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PDA Letter

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May 2006

In This Issue…

PDA Parenteral Drug Association

Connecting People, Science and Regulation℠

An Interview with Emer Cooke: The EMEA Inspections Sector

In planning for the PDA/EMEA Joint Conference, PDA had the opportunity to talk with **Emer Cooke**, Head of Inspections Sector, EMEA, about the functions of the Sector and current issues of interest to the EMEA. The interview was guided by **Tim Marten**, DPhil, AstraZeneca, member of the PDA Board of Directors and the co-Chair (along with **Anders Vinther,** PhD, of CMC Biopharmaceuticals) of the PDA/EMEA Joint Conference. Cooke is the lead EMEA member of the conference planning committee.

Note: The views stated in this interview, are those of the interviewee and should not be construed or quoted as made on behalf of the EMEA and/or its scientific committees.

Tim Marten: Can you explain for our readers your role in the EMEA?

Emer Cooke: I am head of the inspections sector in the EMEA. To understand what that means I must explain a little about how the EU is structured. The EMEA is the technical and scientific secretariat that coordinates the work of the EU Member States in the area of authorization and supervision of medicinal products. The inspections sector is responsible for coordinating inspections in the areas of GMP, GLP and GCP that are requested by scientific committees of the EMEA. We also coordinate requests for inspections in the area of pharmacovigilance.

…I've also learned there is rarely a right or a wrong way of doing things—there are simply different ways.

Can you share with us your background, and your "path" to the EMEA?

I'm a pharmacist, with a post-graduate degree in pharmaceutical chemistry and a Masters in Business Administration. I worked in

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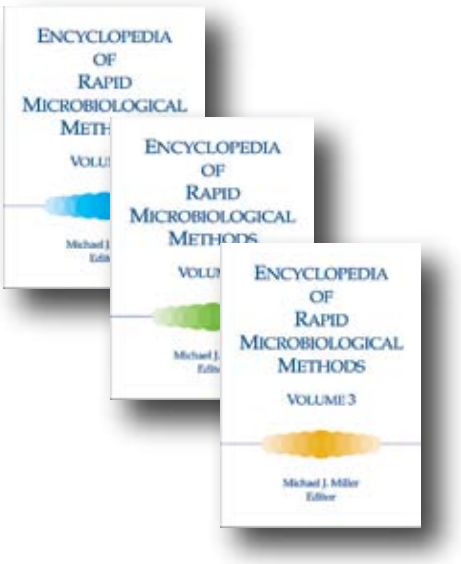

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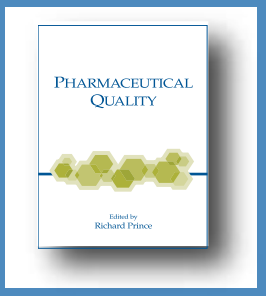

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PDA Past Leader Spotlight: Clarence Kemper, PhD, President 1994-1995

Walter Morris, PDA

This year, in celebrating PDA's 60th anniversary, the *PDA Letter* is publishing a series of articles highlighting important contributors to the Association. This month, the "Past Leader Spotlight," continues with Dr. Kemper, who was the first volunteer head of the Board to be called "Chair." At the same time, the title of PDA's paid Executive Director was changed to "President."

PDA: How/why did you become involved with PDA?

Kemper: I first became involved with PDA as an exhibitor. From the time I became president of Kaye in 1961 until the early 1970's, Kaye was primarily a consulting firm. Then, in 1972, we introduced our System 8000, which was a very accurate data logger for measuring temperature with thermocouples. I think it was in 1974 that we got a call from someone at Baxter Laboratories wanting to know if the System 8000 could be used for monitoring the temperature of rabbits in pyrogen testing. While we were demonstrating its capabilities, one of the engineers asked if it could be used to measure the temperature inside a steam autoclave. That meeting was a turning point for Kaye Instruments, because within a few months both Baxter and Abbott were buying System 8000's to measure the temperature distribution inside their steam autoclaves. At that time, FDA was starting to require validation of steam sterilization processes to accuracies that could not be achieved with the instrumentation that had been used in the past. FDA's initial focus was on the large-volume parenteral manufacturers such as Baxter and Abbott.

In one of my meetings at Abbott, someone asked if we could make a system with an output that looked like a strip-chart recorder. That led to the development of our Digistrip Recorder, which was the first system that we sold specifically to the pharmaceutical industry. In the summer of 1976, I asked our contacts at Abbott and Baxter if there was an organization representing the pharmaceutical industry that might have a trade show where we could demonstrate our data loggers. They both said that there was a small organization called the Parenteral Drug Association in Philadelphia that had a meeting in New York every year, and that the meeting was coming up in just a few months. When I first called the PDA office they said they were completely booked for exhibits, but that they would put us on a waiting list. In about two weeks they called back and said they had a small booth if I wanted it.

We were still a very small company at the time, so my wife and I put some equipment in the car and drove down to New York. The response was overwhelming. People were lined up at our booth and my wife was writing down names while I demonstrated the equipment. As a result of that meeting, we had more leads than we could handle. For the next couple of years we had trouble just keeping up with the orders generated from that 1976 meeting, and from subsequent PDA meetings. There is no question that our introduction to PDA was a major factor in the growth we experienced after that, and from 1976 on we went to every PDA meeting that had an exhibit.

PDA: What made you decide to run for the PDA board of directors?

Kemper: As I recall, **Fred Carleton** [PDA Executive Director, 1988-1991, past PDA president and board member] asked me if I would become a director. Fred was a major force within PDA at that time and I am sure I was elected because of his endorsement. I was a little surprised, because back then incumbents would usually get re-elected, and there were relatively few new directors. I served continuously on the Board from 1980 through my term as past president, which was 1997.

PDA: It is really not quite accurate to say you rose through the ranks of service at PDA. You went right to the Board.

Kemper: Yes, PDA was just starting to form committees back then, and there weren't a lot of committees you could serve on. Most of the committees were regulatory committees formed to respond to some FDA action or proposed action. The mid-1970's was when the industry was suddenly faced with the validation issue, and we were trying to figure out exactly what we had to do and how we should respond to some of FDA's guidelines. I think almost all of the committees that were put together back then were technical committees addressing those issues.

PDA: So the regulatory component has really been an important function of PDA?

Kemper: Oh, absolutely. In fact, to me, that was one of the strengths of PDA. The Association was an effective avenue of communication with FDA on a technical level, as opposed to ➤

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the PMA, which dealt much more with the management and legal level. I think PDA filled a very valuable role in helping to get an understanding, from a technical standpoint, between FDA and the industry in terms of how things should be done on the shop floor—real how-to information.

PDA: By the 1990's, the international focus of PDA was broadening, with a few international chapters functioning. What was it like for you to be one of the leaders of PDA during this exciting time of rapid growth and great contribution of the organization?

Kemper: It certainly was. **Ed Fry** had taken over as Executive Director in 1991, about three years before I became president. It was extremely exciting. I remember Ed, my wife and I took a trip to Southeast Asia, visiting Australia, Singapore, and Indonesia. We spent several weeks over there meeting with people who wanted to form chapters and become associated with PDA. On another trip, we visited Japan and Taiwan. Japan already had a chapter that was very active. I remember the industry in Taiwan was most anxious to form a PDA chapter, as were the industries in Singapore, Indonesia and Australia on our previous trip. All four places formed chapters shortly after our visits.

