff and then try to sell it. Instead of trying to *push* products or services onto the customer, change the business to let customers *pull* products or services when they need them. Any business can employ the principles of "lean thinking" to deliver what customers want when they want it.

Pushing products or services on customers results in excess inventory, both finished goods and raw materials. *Pull* companies only make the product or deliver the service when the customer requests it. Think of it this way: Inventory is fundamentally evil. It has to be stored, managed, moved and so on. It eats up time and money that could be employed elsewhere.

Pushing causes the ordering of large batches of raw materials and the production of large batches of product. Using a *pull* system results in ordering and the production of as small a batch as possible. The ultimate form of this is called "one-piece flow."

When people hear this, they often ask: "What about economies of scale?" GM and Chrysler are examples of the problems that result from economies of scale thinking, too much inventory. Consider a better alternative: *Economies of Speed.*

Pushing products or services results in delays between steps in the value stream that slow the delivery of the product or service. Even though employees seem to be working hard, if you watch the product or service it spends a lot of time waiting on the next step in production. Even if the production line is fast, the delays between an order, scheduling, production, delivery, invoicing and payment are often excessive.

The 3-57 Rule: Employees work on the product or service as little as 3 minutes out of every hour, resulting in 57 minutes of delay. Most people doubt this, but when managers shift their attention from the employees to the product, they discover that this holds true in all processes—office, back room, billing, purchasing, etc.

Now for the good news; every 15 minute per hour reduction in delay will:

- Double productivity
- Increase profit margins by 20%

How is that for stimulus?! Having worked on many projects to reduce delays, it's often easy to reduce delays by 75% or more (45 minutes/hour) which can increase profit margins by 60%! Instead of having to work harder, employees discover that they have more time to do it right the first time. Why? Because they aren't constantly picking up and putting down the product or service. In true one-piece flow, the product is worked nonstop which results in far fewer errors and faster delivery, which delights customers.

Many service business owners think that they can't apply the principles of "lean manufacturing," but nothing could be farther from the truth. Hospital emergency rooms are a service, aren't they? Press Ganey, which monitors emergency room turnaround times, recently reported that the average emergency room stay is four hours! Robert Wood Johnson Hospital (winner of

$timulu$ Plan

By Jay Arthur

the 2005 Baldridge Award for Quality) turns discharged patients in 38 minutes and admitted patients in 90 minutes. Healthcare professionals gasp when they hear these turnaround times. And the hospital has had a double digit growth rate and had to build a new wing onto the hospital to handle the load coming out of the emergency room.

Opportunity: Companies that reduce cycle times by eliminating delay grow three times faster than their competition.

The business that employees the economies of speed by reducing delays will garner more customers and more profits than their competition. Encourage employees to start streamlining their process today.

Stimulus 3
Optimize

Once businesses remove the slack from their value chain by switching to a pull system, it's time to start optimizing the process to eliminate defects and deviation.

Every business makes mistakes. Every product or service process varies slightly. Finding and fixing mistakes, errors and variation in the finished product can eat up 25-40% of the total budget. And, as little as 4% of the business produces over 50% of the defects and deviation (The 4-50 Rule).

Eliminating defects is easy:

- Count the number of mistakes, errors or defects in a process (e.g., order errors, product defects, billing errors, etc.)
- Categorize the defects by process step (e.g., order entry, packaging error, etc.)
- Change the process so that it is impossible to make that mistake

Too many businesses get caught up in blaming employees for mistakes. Systems and processes let employees make mistakes. When the system or process gets changed so that it is impossible to make the mistake, employees stop making them.

Tip: Blame the process, not the people.

Eliminating deviation is a little bit more challenging, but not that difficult:

Measure the variation in the product or service (usually some plus-or-minus, over/under variation of length, weight, time, etc.).

Evaluate the root causes of deviation from the customer's target value (e.g., machine setup, maintenance, etc.).

Change the process to minimize deviation.

Implement a measurement and monitoring process to make sure the machines or process don't drift from the target value. This usually involves some form of statistical process control (SPC). Hospitals, for example, measure infection rates; manufacturing plants measure dimensions; banks measure customer wait times; and so on. Inexpensive Excel-based SPC software can do this easily.

Employee Stimulus Plan

Each of these steps—simplify, streamline and optimize—can engage employees in the quest for excellence. They've grown tired of serving customers badly and they've also grown tired of trying to get anyone to listen to their improvement ideas.

By engaging employees in each of these three steps, they become renewed rather than burned out. It's a simple way to break the angst over the economy.

Jump Start Your Stimulus Plan

Businesses can wait on the government to throw some money their way or they can start finding ways to simplify, streamline and optimize the business to squeeze more profit out of the existing revenue stream. Engage employees in:

- Getting rid of the clutter
- Eliminating unnecessary inventory and delays
- Reducing or eliminating defects and deviation

Set BHAGs (Big, Hairy Audacious Goals) to reduce delay, defects and deviation by 50% in six months or less. It will stimulate your business, your employees and, most importantly, your customers.

About the Author:

Jay Arthur, the KnowWare Man, is author of *Double Your Profits: Plug the Leaks in Your Cash Flow.* He has spent the last 20 years helping companies maximize revenue through the "Lean Six Sigma System," a collection of audio, video, books and software. Jay is also the author of *Lean Six Sigma Demystified* and offers online lessons at www.qimacros.com/freestuff.html

Recipients of the 2008 Honor Awards

www.pda.org/2008honorawards

The honor awards have been bestowed to esteemed PDA members since the first award was given in 1958. It is our intention to highlight the 2008 Honor Award Winners who were recognized at PDA's Annual Meeting banquet. **[Editor's Note:** We have selected three of PDA's 2008 honored members to highlight in this issue. Be sure to look at this section in future issues for additional winners! You can also read all about the award winners online at www.pda.org/2008honorawards**]**

Distinguished Service Award

This award is given in recognition of special acts, contributions or services that have contributed to the success of PDA. For 2008, seven members received the award, four of whom were highlighted in the previous issue.

Masashi Imamura

Masashi has been a Board member of the PDA Japan Chapter and the Chairman of the Japan Chapter's Annual Meeting since 2005. He also has been a member of the Japanese Program committee of the 2006 Asia-Pacific Congress and Chairman of PDA's Japan Chapter's API committee since 2006. Masashi has been involved in the 2006, 2007 and 2008 PDA/FDA Joint Regulatory conferences. He has also increased PDA's Japan Chapter's membership.

Zena Kaufman

Zena has been an active member for over 15 years. During that time, she was Chair of the Regulatory Affairs & Quality Committee (RAQC) GMP Task Force, which drafted comments for the FDA draft documents written as part of the GMPS for the 21st Century. She is currently the Immediate Past Chair of the RAQC. Last year, she chaired the FDA/PDA Co-Sponsored Conference Series on Quality Systems that were held in the United States, Europe and China, giving an overview of the Pharmaceutical Quality Systems and case studies.

Louis Zaczkiewicz

Louis is a funding member of and the Immediate Past President of the PDA New England Chapter. He is currently an active member at-large. Louis set the bar very high for all PDA chapter leaders by hosting quality local meetings and facility tours on a regular basis, producing timely and interesting chapter newsletters and being actively involved in the Chapter Council as a Co-chair. He most recently helped PDA draft and publish the first-ever PDA Chapter Handbook. Louis is also Co-chair of the Membership Advisory Board, helping PDA to improve member services and grow PDA.

Distinguish yourself!
Join a chapter or a task force. Learn about all PDA volunteer opportunities at *www.pda.org/getinvolved*

Volunteer Spotlights

Read more about our volunteers at www.pda.org/spotlight

Sandeep Nema, PhD, Executive Director, Pfizer

PDA Join Date: 1991

Areas of PDA Volunteerism: Pharmaceutical Development Interest Groups Section Leader (2005-2009);"Formulation and Characterization of Sterile Drug Products" course Instructor (1996-99); PDA Annual Meeting Planning Committee member (2002, 2003); Prescription for Successful Contracting: Your Product from Concept to Commercialization planning committee member (2000)

Professional Awards Won: Pfizer Global Research and Development Achievement Award; Pharmacia Preclinical Development Impact Award; Co-recipient of PDA Foundation research grant in the field of Parenteral Sciences.

Why did you join PDA and start to volunteer? I initially joined PDA mainly for networking and learning from technical experts. I did not realize other benefits that PDA provides to its members including an opportunity to influence regulatory environment, expand scientific frontiers, the PDA Journal, the newsletter and forums to share information

Of your PDA volunteer experiences, which stand out the most? Being the Section Leader of the Pharmaceutical Development Interest Groups, working with various Interest Groups and bringing new groups forward to meet the needs of membership

Which member benefit do you most look forward to? The PDA Technical Reports.

Which PDA event/training course is your favorite? The PDA/FDA Joint Regulatory Conference is a great event to learn about the current regulatory and technical environment. It provides an excellent networking opportunity.

What would you say to somebody considering PDA membership? It is a must for those working in the pharmaceutical field.

Phillipe Gomez, Biopharm Specialist/Key Acct. Manager, Sartorius Stedim Biotech

PDA Join Date: August 2002

Areas of PDA Volunteerism: PDA French Chapter President and cofounder (2004); Committee member for Annual Meeting and workshops in France and Europe; President and cofounder of Endotoxin Working Group in collaboration with the Société Française des Sciences et Techniques Pharmaceutiques; Delegate of the 2010 Manufacturing Excellence planning committee

Interesting Fact about Yourself: For 15 years I had the chance to work as a technology director in a pharmaceutical company, where I was in charge of technology transfer activities on a worldwide basis. Sometimes when in the middle of nowhere, I had to understand the differences existing between countries, cultures and perceptions around the world (and with food as well!). I try to keep these multicultural aspects in my daily work.

Why did you join PDA and start to volunteer? I had been working in the pharmaceutical industry for several years when I had the chance to meet Maik Jornitz who introduced PDA to me. It then appeared quite obvious that the networking opportunity generated and the amount of valuable information shared made joining PDA a "must" rather than a "nice to have."

Of your PDA volunteer experiences, which stand out the most? The creation of the PDA French chapter. Starting from scratch was really a fabulous experience and good learning curve. Also, discussions with regulators and inspectors to get direct answers to your needs during interactive workshops is also one of the great moments that PDA creates!

How has volunteering through PDA benefited you professionally? I have been working in the biopharm industry for over 20 years, trying to find the way through standards, regulations and norms, and we understood early on with JL Saubion, my colleague and cofounder of the chapter, that participating with PDA would make our life easier; working on the GMP for IMP task force or launching the creation of a new technical report on Endotoxins to set up a basis for many untreated areas such as for adjuvants, non soluble products and medical devices brings a lot of valuable information that directly benefits your professional experience. It is also a fantastic network opportunity because PDA brings together individuals from regulatory, manufacturing and the supply side of things and allows for a common understanding that is practical and realistic.

Which PDA event/training course is your favorite? The small size workshops we implement within the PDA French Chapter with the help of the French regulators; the outcome is very positive. These workshops turn into very interactive meetings permitting direct exchange with key speakers and delegates with amazing and fruitful exchange for all parties

What would you say to somebody considering PDA membership? After more than 10 years joining this adventure, it is always a real pleasure for me to be involved and I always get a high return on investment. Being a member not only means a better understanding of regulations or norms, but it's a chance to contribute, influence and help build these documents. So just join, get involved and you will meet so many experienced people able to support you—that membership will also appear to be a must for you!