Of course, PDA was also trying to grow in Europe. We had several very successful meetings in Basel, Switzerland, and were starting to look at how to expand in Europe. We entered into memorandums of understanding with the three European associations that were most similar to PDA (Parenteral Society, UK; A3P, France; and R^3 Nordic) primarily because they were concerned that PDA might become the elephant in the room that tried to take over Europe. Overall, it was a really exciting period and one of tremendous expansion and recognition for PDA, not just domestically, but worldwide.

PDA: Why was Basel selected as the site of the annual meeting at that time?

Kemper: Actually, I was responsible for that, because I knew somebody in Basel—the representative for Kaye in Switzerland—**Bernard Kronenberg**. Bernard was a very active person with good contacts in the pharmaceutical industry. We wanted to have a European meeting, and Bernard said we should look at Basel, because they had a great conference facility and a strong pharmaceutical industry right in the city. I visited there, looked at the conference center, and came back and recommended it to Ed. Bernard was very helpful with that first meeting in getting people to come to the meeting, and in helping us actually run the meeting.

PDA: How important to PDA has this international outreach been?

Kemper: The whole industry had become global, and I think the big concern during my presidency was trying to harmonize global regulations, particularly among Japan, Europe and the United States. It was recognized that we should strive to harmonize regulations throughout the world, but if we could at least get Japan, Europe and the United States harmonized, it would be very beneficial for everyone. I chaired a committee on computer validation that was global. We had representation from Europe and the United States. It was very important to try and get that area harmonized because everybody was going down different paths. I think PDA still would have been a very important association even if it had stayed just domestic, but I don't think it would have been quite as important, nor would it have been recognized quite as well as it is now.

PDA: This early outreach has culminated in events like the first ever PDA/EMEA conference later this year. It shows that you and your colleagues from a decade ago have left quite a legacy for PDA.

Kemper: The PDA/EMEA conference is tremendous. I think the real changes started with the Strategic Plan that was developed during **Bob Keiffer's** term as president [1986-1987]. There were a lot of things in that plan that we took seriously and began to expand the organization into other technologies, specifically biotech and medical devices, and also to expand geographically. When I joined PDA, the membership was almost all in the northeast and in the Chicago area. In the late 1980's and early 1990's there were a few members of the board that wanted PDA to limit its activities to parenteral products, but most of our leaders at the time, including **Jim Agalloco**, **Mike Korczynski** and **Jim Akers,** felt that expansion was important for the future of PDA.

PDA: Let's move on to the Chapters. I'm not sure of your role in them. I know Fred Carleton and Mike Korczynski were strong advocates for them.

Kemper: As I recall, Fred Carleton was one of the strongest advocates for chapters, when he worked for PDA as Executive Director. The Japan Chapter had just been formed when I was president, and Fred and Mike formed a few other chapters. The Board suddenly woke up to the potential that we had in forming chapters and decided that we should make chapter formation a little more ➤

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structured with formal board approval. They decided to set guidelines on how chapters would be formed and how they would relate to the central organization. While I was always supportive of chapters, I didn't play any specific key role in their development. I would say it was Fred Carleton number one and Mike Korczynski number two who spearheaded the chapter movement.

PDA: Did you play a role in formalizing any of the rules to govern the chapters?

Kemper: Oh yes. Those rules were developed in the early 1990's, and even through my presidency we were still struggling with some of the issues. I think the rules were developed over a period from about 1989 to about 1998. They were pretty well settled by the time my presidency was over, but there were still some outstanding issues.

PDA: Diversity was a concern back in the 1990's. You oversaw changes to PDA's governance that addressed this issue.

Kemper: Yes, in the early 1990's there was concern that the PDA Board generally consisted of the same people. This was not surprising because these were people who worked very hard for PDA, and who had been the cornerstones of making the organization grow. When they would run for reelection, they would always get elected. It was very difficult for any new person to be elected to the board. You might have one or two each time, but that was it.

There were a number of people who thought it would be better to get some turnover on the board, and there were a number of other ideas for change floating around at the same time. As a result, we decided to redraft the bylaws. I basically took that task on as my responsibility, although a lot of other people worked on it, and I pulled it all together. We put in term limitations and the automatic progression from chair-elect to chair and chair to past-chair. That is also the time we changed the name of the top volunteer person from "president" to "chair" and renamed the "executive director" "president."

Some people had been unhappy with the nominating committee on occasion in the past, because they had nominated some of their own members to the board. They were the best-qualified candidates, so there should have been no problem, but to address those concerns, we decided that the chair-elect, the chair, and the past-chair would be the nominating committee. Since none of these three people would be running for anything, we thought that was a solution to any concerns. I think it has worked out very well. At least I haven't heard any complaints.

PDA: The new system with the chair-elect, chair and past-chair all on the board has resulted in new blood as well as preserving institutional knowledge. It is unique. Was it a novel approach or something you had seen elsewhere?

Kemper: Actually, I had seen the chairman progression part in an organization that my wife was involved with at the Museum of Fine Arts, Boston. Under that system, you have a three-person team leading the organization. The chair-elect has two years to prepare to become chair and the person who just left the chair is there to pass on his or her experience and knowledge.

PDA: Around your time as president, the PDA/FDA Joint Regulatory Conference was becoming one of the Association's signature meetings. What did this meeting mean to the Association by the time you were president?

Kemper: Ed Fry was very instrumental in developing a cooperative attitude between PDA and FDA. I guess the annual meeting was still bigger than the FDA meeting when I was president, but it was very close. But in terms of importance, the FDA meeting was considered the most important meeting. I was with Kemper-Masterson (KMI) at the time, and came to all of the PDA/FDA meetings, because that was our business then— trying to get FDA approval for our customer's manufacturing facilities. To us the PDA/FDA meeting was the most important meeting of the year anywhere.

PDA: When did you form KMI?

Kemper: I left Kaye and formed KMI in 1989. Even that career move was the direct result of a PDA activity with which I was involved. As I mentioned previously, I had been chair of the PDA committee on the validation of computer systems. In the mid-1980's, FDA came out with a requirement that all computer systems used in GMP applications had to be validated. But nobody knew exactly what that meant. As a result, PDA formed a committee to help establish guidelines. We had **Ron Tetzlaff** from FDA on the committee and a really outstanding group from industry. That was in the mid 1980's. By 1989 I felt there was a need to form a consulting firm to attack that specific problem. I was very fortunate to have **Mike Masterson** as a partner in that venture. Mike had been the Manager of Application Engineering at Kaye, so we knew each other well.

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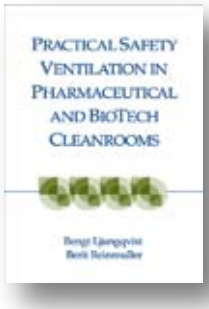

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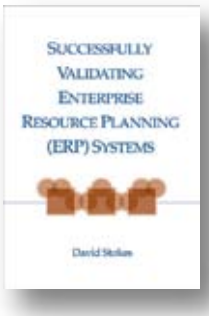

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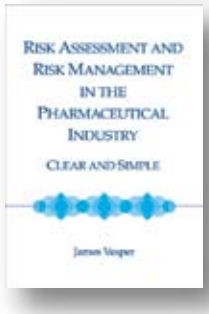

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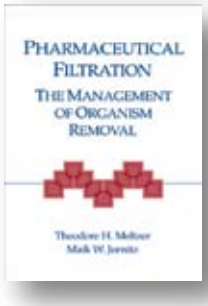

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Recent Sci-Tech Discussions:
GLP/GMP Regulations vs. ISO 9000

The following unedited remarks are taken from PDA's Pharmaceutical Sci-Tech Discussion Group, an online forum for exchanging practical, and sometimes theoretical, ideas within the context of some of the most challenging issues confronting the pharmaceutical industry. The responses in the Sci-Tech Discussions do not represent the official views of PDA, PDA's Board of Directors or PDA members. Join at www.pharmweb.net/pwmirror/pwq/pharmwebq2.html.

In this month's PDA Pharmaceutical Sci-Tech Discussion Group selections, we continue the debate about the value of ISO standards to a GMP/GLP-compliant pharmaceutical manufacturer/laboratory. The debate started over a simple question about the difference between ISO 9000 and the regulations. Below, we pick up the dialogue with the 14th respondent. In the April issue of the PDA Letter, we published responses 9-13.

What are the differences between GLP/GMP and ISO 9000 regulations in the pharmaceutical industry? Are GLP/GMP fully compatible with Total Quality Management? For me, the fundamental difference between GMP and ISO is that both have different agendas: GMP is mandatory; ISO is an unnecessary complication.

Respondent 14: I have long believed that GMP facilities should be adequate and that ISO was a creation by consultants to create a new very profitable venue….I have in recent years been appalled by the condition of several contract manufacturers in the United States and the failure of FDA inspectors to find incompetence at the facilities or even when found, to take significant action as most likely the companies would go under trying to comply.

The benefit of ISO is that all facilities would be required to be audited by a third party, and, as long as those third parties can remain objective, the facilities would have to maintain a level of quality to remain certified. I am fast leaning towards the fact that the only way to ensure manufacturers of drug product are in control is to require something like ISO cert….

Respondent 15: From a U.S. regulatory perspective, you might want to reference the FDA's June 2003 FAQ (Frequently Asked Questions) statement on the relationship between the FDA's quality system regulation for devices, Part 820, and ISO 9001, the status of harmonization, and the reasons why FDA chose harmonization over ISO adoption. Please refer to fda.gov/cdrh/devadvice/iso9001.pdf for the file.

Respondent 16: A firm can't overlook the GMP regulations as they are bound to law. But it can overlook the ISO regulations, and the worst loss it can face is it may lose the ISO recognition (or alternatively a firm [might not apply for ISO renewal]). They can apply fresh for the ISO license after a period of time without having impact on the past….

Apart from that one can't say that only GMPs are politicized. With increasing number of third parties (for ISO audits), lack of territory restriction of these third parties, and a competition between these third parties may result in politicizing ISO also.

If a firm alternatively wishes to go hand in hand with GMP and ISO, it would ultimately result in improving quality and customer satisfaction, in addition to increasing the final price/cost of the product….

Respondent 17: I was very recently in Cyberabad, India (a suburb of Hyderabad), performing a GMP assessment. On the way to the factory, there were several large signs at the side of the road proclaiming that: "You are entering Cyberabad, India's first ISO 9000 police district." When I asked my local company hosts what this meant to them, they advised that since the awarding of ISO 9000 certification to the local police district two years previously, it now took five times more forms to be completed to report a crime, and that the success rate of the police in solving crimes had fallen dramatically since being granted ISO 9000 certification….

Respondent 18: I will agree with [Respondent 17's] story about Cyberabad. There may be many more such stories. I would also like to add that here, at least in India, my opinion about ISO is [as said previously] "the example of a process becoming an endpoint unto itself and more important than the original goal it was intended to address."...When I was in an engineering consulting firm long back (1994) when very few Indian companies were having ISO certification, my company had just [been ISO certified]. [The] joke was "you have to follow design steps written in the manual—even if the ➤

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manual was wrong—without any argument."
I have seen in same Hyderabad a pharma unit operating in a hut like shed proclaiming ISO certification….

Respondent 19: I've read on this board about how great ISO is compared to GMP as a quality system. I'm not convinced. I worked at a non-pharma biotech that was ISO certified, by none other than Lloyd's, and our quality systems were okay, but not as good as some of the non-ISO pharma quality systems I had worked under previously or since. I think that sums it up for me. You have to see ISO and GMP when they're not combined to appreciate the strengths and weaknesses of both.

Respondent 20: It may be worth looking at the UK "Orange Guide." In Chapter 1 "Quality Management" it states in the introductory "Principle" paragraph:

"...there must be a comprehensively designed and correctly implemented system of Quality Assurance (QA) incorporating Good manufacturing Practice (GMP) and thus Quality Control (QC)...."

The clear implication is that GMP is a subsidiary part of a Quality Management System and is not a QMS in itself. ISO on the other hand clearly is a QMS.

PDA Past Leader Spotlight: Clarence Kemper, PhD, President 1994-1995, continued from 10

In 1991, Ron Tetzlaff agreed to join our staff, which had a tremendous impact on the growth and future of KMI. Once again PDA played a role, because if Ron had not gotten to know me through the computer validation committee I doubt he would have left FDA to join our firm. One of the reasons that KMI grew so rapidly and had such a good reputation was that people knew us through PDA. A consulting relationship is built on trust, and PDA helped us establish that trust. PDA certainly played a very important roll in my business life from the mid-1970's through the 1990's.

PDA: What do you do now?

Kemper: My wife and I are enjoying retirement. We built a new home in Winchester, Massachusetts and are just enjoying retirement.

PDA: Dr. Kemper, on behalf of PDA, I want to thank you for taking this time to speak with me. We hope to see you, if possible, at the 2006 PDA/FDA Joint Regulatory Conference to help us celebrate our 60 years.

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PDA Interest Groups & Leaders

PDA Interest Groups are divided into five sections by subject matter. This aligns them for improved effectiveness, supports increased synergies between them and provides opportunity for Interest Group members to play a more active role in Task Forces. The five sections are Quality Systems and Regulatory Affairs, Laboratory and Microbiological Sciences, Pharmaceutical Development, Biotechnological Sciences and Manufacturing Sciences. Any PDA member can join one or more Interest Group. Please go to www.pda.org/science/IGs.html for more information or contact the Interest Group's leader.