Please Welcome the Following Industry

Frank Adair, Halo Pharmaceutical

Daniel Albrecht, Dr. Albrecht Consulting

Pat Allen, Murex Biotech

Maria Austero-Macavinta, Roche

Maheshkumar Bhatt, Torrent Research Centre

Ulrike Alberg, Bayer Schering Pharma

Daniel Albrecht, Dr. Albrecht Consulting

Pat Allen, Murex Biotech

Margit Andersen, NNE Pharmaplan

Deanna Anderson, Hospira

Alessandra Antonnicola, Haupt Pharma

Maria Austero-Macavinta, F. Hoffmann-La Roche

Gerald Barr, Schering-Plough

Laurent Barrelle, BD

Stephanie Bartko, Catalent Pharma Solutions

Todd Battistoni, Genentech

Benjamin Beaulieu, Teva Parenteral Medicines

David Beer, Novartis Institute for Tropical Diseases

Christian Berg, Genentech

Gloria Berrios, Eli Lilly

Maheshkumar Bhatt, Torrent Pharmaceuticals

Sam Biswal, Scalable Systems

Jaime Blanco, Genentech/Roche

Almira Blazek-Welsh, Cardiome Pharma

Kristin Blitsch, Gen-Probe

Lesley Anne Bobiak, Merck

Crystal Booth, Eisai

Peter Bosshard, F. Hoffmann-La Roche

Thomas Britton, Millipore

Peter Burke, Genzyme

Claire Burrows, Millipore

Kathryn Butler, Charles River

Daman Chadha, Baxter Healthcare

Alexis Chalfant, Cryovac Sealed Air

You Hao Chang, Ta Fong Pharmaceutical

Shu Yuen Chao, Moye Engineering

Carlos Chavez, BiogenIdec

Amy Chess, ImClone Systems

Xiao Wen Chou, Anchem Pharmaceuticals

Wayne Christ, Abbott Laboratories

You-Hao Chung, Ta Fong Pharmaceutical

Dana Cipriano, WuXi AppTec

Andrew Cockshott, Eli Lilly

John Coffey, Pharmalucence

Eric Cooper, Kimberly-Clark

Marcia Ann Coyne, Genentech

Jo-Ann Coyne, Stiefel

Michael Cunningham, Millipore

Parul Daphtary, Bristol-Myers Squibb

Brian Davis, University of California San Fransisco

Steven Dawson, Genentech

Edward Day, FDA

Johannes de Koning, Hal Allergy

John De Los Santos, Genentech

Norma Delaney, Bristol-Myers Squibb

Jessica Dimino, Owens & Minor

Susan Ditty, Life Technologies

Diane Dong, Abbott Laboratories

Avery Edwards, Clarkston Consulting

Kenneth Eicher, Abraxis BioScience

Ann Farnsworth, Merrimack Pharmaceuticals

Catherine Finnegan, FDA

Paula Flynn, Infinity Pharmaceuticals

Kenneth Ford, Merck

Ren Yo Forng, MedImmune

Kathleen Francissen, Genentech

Darlene Fresia, Wyeth Biotech

Arima Fukunishi, Boehringer Ingelheim

Matthew Fulcher, Talecris Biotherpeutics

Prateek Gadhoke, Bristol-Myers Squibb

Giovanna Garcia, Terra Farma Andina

Jacqueline Garfield, LifeCell

Michael Gibson, Hospira

Francoise Gilles, Vetter Pharma

Jeffrey Givand, Merck

Oskar Gold, Vetter Pharma

Carolina Gonzalez, F. Hoffmann-La Roche

Jamie Goodman, Bayer Healthcare

Odile Granju, Solvay Pharmaceuticals

Roy Greaves, Lantheus Medical Imaging

Robyn Greczek, MedImmune

Carrie Grimes, Abbott Laboratories

Patrick Grueninger, Helvoet Pharma

Mali Gupta, Campbell University

Natasha Guss, Chesapeak Biological Labs

Cate Halmagyi, Phebra

John Hamilton, Foft Dodge Animal Health

Brent Hammell, Bristol-Myers Squibb

Eva Hao, Innopharmax

Brian Hatch, Eli Lilly

Michael Hayes, Talecris Biotherapeutics

Robert Hazemoto, Life Technologies

Reiner Hedderich, Heipha Dr. Mueller

Jason Hendershott, Ben Venue

Enoc Henry, Biogen Idec

Wanda Hernandez, Eli Lilly

Mihara Hiromi, Takeda Analytical Research Laboratories

Youn Byong Ho, Handok Pharmacentcals

Young Ho, Yuhan

John Hoffman, Allermed Laboratories

Steven Honey, CSL

Yih-Ming Hsiao, Winston Medical Supply

CS Hsu, Innopharmax

Hussein Hsu, Weidar Pharma

Stephen Hsu, GlaxoSmithKline

Shih-Cheng Hu, National Taipei University of Technology

Mark Iampietro, Unilife Medical Solutions

Sabine Inghelbrecht, J&J

Hironori Inutake, Dainippon Sumitomo Pharma

Leaders to the PDA Community

Hideki Ishiwata, Daiichi Sankyo

Taichi Ito, World Courier

Sushil Jaiswal, Macleods Pharmaceuticals

Audrey Jia, FDA

Victoria Jimenez-Morales, Genentech

Jeffrey Jimmo, One Source Environmental

Jitendra Jindal, Advanced Microdevices

Susanne Joerg, Novartis Pharma

Melissa Johnson, Cook Pharmica

David Jones, Eli Lilly

Cindy Jung, Merck

Shashi Kaithamana, Human Genome Sciences

Amy Kalista, ImClone Systems

Richard Kalman, Allergan

Melissa Kanar, Facet Biotech Corporation

Ernst Kasper, F. Hoffmann-La Roche

Debra Katter, BRPPD

Toshio Kawakita, Shionogi & Co.

Yuji Kawamoto, Astellas pharma

John Kearney, GlaxoSmithKline

Gert Jan Keizer, Solvay Biologicals

Fazal Khan, Merrimack Pharmaceuticals

Gazala Khan Koticha, Dr Reddy's Laboratories

Bahram Khyltash, AMP

Bahram Khyltash, Alliance Medical Products

John Kim, Bayer Healthcare

Tamarah King, West Pharmaceutical Services

Peter Kitz, Merck

Douglas Kline, Douglas Kline UG

Chia Phei Kok, Visentic Solutions

Hwa Jiuan Kok, Health Sciences Authority

Alona Korol, Dexcel

Kevin Krebs, Dentsply Pharmaceutical

Timo Krebsbach, Labor L+S AG

Adam Kulczyk, Genzyme Corporation

Fares Lahoud, Genzyme

Uffe Larsen, Novo Nordisk

Gary Lazarus, Bristol-Myers Squibb

Tannie Le, Bayer Healthcare

Corine Lecomte, GlaxoSmithKline

Matthew Lee, Genemed

So-Yan Leung, Genentech

Nimrod Lev, Medimop Medical Projects

Amir Lev, Medimop Medical Projects

Kara Levine, Millipore

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Richard Levy, PhD, PDA

PDA is bringing our *Sterilization Technology Today and Tomorrow* conference to San Juan Puerto Rico, following successful meetings in New Jersey and California. This new conference will give you the opportunity to learn about recently updated methods and technologies, as well as those in development for future use for the sterilization of materials, components and finished pharmaceutical/biopharmaceutical products.

The meeting planning committee's goal in developing this meeting is to present the most advanced approaches to sterilization by subject matter experts directly involved in the development and application of these technologies. The agenda was designed to include sessions covering industry best practices in the form of new technical reports (TRs), which are developed with input from global PDA members, industry experts and regulators. For example, new TR's on Sterile Filtration, Steam-in-Place, Dry Heat and Parametric Approach are included.

Additional sessions were developed on past, present and future directions of sterilization technology, radiation and dry heat sterilization, microbial control using gas and regulatory and compendial considerations for sterilization. There is also a session on the application of risk management to sterilization processes.

Featured presentations include:

Sterile Products Manufacturing Historical Perspective, by Kris Evans, Amgen

The Importance and Future Direction of Sterilization Processes, by James Agalloco, Agalloco and Associates

New Methods in Sterilization, by Alpaslan Yaman, PhD, Pharma & Device Consulting

Validation of Microbial Retention, by Jerold Martin, Pall Life Sciences

Challenges and Solutions in Stopper Sterilization, by Bart Burgess, West Pharmaceutical Services

Terminal Sterilization of Prefilled Syringes, by Kevin Trupp, Hospira

Chlorine Dioxide: An Alternative Agent, by Mark Czarneski, ClorDiSys Solutions

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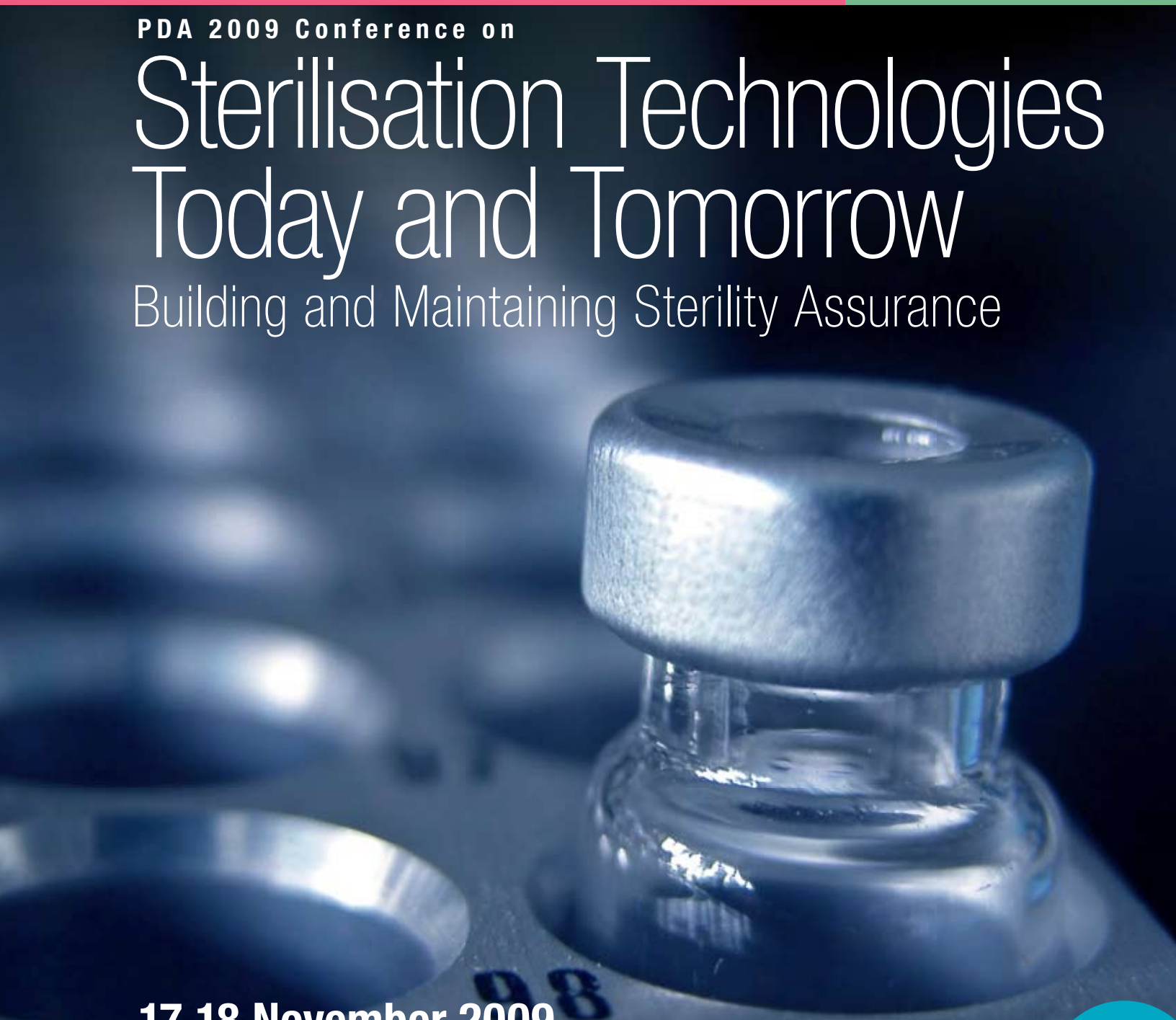

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The Sterilisation Technology conference will review existing and future technologies for building and maintaining an adequate sterility assurance level when sterilising materials, components and finished bio/pharmaceutical products and medical devices within the healthcare industry. Presentations from industry and regulatory experts will cover the range of available technologies in current use, along with expected new approaches for the manufacture of e. g. sterile products, immediate containers or medical devices.

Faces and Places: Cell Substrate Workshop

(l-r) Andrew Kerr, BioReliance; Linda Hendricks, Centocor Research and Development; Sally Baylis, Paul-Ehrlich Institut; Dayue Chen, Eli Lilly; Konstantin Konstantinov, Genzyme; John Kolman, BioReliance; Ivar Kljavin, Genentech; Rangarajan Sampath, Ibis Biosciences; Gay Gauvin, Amgen

(l-r) TW Tanaka, BCG-Japan; Robert Weaver, Amgen; Gay Gauvin, Amgen; Arifa Khan, FDA; Ruth Cordoba-Rodriguez, FDA; Barbara Potts, Genentech; Mike Rubino, Eli Lilly

Kathryn King, FDA, meeting Co-chair, listening intently to the presentations in preparation for her final summary session.

John Petricciani

Attendees at the Cell Substrate Workshop listened and interacted with speakers.