North American Interest Groups

Section Leader	Frank Kohn, PhD *FSK Associates*	David Hussong, PhD *U.S. FDA*	Don Elinski *Lachman Consultants*	Sandeep Nema, PhD *Pfizer Inc.*	Robert Dana *PDA*
Section Title	**Biopharmaceutical Sciences**	**Laboratory and Microbiological Sciences**	**Manufacturing Sciences**	**Pharmaceutical Development**	**Quality Systems and Regulatory Affairs**
Related IGs and Group Leaders	**Biotechnology** Group Leader: Frank Matarrese *Frank Mataresse GxP Consulting* E-mail: frank_matarrese@alamedanet.net **Lyophilization** Group Leader: Edward H. Trappler *Lyophilization Technology* E-mail: etrappler@lyo-t.com **Vaccines** Group Leader: Frank S. Kohn, PhD *FSK Associates Inc.* E-mail: fsk@iowatelecom.net	**Analytical Labs/ Stability** Group Leader: Rafik H. Bishara, PhD *Eli Lilly & Co.* E-mail: rafikbishara2@yahoo.com **Microbiology/ Environmental Monitoring** Group Leader: Jeanne E. Moldenhauer, PhD *Vectech Pharm. Consultants, Inc.* E-mail: jeannemoldenhauer@yahoo.com **Visual Inspection of Parenterals** Group Leader: John G. Shabushnig, PhD *Pfizer Inc.* E-mail: john.g.shabushnig@pfizer.com	**Facilities and Engineering** Group Leader: Don Elinski *Lachman Consultant Services, Inc.* Email: d.elinski@lachmanconsultants.com **Filtration** Group Leader: Russ Madsen *The Williamsburg Group, LLC* E-mail: madsen@thewilliamsburggroup.com **Pharmaceutical Water Systems** Group Leader Theodore H. Meltzer, PhD *Capitola Consulting Co.* E-mail: theodorehmeltzer@hotmail.com **Sterile Processing** Group Leader: Richard Johnson *Fort Dodge Animal Health* E-mail: johnson@fdah.com	**Clinical Trial Materials** Group Leader: Vince Mathews *Eli Lilly & Co.* E-mail: vlm@lilly.com **Combination Products** Group Leader: Michael Gross *QLT Inc.* E-mail: mgross@qltinc.com **Packaging Science** Group Leader: Edward J. Smith, PhD *Wyeth Pharmaceuticals* E-mail: smithej@wyeth.com **Process Validation** Group Leader: Harold Baseman *ValSource, LLP* E-mail: halbaseman@adelphia.net	**Inspection Trends/ Regulatory Affairs** Group Leader: Robert L. Dana *PDA* E-mail: dana@pda.org **Quality Systems** Group Leader: David Mayorga *Global Quality Alliance, LLC* E-mail: david@gqaconsulting.com

European Interest Groups

Section Title	Biopharmaceutical Sciences	Laboratory and Microbiological Sciences	Manufacturing Sciences	Pharmaceutical Development	Quality Systems and Regulatory Affairs
Related IGs and Group Leaders	**Biotechnology** Group Leader: Roland Güenther *Novartis Pharma AG* E-mail: roland.guenther@pharma.novartis.com **Lyophilization** Group Leader: Edward H. Trappler *Lyophilization Technology* E-mail: etrappler@lyo-t.com **Vaccines** Group Leader: Frank S. Kohn, PhD *FSK Associate Inc.* E-mail: fsk@iowatelecom.net	**Visual Inspection of Parenterals** Group Leader: Markus Lankers, PhD *Rap.ID GmbH* E-mail: markus.lankers@rap-id.com	**Facilities and Engineering** Group Leader: Philippe Gomez *Sartorius SA* Email: Philippe.gomez@sartorius.com **Filtration** Group Leader: Philippe Gomez *Sartorius SA* Email: Philippe.gomez@sartorius.com	**Drug Device Delivery** Group Leaders: Alexandra Schlicker, PhD *F. Hoffman La Roche AG* E-mail: alexandra.schlicker@roche.com Georgios Imanidis, PhD *University of Basel, Pharamceutical Technology* E-mail: georgios.imanidis@unibas.ch	**Nanotechnology** Group Leader: D F Chowdhury *Aphton BioPharma* E-mail: Fazc@aol.com **Technology Transfer** Group Leaders: Volker Eck, PhD *Nerviano Medical Science S.r.l* E-mail: Volker.eck@nervianoms.com Zdenka Mrvova *Zentiva* E-mail: mrvova@leciva.cz

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- Pharmaceutical Water Systems, Design and Validation
- Risk Management
- Root Cause Investigation for CAPA
- Sterile Pharmaceutical Dosage Forms: Basic Principles

Venue

Sheraton Westport Conference Center
600 Westport Plaza
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PDA Calendar of Events for North America

Please visit www.pda.org for the most up-to-date event information, lodging and registration.

Conferences

May 8-12, 2006
2006 PDA Biennal Training Conference
(Conference, Courses and Exhibition)
Philadelphia, Pennsylvania

July 27, 2006
Status of Moist Heat Sterilization: Revisions to PDA TR-1
Washington, D.C.

September 11-15, 2006
PDA/FDA Joint Regulatory Conference
(Conference, Courses and Exhibition)
Washington, D.C.

October 23-25, 2006
Prefilled Syringes and Drug Delivery Systems
(Conference and Exhibition)
Bethesda, Maryland

October 30, 2006
PDA's 1st Annual Global Conference on Pharmaceutical Microbiology
(Conference and Exhibition)
Bethesda, Maryland

Training

Lab and Lecture events are held at PDA TRI Baltimore, MD unless otherwise indicated.

Laboratory Courses

May 22-24, 2006
Developing a Moist Heat Sterilization Program within FDA Requirements

June 1-2, 2006
Environmental Mycology Identification Workshop

June 28-30, 2006
Environmental Monitoring Database and Trending Technologies

July 18-21, 2006
Pharmaceutical and Biopharmaceutical Microbiology 101

July 25-28, 2006
BioManufacturing Technologies

August 7-11, 2006
Rapid Microbiological Methods

Lecture Courses

May 15-17, 2006
Biotechnology: Overview of Principles, Tools, Processes and Products

September 20-21, 2006
Computer Products Supplier Auditing Model:Auditor Training

Course Series

May 11-12, 2006
PDA Biennial Training Conference Course Series
Philadelphia, Pennsylvania

June 13-14, 2006
Vancouver Course Series
Vancouver, British Columbia, Canada

August 7-9, 2006
St. Louis Course Series
St. Louis, Missouri

September 14-15, 2006
PDA/FDA Joint Regulatory Conference Course Series
Washington, DC

Chapters

May 9, 2006
PDA Metro Chapter
Microbiological Considerations for Oral Solid Products
Clark, New Jersey

May 16, 2006
PDA Southeast Chapter
Operational Excellence in Pharmaceutical and Biotechnology Manufacturing
North Carolina Biotech Center

May 17, 2006
PDA New England Chapter
FDA Inspections
Lexington, Massachusetts

May 18, 2006
PDA Midwest Chapter
Vendor Night and Discussion Groups
Northbrook, Illinois

May 18, 2006
PDA West Coast Chapter
Comparability Protocol Panel Discussion
Millbrae, California

June 7, 2006
PDA Metro Chapter
Viral and Mycoplasma Clearance
Clark, New Jersey

June 12, 2006
PDA Canada Chapter
Annual Meeting
Vancouver, British Columbia

Chapters (cont.)

June 28, 2006
PDA Capital Area Chapter
FDA Inspections and Quality Trends
Gaithersburg, Maryland

July 14, 2006
PDA Delaware Valley Chapter
Risk Assessment
Malvern, Pennsylvania

July 20, 2006
PDA Midwest Chapter
Application of Bacterial Spore Inactivation Kinetics to Risk Estimation in Sterilization Processes
Northbrook, Illinois

August 4, 2006
PDA Midwest Chapter
2nd Annual Golf Outing

Europe/Asia Pacific/Middle East

Please visit www.pda.org for the most up-to-date event information, lodging and registration.