(l-r) Gay Gauvin, Amgen; Hannelore Willkommen, Regualtory Affairs & Biological Safety Consulting; Mike Rubino, Eli Lilly; Robert Kozak, Bayer; Mike Wiebe, Quantum Consulting

(l-r) Arifa Khan, FDA; Stephen Brown, Vivalis; Penny Post, Protein Sciences; Mike Rubino, Eli Lilly; Cherylene Plewa, Amgen; Boro Dropulic, Lentigen; Robert Kozak, Bayer

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Why Training is More Than a ✓ in the Box

Vivian Bringslimark, HPIS Consulting

It's Monday morning, and sitting in your inbox is an email invitation for this year's annual GMP refresher. "Oh Joy," you exclaim, "I can hardly wait!" Please pardon the sarcasm, but many life sciences managers don't feel all warm and fuzzy about compliance training. In fact, most will revert to delay tactics on account of the production schedule or demanding workloads and ask when the make-up sessions are being scheduled.

Let's face it. Compliance required training and other company sponsored training programs can be dry, boring and quite often described as "death by power-point" training. So no wonder folks want to get the training over with and mark it complete. When attendance lags, trainers lament about lack of management support, and management struggles with quantifying the return on their investment other than mandatory training that stays within the law.

The alternative is to deliver training that engages employees, provides meaning to job functions and is directly tied to performance outcomes. "Good" training is training that is effective. And effective training is managed within an efficient and controlled system. "As with any other technological system, the art of employee training should clearly be based upon the science of systematic control." ***(1)***

System and Process: One and the Same?

A system, as *Webster's Dictionary* defines it, is "an assemblage or combination of things or parts forming a complex or unitary whole." Systems can be controlled or allowed to be left in an uncontrolled status. In a controlled system, information is perceived and changes are effected in response to that information. But then what is a process?

A process is a sequential grouping of interrelated tasks directed at producing one particular outcome such as closing a knowledge, skill and/or performance gap. The elements of a process typically include its inputs, value added steps and outputs.

What Makes Training a System?

The answer depends on the reader's viewpoint. Do you consider training as an event where the trainer tells the novice the information or shows a new hire how to perform a task? Or, is there more to training, such as including the effectiveness of the interaction?

Then, how does a trainer coordinate all the pieces and ensure that they are incorporated into the training? They accomplish it by contemplating the whole picture from start to finish. Systems thinking, made popular by Peter Senge, is a conceptual framework for seeing how the parts all fit together. ***(2)*** In this case, it is how the inputs, training design and delivery, and the outputs can be managed whether for one session, one employee or for a series of courses for an entire organization.

So how do novice employees get trained in a consistent and reproducible manner ensuring their learning needs are met in an effective and efficient time frame? By following a controlled process that organizes all the "pieces."

The Training Pieces

The training process also has its inputs, steps and outputs. Training begins with the people, the goals/objectives to be mastered, the information and the tools to be used. Then, the trainer performs a series of actions with the inputs before, during and after training to produce the outputs or the results. **[Author's Note:** See Table 1 on Training Inputs, Process and Outputs, which is modified from Jacobs, RL. and Jones, ML. ***(3)***]

Trainers schooled in the principles of instructional design recognize this description as ADDIE (assess, design, develop, implement and evaluate). ADDIE represents a piece of the process albeit an important part; it is a subprocess. Likewise, the current use of Donald Kirkpatrick's, PhD, Four Levels of Evaluation is also a sub-process. ***(4)*** However, training as a system is more than the design, delivery and evaluation of training. The documentation requirements alone can warrant a separate subsystem. With the use of today's learning management systems (LMS), linkages to the other organizational systems are crucial. At the onset is the integral connection to Human Resources Information Systems (HRIS) for the accuracy and completeness of employee profiles.

The Training System vs. LMS

Reporting compliance training results is a key metric for the management review

Table 1 – Training Inputs, Process and Outputs

Training Inputs	Value Added Steps	Training Outputs
Novice Employee	Trainer's actions to prepare	*Training Performance*–meeting the learning/ performance objectives
Seasoned Employees		
SMEs and Qualified Trainers		
Physical Objects and Tools	Trainer's actions to deliver	Task Performance–as identified by SOP or other established standard
Training Locations Including Work Stations		

quality system. But, having a validated LMS does not automatically guarantee that the training system is in control. Before the data is entered into the database, it follows a series of processes and manual human decisions within the training system or the training processes, if you will. The LMS is not the be-all to end-all. It is only the tool by which we store, sort, decide and report on who is trained and who still needs what additional training.

The training system organizes all the elements, sub-processes and linkages to other systems into a logical flow so that process variability is controlled. Training, like any other system, has its own policy and set of SOPs that need to be followed to consistently produce effective and efficient training outcomes; it is not just printouts of employee training history.

When the training system is in control, someone is responsible for every process and is held accountable by their management. There is also assurance that employees are adequately trained in GMPs and can perform their assigned procedures independently. This is achieved by developing and implementing a systems approach for training so that all the elements come together in a logical process flow. The key elements include: ***(5)***

- ✓ Creation of a training policy
- ✓ GMP and compliance curricula
- ✓ SOP/procedural training
- ✓ Use of qualified trainers
- ✓ Employee qualification process
- ✓ Training documentation process
- ✓ Training effectiveness measures

Once these elements are defined and sequentially placed, the system must connect with quality systems for proper system linkages.

Cross functional Quality Subsystems

While all quality systems are necessary to ensure a state of control, there are three subsystems that stand out as being vitally cross functional in their design:

✓ Change control (document control) can be considered as the heart of an organization. Processes and procedures are defined, validated and controlled within this system.

✓ CAPA/deviation management is the pulse. This system indicates the organization's "health" or compliance performance results.

✓ Training is the "lifeblood" that fuels and sustains the organization. Of the three, training is perhaps the most cross functional system.

Since more than half of identified training requirements are procedures, it is crucial that the training system be designed to interface with change control to ensure employees are in fact current with the ever-changing SOPs. An often overlooked connection is the linkage to CAPA. Once the corrective action has been appropriately selected and approved, the training system captures the training requirement and incorporates it as an input into the existing process.

Another important quality subsystem to consider is internal auditing. An effective training system undergoes a periodic evaluation, but the system review needs to be an independent verification performed by non-training staff. It can easily be included into the scope of QA's auditing program, like any other audited system. The systems view for training ensures these vital connections are present and the exact handoffs are well defined.

Organization Factors that Influences a Training System

- ✓ Business priorities and competing systems goals
- ✓ Nature of ongoing change efforts and process improvement initiatives
- ✓ Perception of the value of training among management, 1st line supervisors and employees
- ✓ Alignment between job expectations and consequences of using SMEs as trainers
- ✓ Willingness of functions to manage and comply with the training system during peak production demands

Proactive Organizations Have an Effective Training System

Best performing companies or highly regarded companies place a value on training, but it is more than mandating an X number of training hours. Yet, that is how some managers define their training program. Study the compliance training program of proactive companies. It is more than the basic GMP guideline for new hires and one annual GMP refresher course. These organizations develop their ongoing GMP training into additional GMP curricula for key compliance positions and include at least a second refresher requirement that allows for employee choice, so that it relates to their job function as is usually a current topic or emerging regulatory trend.

Link Training to Performance Outcomes

Completing identified training requirements by the due date is a minimum performance metric for compliance reporting. But what about the effectiveness of the training that is being delivered? Why are we delivering all this training in the first place? Proactive companies realize that managing their talent pool is more than providing required training.

They share the business goals with their employees, identify the key processes that are responsible for producing the outcomes of value and provide the necessary tools including training and development to ensure that their employees

are provided with the best possible resources to succeed as expected.

In a perfect organization, systems run flawlessly and are unimpeded by the outcomes of other systems. With training being so highly interfaced throughout an organization, this system is constantly being influenced by other organizational systems in which it functions within. [**Author's Note:** See sidebar entitled, "Organizational Factors that Influences a Training System," previous page.]

Quick Fix Solutions

Companies with an uncontrolled training system fail "to develop formal systematic approaches to GMP training and [fail] to install systems of written documentation." ***(1)*** Shortcuts in training become prevalent and give the appearance that training is just one big documentation exercise; a ✓ in the box. The following is a typical scenario that happens when a lot of new hires are brought on board all at once. Unable to slow down the production schedule and not having an excess of available trainers, many new hires find themselves in an office with their training plan in one hand and the SOP binder in the other. The need to supervise them becomes a huge compliance task. "So why not multi-task by reducing their exposure to processes and at the same time complete their training requirements? And then let them follow Joe and Jane around for a few weeks?" While it might seem like the perfect solution, this is not training. It is a waste of time and energy. It creates false "training" expectations for everyone and is certainly not an effective training system.

As a result, we find ourselves as participants in "event-driven" training where the general perception for the learning goal is to "get 'er done" or "just-in-time" training to close out an audit observation by the due date. When you skip through the difficult parts of the training process, especially the identification of the learning/performance need or the why as it relates to the business goals, the training becomes meaningless after the event and makes post-training follow up nearly impossible to measure.

Today's Training Conundrums

The current perception of training sits in the middle of many debates as to its effectiveness, relevancy and value to an organization. This is most unfortunate. Informally, ask professionals from the life sciences arena why this is happening and you will receive a range of responses from lack of management support, to insufficient and boring training. Who's to blame? More importantly, who is going to clarify these perceptions when each is attributing the root cause to the other?

Like any good dilemma, you assess the risks, leverage small, but significant change by applying systems thinking. Start with the business need. What's driving the need for training or the need for performance improvement? Then close the gap using the system approach for training. If you have to redesign your current processes, then do it. The end result will be a more robust and supported training system. In the end, isn't that worth it?

Summary

"The system view helps us to distinguish between the means and ends of our actions." ***(3)*** Integrating the key system elements and the miscellaneous training pieces into one holistic process improves the efficiency of training. The ultimate outcome of the training system is to develop employees' expertise in both the technical functions of an organization, as well as the GMP principles beyond the tasks they perform; thus, ensuring the overall effectiveness of training.

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Vivian Bringslimark provides human performance consulting services for improving people strategies with HPIS Consulting. In her current role, she partners with clients to analyze root causes of human performance gaps and implement appropriate solutions that align with stated business outcomes to bring about more long term and predictable performance resulting in yearly goal achievement and operational excellence. She is on the Board of Directors for GMP Training at the Education Association, Inc. as Chief Communications Officer. Prior to HPIS Consulting, Vivian worked for PAREXEL Consulting as a Senior Consultant re-engineering quality systems and developing organizational effectiveness solutions. Vivian began her pharmaceutical career at Ciba-Geigy in manufacturing and has worked for Watson Laboratories. She is certified in Covey's "7 Habits of Highly Effective People," "What Matters Most," and "Building Trust" courses to expand her role to include leadership and organizational development activities.

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Workshop to Look at Practical Aseptic Process Execution

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Author's Note

The following article is based on the following three fundamental regulatory texts:

The first one is the U.S. FDA's 2004 guidance for industry, *Sterile Drug Products Produced by Aseptic Processing,* which was the first detailed document on this topic and still gives us many precisions and Agency expectations that we do not find in the new Annex 1 of the EMEA.

The second one, well known by Europeans, is the latest version of Annex 1 to the EU GMP Guide setting requirements for the validation of aseptic processes and coming into force March 2009.

And last but not least, on 1 July 2009, PIC/S (Pharmaceutical Inspection Convention – Pharmaceutical Inspection Co-operation Scheme) published an updated version of its "Recommendation on the Validation of Aseptic Processes" (PI 007-5), where section 6 (interpretation of data) was revised based on the revised Annex 1 to the PIC/S GMP Guide. The document is a condensed guide through regulatory requirements and expectations and worth a short discussion.

Aseptic processes are very delicate and complex. As there is no rescue step within the process, aseptic manufacturing renders sterile products only if process design, equipment, premises and correct behavior of the personnel lead to it. Thus, how to validate becomes a crucial question to sustain the claim of manufacturing a sterile product. In adopting a colloquial to characterize the situation, aseptic processes can be seen as "gold in—garbage out" if not conducted correctly. This topic will be discussed in more detail at the *PDA 2009 Workshop on Validation of Aseptic Processes* in Milan, Italy on December 1-2.

Types of Validation

The guide under Section 2.3.2 states that "validation of aseptic processes relies upon prospective, concurrent and retrospective validation as well as re-validation." It is quite astonishing, that retrospective validation is quoted as a potential option. Later in the text, it is characterized as "not a recommended technique for aseptic processes"; however, it is a risky approach and acceptable only in extreme cases, one being the situation of incorrectly documented changes to the process. If there had been substantial changes that were not well or even not at all documented, one could argue that as they had been in place before and had been exposed to a successfully conducted media fill study, the process was valid although there was no adequate documentation to the changes. This still remains a fragile argumentation, because, as they had not been documented correctly, it is difficult to demonstrate that they had been in place at time of the media fill study, for example.