Europe

May 23-24, 2006
Process Understanding and the Future of Validation
(Conference and Exhibition)
Barcelona, Spain

June 7, 2006
PDA Ireland Chapter
Moist Heat Sterilization
Cork, Ireland

June 7, 2006
Status of Moist Heat Sterilization: Revisions to PDA TR-1
Cork, Ireland

June 8, 2006
Status of Moist Heat Sterilization: Revisions to PDA TR-1
London, England

June 19-20, 2006
PDA Training Workshop 2006: FDA's Aseptic Processing Final Guidance
(Workshop and Exhibition)
Prague, Czech Republic

June 27, 2006
Status of Moist Heat Sterilization: Revisions to PDA TR-1
Pavia, Italy

September 27-28, 2006
2006 Visual Inspection Forum
Berlin, German

October 10-13, 2006
PDA/EMEA Joint Conference
(Conference, Courses and Exhibition)
London, England

Asia/Pacific

November 13-17, 2006
2006 PDA Asia-Pacific Congress
(Congress, Courses and Exhibition)
Tokyo, Japan

Online Events

Web Seminars

May 3, 2006
Streamlining Success: Supply Chain Management
1:00 p.m.-2:30 p.m. EST

May 10, 2006
PDA Update: Process Validation of Protein Manufacturing - PDA Technical Report #42
1:00 p.m.-2:30 p.m. EST

May 17, 2006
Validation of Bioreactors in a Biological Production Facility
1:00 p.m.-2:30 p.m. EST

May 24, 2006
Preventing OOS Deficiencies: A Guide to Regulations
2:00 p.m.-2:30 p.m. EST

Quality System Implementation in Start-up Medical Research Companies

Arvilla Trag, Midwest Consulting Services, Inc., and Ursula Busse, PhD, Medicago Inc.

Compliance to regulatory requirements is mandatory for any company in the health sciences sector. This includes young start-up companies, even those that are so virtual that discovery research is contracted out. Quality system implementation is not easy to accomplish for most companies, and it is even more difficult to do in start-up companies due to their particular nature. In this paper, we propose solutions to some of the most common obstacles faced during quality system implementation in these companies.

The Brain of a Quality System: Management

The Problem – Academic Mindset

Many biopharmaceutical/pharmaceutical start-ups are founded by and/or hire the most brilliant research minds in the particular area of focus. In our experience, the professionals in such firms usually have a discovery research background, frequently from an academic institution, and seldom from industry. They understand their area of expertise in exquisite detail, but may have little familiarity with regulated industry. In this new environment, they must be creative and at the same time follow an entirely new set of restrictive rules. For some, the two criteria can appear contradictory. Many in research feel that quality systems are restrictive interfere with their creativity and generate unnecessary paperwork. Compounding the problem is the unfounded belief that quality is the sole responsibility of the quality assurance (QA) and quality control (QC) groups. We often find that attempts to implement a quality system at the research-based companies can result in severe culture shock and resistance to change.

The Solution – Cultural Change from the Top Down

Quality system implementation in an academic environment needs to be accompanied by a cultural change that is promoted from the top down. Visible upper management support, leadership by example and active management participation in the quality system are an absolute necessity for an effective culture of compliance, regardless of the size of the company.

We have found the most efficient way to obtain management support for a quality system is by adopting a marketing strategy and literally selling the concept. Executives tend to be concerned about cost and return on investment; they need to recognize that a quality system is an investment and not an expense. The cost of non-compliance may far outweigh the cost of a quality system. Research scientists, on the other hand, worry about the quality of the data on which they base important decisions and about delays in project timelines. They need to realize that quality systems ensure data reliability, reproducibility and traceability, thus advancing their research by improving the quality of their documentation. Additional suggestions to promote cultural change appear in the box at the right.

Attaining Management Support for Quality Systems

- Involve people actively and be open to their suggestions. Staff from all disciplines will be more willing to adhere to quality system requirements if they feel that their expertise has contributed to the system.
- Select the loudest skeptics (not always easy!) and the natural leaders in the lab (people that other employees listen to) for the QS team.
- Use visual reminders. Like street signs that remind drivers of traffic rules, visual reminders in the lab will remind people that they need to follow an SOP for this particular equipment, fill out a form etc. This helps change their working habits.
- Promote the use of a common terminology. Language is an important part of culture; teaching people the right "GxP" terminology and harmonizing the use of these terms across the organization promotes cultural change.

Once management is convinced of the importance of a quality system and understands that it must take active leadership role in the implementation and maintenance thereof, half of the battle is won.

Next, quality must become a concern for each department, rather than the sole responsibility of QA. Ways to achieve this include incorporating quality compliance into project goals for all team members and emphasizing the connection between quality and other company goals such as sound science, IP protection and company success. ➤

Announcement and Call for Papers

2006 PDA Asia-Pacific Congress

Tokyo, Japan ◆ 13-15 November 2006

Call for Papers

Dear Colleagues,

PDA is seeking scientific abstracts for presentations 20 minutes in length, that present lectures, case studies and experiences in the following areas:

- International regulatory and harmonization initiatives
- Industry manufacturing/product trends
- Risk management and risk-based GMP
- Disposables technology in manufacturing
- Blend uniformity and solid dose manufacturing
- Validation of pharmaceutical and biotech processes
- Viral safety
- Process analytical technologies (PAT)
- Quality management systems for pharmaceuticals and biopharmaceuticals
- Industry case studies – compliance and quality issues
- GMPs during clinical development
- Rapid microbiological technology and methods
- Barrier systems – Cleanrooms, Isolators, RABS
- Sterilization science
- Environmental monitoring
- Water systems including microbiological issues
- Computer validation
- Part 11: Electronic records/electronic signatures
- Aseptic processing of medicinal products

ABSTRACTS MUST BE RECEIVED BY MAY 31, 2006 TO BE CONSIDERED

Abstracts must be noncommercial in nature, describe new developments or work, and contribute to the body of knowledge relating to pharmaceutical manufacturing, quality management and technology. Industry case studies demonstrating advanced technologies, manufacturing efficiencies or solutions to regulatory compliance issues are preferable and will receive the highest consideration. All abstracts will be reviewed by the PDA International Program Committee for inclusion in the meeting or in poster sessions. Commercial abstracts featuring promotion of products and services will not be considered.

Please submit your abstract(s) to the PDA International Program Committee via e-mail or fax to:

Attn: Luis Castro, PDA at castro@pda.org or fax at +1 (301) 986-0296

Please include the following information. Submissions received without full information will not be considered:

- Title of presentation
- Presenter
- Biography of presenter
- Additional authors
- Full mailing address
- Phone number
- Fax number
- E-mail address of the presenter
- 2-3 paragraph abstract, summarizing your topic

Upon review by the program committee, each person who submits an abstract will be advised in writing of the status of his or her abstract after July 1, 2006. PDA will provide one complimentary meeting registration per presentation. Additional presenters will be required to pay appropriate conference registration fees. With the exception of health authority speakers, all presenters are responsible for their own travel and lodgings.

ATTENTION EXHIBITORS

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Quality system implementation should be started as early as possible to allow for the cultural change to be completed in time. However, when started too early, years before pre-clinical studies, business issues are likely to take primacy over quality issues, making it harder to convince management to support the quality system.

The Skeleton of a Quality System: Documentation

The Problem – Lack of Adequate Documentation

Regardless of where a start-up company falls on the drug development continuum, from discovery research to marketed product, documentation is the absolute foundation of all quality systems and compliance efforts.