The Role of Media Fill Studies

Under Section 2.3.8 is written that "process simulation studies (media fills) are simulating the whole process in order to evaluate the sterility confidence of the process." Later in the section, the statement is made that, "each process simulation trial is unique and so it is not possible to extrapolate these results directly to actual production contamination rates." This somehow follows the thinking expressed on various occasions that an aseptic process cannot be validated to the rigor and expectations of all other pharmaceutical processes.

James Agalloco, President, Agalloco & Associates, in a comment to the U.S. FDA proposed changes to the cGMP regulations that required aseptic processing to be validated. He wrote "aseptic-processing simulations cannot validate an aseptic process. The results obtained demonstrate the capability of the facility, equipment and operational controls to provide a minimal microbial contamination rate in a single event. They cannot be utilized to predict the outcome of a similar process performed at a different time, and thus cannot "validate" the aseptic process. Successful aseptic processing incorporates a myriad of necessary controls; however, these controls, alone or in concert, cannot be relied upon to support the absence of microbial contamination as is routinely accomplished in sterilization validation."

In the "General Comments" section at 4.1.1 of the document about media fills, it is pointed out that the "media fill should emulate the regular product fill situation in terms of equipment, processes, personnel involved and time taken for filling as well as for holding." There are considerations on time, inert gas versus sterile filtered air, the medium, temperature and pH. The guide continues to discuss, in section 4, the different formulations like liquid products, injectable powder products, suspension products, freeze dried (lyophilized) products, and continues on with semi-solid products (e.g., sterile ointments).

In section 4.7, "Clinical Trials Materials and Small Batch Size Products," paragraph 4.7.1 states: "As processes for smaller quantities (less than 3000 units) do not allow an interpretation,

It is quite astonishing, that retrospective validation is quoted as a potential option.

according to chapter 5 of these recommendations, any presence of microbial contamination should be regarded as an alert limit. Monitoring and test conditions, like incubation or media selection remain the same as for commercial production runs." That is followed by paragraph 4.7.2 where it is written: "The size of media fills for small batch size products should at least equal the number of containers filled for the commercial product." This leaves room for interpretation of what would constitute an acceptable scenario and if a bracketing approach was feasible or if for each batch size a media fill simulation was necessary. It seems to be industry practice to have a media fill study run at the minimum volume and number of units that can be run on the equipment. All lower volumes and numbers of units would then be manufactured manually. Although, it is fair to say that for manual filling it can be extremely difficult to demonstrate that sterile products can be made. But this is out of the scope of the recommendations discussed here.

The approach to the "Biological and Biotechnology Products" in paragraph 4.8.1 is worth mentioning as it suggests that: "The manufacture of these products varies, such that there is not one single process. It may be more practical to validate the various segments of the process individually. The frequency of the revalidation should relate to the one of regular, commercial production." This is interesting, as here to have a "taylorized" approach is considered acceptable. The difficulty, however, is to show that no accumulation throughout the sequence is generated, or in other words the process as a whole is still conforming to the initial requirements. Without a good risk assessment and management processes for such segmented approaches, it is complicated to define alert, action and acceptance limits.

A similar approach is taken for "Sterile Bulk Pharmaceuticals," where it is written in paragraph 4.9.2: "The aseptic manufacture of sterile bulk drug substances is a difficult process, which may have numerous individual segments that need to be validated. The possibility of microbial ingress into the system has to be considered after each step of the routine production." And it continues in paragraph 4.9.3: "The validation may include segments, where the use of growth media is not feasible." If read literally, it could be interpreted as a step where no media fill simulation can be performed; hence, demonstrating that the process renders sterile product is based on a risk assessment and management exercise. This is complicated to demonstrate and needs special attention as well as occasionally some experimental evidence.

Process Simulation Test Conditions

Test performance criteria given in section 5.1 states that the media fill study should follow, as closely as possible, the process to simulate and that worst case conditions should be chosen. In paragraph 5.1.6 it mentions that "simulation tests should be performed on different days and hours during the week and not only at the beginning of a work day," and paragraph 5.1.8 says that: "In order to find the possible source of contamination it may be a good advise to video tape the aseptic fill and also number the individual vials or segregate vials in chronological order during incubation." These requirements are obviously trying to include as many variables as possible in the study and to make incidents of any kind traceable. It is also worth discussing the value of videotaping. If this was an appropriate tool to investigate deviations, there is no good argument to not do this on a routine basis. However, also the opposite is true: If it wasn't a help in such investigations, it will distract from other relevant routes to follow. It is foreseeable that with increased quality and resolution of monitoring by videotaping, this technique will one day become routine also in batch manufacturing. But, the more monitoring data that is available makes critical selection become an issue, and getting the crucial information turns into looking for a needle in a haystack.

With regards to test frequency, there are several interesting points to discuss. One being the concept of performing three consecutive and satisfactory "start-up" simulations to be followed by one periodic "on-going" simulation test. The guide describes that each shift and each process line should be covered; this in turn would establish the need for each individual operator to be included in such a study twice a year at least. Also, it is worth noting that the test includes process lines or better equipment and environment used. This in turn could be interpreted that, for example, all individual preparatory vessels, as they are part of the equipment forming a process line, need to be included in the test twice a year and that there is no waiver for identical parts, making it potentially, not feasible to test only one vessel as a substitute for all others.

Interpretation Of Data And Environmental And Personnel Monitoring

This chapters follows the EU GMP Guide as detailed in Annex 1. However,

there are some more precise indications given, for example paragraph 7.2.1 on non-viable monitoring gives the following guidance: "The location chosen for monitoring should be checked to ensure that the positions reflect the worst case. For room monitoring, the counts should be performed in locations where there is most operator activity. For the filling environment the counts should be performed adjacent to the filling zone and where components are exposed in such way as to detect operator activity within these areas. Monitoring with sampling probes located in such a way that they monitor the air from the HEPA filter rather than the air immediately surrounding the critical zones should be avoided. However, the location of the sample device should not compromise the laminarity of the air flow in the critical zone. Initial validation should be checked to confirm that worst case positions have been adequately identified. These may be reconfirmed during process simulation tests." A very similar statement is given on microbial monitoring in paragraph 7.3.2, so it boils down to the need to justify the location of monitoring devices, may it be probes or settle plates, by showing that they are close to or within zones of operator activity.