Most start-up companies are aware they are required to have written procedures. Generally the first thing they decide to do is write SOPs for lab methods. Everyone in the lab is told to write an SOP. There is usually no format provided, and no explanation that an SOP is different from a protocol. Resistance is the usual outcome, followed by creation of a chaotic collection of documents that only a select few people are aware exists, and few bother to read and/or follow. Every time another procedural need is identified, somebody is assigned the task of writing an SOP. It is seldom understood that simply having written procedures is not enough—they must also be followed.

When companies fall short of regulatory expectations in the lab, it is usually because of the lack of adequate documentation. One of two extremes is usually seen—either documentation is carried to the extreme of auditing office supply vendors (this extreme is seldom seen), or there is almost no documentation at all, unless it is of selected data that supports a particular goal (a situation made worse when this data is captured on sticky notes or loose scraps of paper).

The Solution – Build an Intelligent Documentation System

1) Most importantly, start at the top. Create a documentation system that supports compliance from executive management down, specifically designed to start with a foundation of policy documents (the company's quality manual) and build upon that. Policy statements identify what your company is doing and what measures it will take to be in compliance. They describe the systems your company will have in place for compliance in the six major systems, defined by the U.S. FDA: quality, facilities and equipment, materials, production, packaging and labeling, and laboratory controls. If there is a compliance area that does not apply to your company because you do not perform the operations addressed (for example, packaging and labeling control), you should nonetheless have a written policy statement that specifies your company does not perform packaging and labeling, and therefore will have no written procedures on the subject. Policy documents should be read, understood and signed by the most senior management.

2) Simplify. Most documentation systems can be incredibly complex, especially in the context of a small start-up company. Without a working, centralized documentation system, any attempt at compliance will fall short. Develop an SOP format and have a training session on SOP writing before asking people to write SOPs. Keep it simple—if there is an operations manual associated with a particular piece of equipment, don't write the whole manual into the SOP, simply incorporate it by reference.

3) Ensure traceability. The new "quality by design" philosophy and ICH Q8 show that regulators are more and more aware of the importance of data obtained during the research phase of a project. Therefore, one must ensure data traceability in order to reliably return to your development data years later, when regulators, inspectors or even clients (in the case of CMOs and CROs) may ask for it. Traceability also ensures patent protection in case of a dispute and strengthens a company's intellectual property (IP) position. (The IP issue is usually a good selling point to upper management!)

4) Prioritize documentation. Work load in young companies is often overwhelming relative to staffing levels, and it is easy to save time by skipping documentation when you have to deliver results. It is easy to say, "I know it is important but I did not have time to do it!" What this actually means is: "I did not take the time to do it". Management needs to insist on expecting results and proper documentation.

The Heart of a Quality System: Quality Assurance

The Problem – Lack of Industry Experience

When the senior management of a start-up company has no drug industry background, it is seldom apparent to them that the company truly needs some staff with industry experience. In the absence of anyone with experience, good intentions rapidly become snarled

in a confusing web of regulations and guidance documents. An excellent example of this is a very small company that had its QC lab personnel performing all physical testing and performing all QA responsibilities as well. The result was significant conflicts of interest. Because 21 CFR 211.22, which requires a "quality control unit," does not distinguish the functions of QA and QC, this firm did not understand that the two functions should be separate in the absence of an experienced industry pro.

Hiring an expert in compliance is often too expensive for start-ups, but is preferable when feasible. As a result, such firms typically assign the QA function to a member of the existing research staff. If a QA professional can be hired, he/she needs to be trained on the technology under development since quality systems often need to be tailored to the manufacturing strategy.

The Solution – Dedicate the QA Staff Full-Time

Make the QA function a full-time position, because the workload of the QA function is very time consuming. Documents must be identified, generated, controlled, distributed, revised, retrieved and archived in a controlled manner. Training must be scheduled and training records must be maintained. Traceability must be assured. Data must be audited and securely stored. Constant review of a dynamic compliance environment must be performed and the quality system must be readapted to the changing priorities and strategies of the start-up company. Contractors must be qualified, and contractor quality agreements and records must be reviewed. It is not realistic to think that an employee spending only 20% of his/her time on compliance is going to keep up with the workload and maintain a compliant state. Also, a part-time QA person might draw unwanted attention from the regulatory authorities.

When assigning the QA function to an in-house scientist, choose a candidate who has strong leadership capabilities and the willingness to learn by doing. Obviously, if someone on staff has at least a little knowledge of GxPs, they should be considered.

For less than the cost of hiring a QA expert, start-ups can contract with an experienced consultant to work with the new QA staff person. Consultants can provide an "on-demand" solution at the right price.

Getting Your Quality System to Work: Training

The Problem – Lack of Understanding

Compliance neophytes often ask "How do I know that I am compliant?" Answering: "Just adhere to the SOPs" is not enough, the employee also needs to know and understand which SOPs he/she has to adhere to and why. The key to this understanding is training, training and… training.

The Solution – Training

Training cannot be overvalued. It is not enough to provide compliance training only to those staff that are "hands on" in the drug development process—executive management and administrative personnel need to be aware of compliance requirements and issues, too. Awareness promotes understanding, and understanding promotes compliance. (Just think about all the times your parents said you had to do something "because I said so!")

Orientation training in GxP compliance should be given to every ➤

Recommended Resources

You may find these resources to be excellent references and supplements to the topic discussed in this article.

TRI Courses

The PDA Training and Research Institute offers the following courses aimed at keeping you compliant and ahead of the curve on compliance and quality system issues:

- Approaches to Performing Self-Inspections as Part of a Total Quality System for Applied Quality Systems
  June 13, 2006, Vancouver, B.C., Canada
- Quality System Strategies for Investigational Drugs
  October 10-11, 2006, London, England
- Minimizing the Legal, Quality & Compliance Pitfalls of Contract Manufacturing
  October 18, 2006, Boston, Massachusetts

For more information on these and other courses, visit www.pda.org.

On-Demand Recordings

- FDA and Industry Perspective on Quality Systems
- Technical Training as Part of an Operation Quality System

For more information or to purchase an On-Demand Recording, call PDA Programs and Meetings at +1 (301) 656-5900 ext. 158.

Publications

- *Pharmaceutical Quality Systems*
- *Quality Control Systems for the Microbiology Laboratory: The Key to Successful Inspections*

WINNER, 2004 PDA/DHI Distinguished Editor/Author Award

- *Pharmaceutical Quality*

For more information or to purchase these publications, visit www.pda.org/bookstore.

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new employee as soon as possible after date of hire. All new employees should be required to read (and understand) the company's policy documents. Refresher courses to keep up with new requirements and developments should be provided once per year, at a minimum, with mandatory attendance. Part of the training should involve an overview of the history of GxPs that clearly shows that these regulations were developed to protect people's health—not to restrain a scientist's creativity or generate tons of paperwork! Employees need to be made aware of the potential impact of their actions. They should be reminded that their daily work contributes to the development of a medicinal product that will eventually be administered to a patient. And this patient could be themselves or someone close to them.

Training records are the most frequently cited deficiencies in GxP audits, both by FDA and the industry. Training must be thoroughly documented. This is not only a compliance issue; it is also a good business practice.

In Summary

Ensure management support.
Obtain management buy-in into the quality system as early as possible. Quality system implementation, maintenance and improvement can only be achieved with the active participation of managers.

Simplify.
Do not over-complicate the level of compliance. If it is company policy to license out new substances after preliminary preclinical studies are completed, you don't need to have your people working to full GMP standards.

Establish written policies.
Written policies help define the company's compliance position and management's expectations of staff with regard to compliance. They also serve as a foundation for other documents that are needed, and help identify those that are not.

Assign a compliance FTE.
A full-time QA/compliance person is a tremendously important investment for the start-up company.

Provide training.
Regulated industry is a completely new environment to many people in a start-up company. These people cannot be expected to be in compliance if they do not know what that means, so inform them, train them, and document the training.

About the Authors

Arvilla Trag is founder and president of Midwest Consulting Services, Inc. She is responsible for compliance audits, GMP training, Quality System development, and regulatory filings for her clients.

Dr. Ursula Busse is Director of Quality Assurance and Regulatory Affairs at Medicago Inc. She is responsible of developing, implementing, managing and improving the company's quality system. She is also in charge of planning and coordinating validation activities and regulatory submissions.

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An Interview with Emer Cooke: The EMEA Inspections Sector, continued from cover

several industry positions in Ireland in research and development, and then served as a pharmaceutical assessor in what is now called the Irish Medicines Board. In 1992, I joined EFPIA as manager of regulatory and scientific affairs. I then joined the Pharmaceuticals Unit of the European Commission in Brussels, where I stayed for four years. I came to my current position at the EMEA in July 2002.

What is the size and scope of the Inspection Sector?

We have 19 people working in the Inspections Sector. We have a number of key coordination functions. For example, we chair inspectors working groups, both GMP and GCP, with representatives from all the member states. The tasks of these inspectors groups are to create new inspection guidance, agree on harmonized interpretation of guidance and to consider standards for both the inspectorates and industry in the EU. We also serve as the secretariat for the Quality Working Party, manage the sampling and testing schemes for centralized products and oversee the implementation of mutual recognition agreements.

Our scope is all GMP and GCP issues associated with both human and veterinary medicinal products. This includes blood products, biological products, vaccines and many other areas. Our scope *does not include medical devices*, and this is a common misunderstanding. In short, anything that falls under the category of medicinal product in Europe comes under European GMP.

Many people talk about the "EMEA Inspectors." Do you have your own inspectors?

No, we don't. The EMEA doesn't employ any actual inspectors. All of the professional inspectors who work on our behalf are employed by the national authorities in the EU Member States. Some of the people who work in the Inspections Sector have experience or background in inspections, but once they come to work for us their role is one of coordination and support for the network.

...in the smaller EU, it was frequently appropriate to provide statements of guidance in a more general way. These days it is sometimes more appropriate to provide detailed statements in order to aid everyone's understanding.

What are the most valuable things you have learned about the EMEA and the EU regulatory system?

The whole concept of the European Union and the regulatory framework requires cooperation between the Member States, clarity of requirements and interpretations, and a lot of good will for people to work together for the same goals. I've learned that there are great opportunities to get people to work together to improve operations, avoid duplication, and generally work in the interest of the European public health.

I've also learned there is rarely a right or a wrong way of doing things—there are simply different ways. It's very important to understand that—one can't come into this environment and expect a straightforward answer to some of the issues we face. The input we receive from the EEA national authorities provides a foundation for workable solutions. There are many rich opportunities for mutual learning in the European system.

Are there any particular areas where improvements are needed?

The EU is a dynamic environment. When the EMEA was set up in 1995, we had 15 Member States; today we have 25. We will have two more Member States added next year, and will start work soon with Croatia and Turkey on pre-accession discussions. The effect of this is that the complexity of our work actually increases with the addition of new Member States. Things that had been generally understood and accepted before may need to be reconsidered and restated in the wider environment. There are different demands both from industry and the regulators that has an impact on the nature of policy and guidance from the EMEA. For example, in the past, in the smaller EU, it was frequently appropriate to provide statements of guidance in a more general way. These days it is sometimes more appropriate to provide detailed statements in order to aid everyone's understanding.

I think we still have work to do in terms of cooperation on inspections outside the EU in order to make sure information is shared on adverse findings. I believe the "Rapid Alert" system works well and may provide models for other improvements. We also need to do more training programs across the Member States. While there are many excellent training programs at ➤

the national level, there are some issues which are better addressed by EU-wide centralised training, for example the European regulatory environment, the classification of inspection deficiencies and the newer concepts of PAT and design space.

Finally, the whole area of good distribution practice needs to be addressed. With the increasing concern about counterfeiting of medicinal products, the entire aspect of good distribution practices is an area where progress can be made.

Do you think more legislation to control counterfeiting is likely?

There are many activities already underway in the area of counterfeiting. We have initiatives by WHO, the Council of Europe and the European Commission relating to this. Eventually it seems possible that some new legislation may be appropriate. But I also believe quite a lot can be done under the current system. We have a good system in Europe for licensing of distributors and wholesalers, and we have specific requirements for the persons who work in those companies. However more can be done. A first step would be to make sure that all the Member States and national authorities are operating in the same way and taking similar approaches to this—a bit more emphasis on this area would help to prevent some of the problems.

Many companies in Europe operate globally, and ICH doesn't cover many other countries in the world. Do you see anything that the EMEA can do to help harmonization in non-ICH parts of the world?

In terms of the EMEA specifically, the opportunities are limited. But there are other fora where harmonization work facilitates the extension of standards equivalent to those in Europe to other countries. I particularly should mention the work of the PIC/S, where there are currently 29 members. Of course, many of the PIC/S members are European, but we also have other members from countries outside the ICH area including Singapore, Malaysia, Canada, Australia and New Zealand. All of the members have agreed to work according to the same GMP standards.

The EMEA website has just been revised and updated, and I would encourage everyone to take a look at it.

We also must recognize the long-time work of WHO. We cooperate with the WHO technical working groups on the development of standards that are compatible with European interpretations.

So Europe is actively involved in the overall global harmonization arena.

Can you tell us a bit about the changes in the EMEA website?

The EMEA website has just been revised and updated, and I would encourage everyone to take a look at it. It now includes more detailed information on the activities of the Inspection Sector. You will find any new guidances relating to GMP and GCP and a section on "What's new." This updated format will be much more helpful for our constituents. There is also a provision for asking GMP questions to the Inspections Sector, by submitting questions to gmp@emea.eu.int

EMEA home page:
www.emea.eu.int

EMEA Inspections Sector:
www.emea.eu.int/Inspections/index.html

Before my next question, I would like to thank the EMEA, on behalf of PDA members, for the time that you and your staff have invested in the development of October's PDA/EMEA Joint Conference agenda. Could you describe what you would like to see happen at this conference? How will you and the EMEA view it as a success?

What I'd like to see is better understanding of the EU regulatory system, in particular the GMP aspects of that system. This includes a better understanding of how the authorities of all the Member States work together and how the whole network functions. It is very important that this is a European-focused conference. I see this as an excellent opportunity to promote the way Europe works in this area.

You clearly have an interesting and demanding job. In closing, can you tell us what you like most about working at the EMEA?