Staff Training

Chapter eight is focused on the training of all the people involved in the validation process. At section 8.1 it says, "The routine training of personnel who works in a controlled environment needs special emphasis as people are potentially one of the main source of micro organisms in the environment."

To move again on Agalloco's assertion that says we cannot validate aseptic processes with the same confidence level as other processes, one of the key points that we will have to discuss is the training, qualification and motivation, of the operators who must understand that between two media fill trials (MFT), each bad practice in the critical area may involve contaminations in one or a few number units that have almost no chance to be detected at final control of sterility.

It will be interesting to hear filter manufacturers discuss if and what new developments are foreseen to eliminate potential causes of contamination …

Important Factors In Validation Of Aseptic Manufacturing

This section discusses a not exhaustive list of other important factors. Those include container/closure integrity testing; equipment cleaning and sterilization; disinfection; filter validation; vent filters; equipment maintenance and testing; blow fill/form fill seal; and sterility testing.

Just to pick two of those which will be discussed during the *PDA 2009 Workshop on Validation of Aseptic Processes,* it is interesting to read in paragraph 9.3.2.1 about clean-in-place/sterilize-in-place (CIP/SIP): "Validation of these systems may be difficult because of the potential incompatibilities in requirements for the design of CIP and SIP facilities. All systems have dead legs to a greater or lesser extent and the required orientation of the dead legs differ for CIP and SIP. The orientation for CIP dead legs is slightly sloping so that the cleaning solution can enter and also drain away. The dead leg for SIP is vertically up so that steam can downwardly displace the air." This clearly puts burden on the qualification and validation aspects of such solutions to demonstrate that this inherent issue is taken care of. Another topic cited is vent filters, in paragraph 9.6.1 it is written: "It is important that the integrity of critical gas and air vent filters is confirmed immediately after the filling and if it fails, the disposition of the batch determined. In practice, vent filters fail the integrity test more frequently than product filters, as generally they are less robust and more sensitive to pressure differentials during steam sterilization." From a user point of view, it will be interesting to hear filter manufacturers discuss if and what new developments are foreseen to eliminate this potential causes of contamination at the upcoming PDA workshop in Milan.

In summary, it can be stated, that aseptic manufacturing is a special, complex and very demanding production. It relies on excellent performance of man and machine at all times. It is also evident, that of these two components, man is the most unpredictable one. The PDA workshop on Validation of Aseptic Processes, in Milan, Italy on December 1-2, is designed to help get the right understanding of what technology is out to make better medicines in aseptic manufacturing and what operators need to learn and understand about criticality in their practical process executions.

And to finish with common sense…two principles that must be remembered and will be discussed for those that conceive the validation master plan and the MFT procedures: One cannot validate "bad practices" by MFT, even if you win three times you were only lucky!

Only validate what production needs!

We hope to see you there.

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Container Closure Systems and Products Lifecycle
October 8, 2009, 1:00 p.m. - 2:30 p.m. (ET)

The container closure system is an intrinsic part of the parenteral product and essential to delivery and handling of the pharmaceutical product. It defines the closure, protection and functionality of a container while ensuring the safety and quality of the drug product over the product shelf life. Changes to components and materials, suppliers and processing flow are also part of product life cycle. This presentation will discuss general aspects related to the parenteral container closure systems qualification for their intended use. Case studies for implementation of the change to components and modernization of container closure systems for marketed products will be presented.

Presented by

Mihaela Simianu, PhD
Research Advisor, Manufacturing Science and Technology
Eli Lilly and Company

New Technologies to Meet Temperature Challenges During Storage and Transportation
October 13, 2009, 1:00 p.m. - 2:30 p.m. (ET)

Transportation has been identified as the weakest link of the drug supply chain in terms of temperature control. As a consequence, it is necessary to implant appropriate temperature control strategies to fully comply with the various guidelines for temperature control of drug products during transportation. In this presentation, we explore the latest available equipment for a safe and efficient supply chain, and to ensure the implementation of the right technologies. This comprises monitoring solutions, such as time-temperature indicators, data loggers, RFID sensing technologies, but also the various models of insulated shippers and refrigerants. Environmental control systems that are inexpensive and don't burn fuel are also reviewed as well as temperature-controlled transportation modes.

Jean Bédard, MBA
Vice-president and CEO
Alternative Technologies Pharma, Inc.

Managing Cleaning Validation & Assessments Sans Paper - A Case Study
October 21, 2009, 1:00 p.m. - 2:30 p.m. (ET)

This web seminar demonstrates Paperless Cleaning Validation and Assessments. This Paperless platform leverages web 2.0 technology to change the current paradigm. This platform can increase efficiencies while saving millions of dollars for the FDA regulated industry. Attendees will witness this paperless platform in action. The current fiscal state of the pharma industry coupled with FDA's Quality by Design (QbD) initiatives makes it inevitable for the status quo to take the typewriter route.

Jim McElroy
Manager,
Compliance Engineering
Novartis

Nagesh Nama
President
ValiMation, Inc.

Membrane-based Sample Preparation for Mycoplasma or Virus Capture, Lysis, and Nucleic Acid Purification and Detection
October 29, 2009, 1:00 p.m. - 2:30 p.m. (ET)

The detection of mycoplasma and viral contamination in a timely, simple, and effective manner is a subject of high interest in biopharmaceutical manufacturing. Mycoplasma and viral detection based on growth and infectivity assays, respectively, are time-consuming and labor intensive. Traditional microbiological methods could advantageously be replaced by Nucleic Acid Amplification Testing for earlier detection. These methods are nonetheless hampered by their companion sample preparation methods.

Julie R. Murrell, PhD
Senior Scientist
Millipore Corporation

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When to identify ?

"Sequencing of the 16S ribosomal RNA gene to identify the class, order and genus of a microorganism is now an integral part of the approach to microbial taxonomy, but this gene is not useful for identifying many microbes at the species level."

Source: RECONCILING MICROBIAL SYSTEMATICS AND GENOMICS - ASM REPORT 2006

"With many isolates phenotypic identification is completely adequate and the added expense of using a genotypic identification system is not justified."

VITEK 2 compact

Source: PDA JOURNAL OF PHARMACEUTICAL SCIENCE AND TECHNOLOGY, 2008.

When to investigate ?

"...it may be necessary to employ sensitive typing techniques to demonstrate that a microorganism isolated from the product test is identical to a microorganism isolated from the test materials and/or the testing environment."

Source: EP 5.1.9

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