There is so much for me to appreciate. I like the diversity of dealing with people in a multicultural environment. I get great satisfaction in helping people from different organizations and traditions find solutions that allow them to work together for the greater good. There is always something new on the horizon, a new issue that needs a solution. I enjoy all of this tremendously, and I feel very fortunate to be in a position to contribute.

2006 PDA/EMEA Joint Conference




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PDA Welcomes its Newest Chapter: The Ireland Chapter

Following proposals from the Irish membership, the PDA Board of Directors approved, in December 2005, the establishment of an Ireland Chapter to specifically service the needs of the pharmaceutical industry in Ireland. The Inaugural PDA Ireland Chapter meeting and officer election took place in the Cavanagh Pharmacy Building, University College Cork on March 7, 2006. The meeting was attended by **Bob Myers** and **Georg Roessling**.

The following officers and committee members were elected:

President:
Frank Hallinan, *Wyeth Biopharma*

Vice President:
Colman Casey, *School of Pharmacy, UCC*

Secretary:
Paul Logue, *Elan Corporation*

Treasurer:
Joan Fitzgerald, *Allergan Pharmaceuticals*

Committee:
Catherine Adley, *UL*

Marese Bermingham, *CIT*

Maire Callaghan, *ITT*

Jean Foley, *GE Healthcare*

Brendan Griffin, *UCC*

Jeff McBride, *KE Consulting*

Mike Morris, *Irish Medicines Board*

Pat Nagle, *Schering Plough*

Philip O' Connell, *GE Healthcare*

Alice Redmond, *Project Management*

Frank Riedewald, *EG Pettit*

The Chapter held its first formal meeting on April 4, 2006. At that meeting the chapter adopted their bylaws and agreed to hold two technical meetings per year and formed a subcommittee to look into the feasibility of forming a student chapter.

The Ireland Chapter is off to a great start. If you are interested in getting involved with the Chapter please contact Frank Hallinan by phone at +353 1 4694342 or via e-mail at hallinf@wyeth.com.

Next up, the PDA Ireland Chapter will host an interactive workshop on PDA Technical Document No. 1 – *Industrial Moist Heat Sterilization*, June 7, 2006 at the Maryborough Hotel in Cork. For more information and to register, contact Anne-Marie Duggan at annemarie.duggan@pmg.ie.

Left to right: Torsten Schmidt-Bader, Joerg Zimmermann, George Roessling, Bob Myers, Colman Casey and Frank Hallinan

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Industrial Moist Heat Sterilization: PDA Technical Report No. 1

Update and Interactive Discussion

These conferences will provide an opportunity for attendees to participate in an interactive discussion in which they will learn about and contribute to the 2006 revision of PDA Technical Report No. 1, Draft No. 18, *Validation of Moist Heat Sterilization Process – Development, Qualification and Routine Control*. As part of the revision process, the PDA Committee of Revision is soliciting feedback on Draft 18, which will be available to all attendees for review prior to the conference dates. Also, those who have provided input on prior revisions of TR#1 will have the opportunity to comment on an advanced copy of the working draft. PDA's intent is to publish the final Technical Report in early 2007.

Invited members of the TR#1 Committee of Revision include:

- **Kris Evans,** CDER, FDA
- **Nigel Halls,** PhD, IAGT Ltd.
- **Richard Levy,** PhD, PDA
- **Robert Myers,** PDA
- **Mike Sadowski,** Baxter Healthcare
- **Kevin Trupp,** Hospira

Four Conference Dates Just Announced:

- **June 7: Cork, Ireland**
- **June 8: London, England**
- **June 27: Pavia, Italy**
- **July 27: Washington, DC (Bethesda)**

To view the agenda for each session and to register, visit www.pda.org

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The Foundation for Business Success – the 2006 PDA/FDA Joint Regulatory Conference

Cindy Rockel, Millipore and 2006 PDA/FDA Joint Regulatory Conference Chair

The PDA/FDA Joint Regulatory Conference Program Planning Committee is pleased to invite you and your colleagues to attend the *2006 PDA/FDA Joint Regulatory Conference*, September 11-13, 2006 in Washington, DC. This year's conference theme, *The Foundation for Business Success: Continuous Improvement Throughout the Product Life Cycle*, focuses on the strategic roles regulatory affairs, quality and manufacturing have in the increasingly more global and competitive business environment. As the industry strives to achieve continuous improvement throughout the product life cycle, these disciplines drive the adoption of new worldwide regulatory initiatives within pharmaceutical and biopharmaceutical companies, and their supply chain partners.

At this year's conference you will learn how the foundation of your firm's business success can be built on continuous improvement. As in past years, the conference will provide a forum which supports collaboration, education and networking between FDA and the pharmaceutical and biopharmaceutical industries. The plenary sessions and three complementary learning tracks—regulatory affairs, quality systems and manufacturing—will engage you and your colleagues in unmatched discussion with senior-level industry executives and top FDA officials.

Each plenary session will provide an overview of the business and regulatory perspectives being emphasized for that specific day.

The opening plenary sessions will include an FDA presentation entitled "Trading Regulatory Reform for Scientific Excellence." Industry CEO's and academia will lead an international panel discussion on strategically positioning quality as part of the corporate value proposition.

On the second day, FDA and industry will combine presentation and panel discussions on the impact and application of ICH Q8, Q9 and Q10, including opportunities, challenges and downstream implications of these guidances.

The closing plenary will combine commentary from FDA with a presentation of a continuous improvement model by an internationally known electronics company.

New this year, the concurrent sessions will be dedicated to FDA and industry perspectives on a single topic. There will be four ICH sessions offered in this format, covering regulatory and quality viewpoints, including presentations from firms involved in the FDA pilot program.

Attendees will be able to choose from the following tracks:

- **Regulatory Affairs sessions** will discuss regulatory challenges throughout the product life cycle, beginning with early phase development/IND submissions to post-market approval, including a new guidance for medical devices. This track will show how seamless and effective integration of regulatory affairs into the product life cycle benefits the corporation and ultimately the patient.
- **Quality System sessions** will focus on the product life cycle from GXP Phase 1: Guidance for Early Phase Material and how to leverage your quality systems to drive continuous improvement. This track will demonstrate why quality needs to be part of the corporate value proposition, with corporate culture embracing quality management principles throughout the organization top-down.
- **Manufacturing sessions** will discuss the product life cycle from both external and internal points of view, covering contract manufacturing, tech transfer, the new process validation guidance and conclude with continuous improvement tools and techniques. This track will emphasize manufacturing as the business catalyst for executing policy and procedures, with external regulatory guidance, to produce safe and efficacious drugs for patients.

A final technical component of the conference includes **twelve PDA Interest Groups** will meet throughout the conference. Many of these meetings will offer complementary technical and regulatory discussions to the concurrent sessions.

The Exhibit Hall, with representatives from technology providers to pharmaceutical services, will be a favorite gathering spot throughout the conference. Following the conference, the **PDA Training and Research Institute** will provide a comprehensive slate of lecture courses for *Career-long Learning*[SM].

continued on bottom of next page

PDA Pharmaceutical Anti-Counterfeiting Forum: Focus on Technology Solutions

Michael N. Eakins, PhD, Eakins & Associates

PDA held an extremely successful first conference on the increasingly important topic of pharmaceutical anti-counterfeiting in Bethesda on March 1-2, 2006. The program committee, consisting of **Michael Eakins** (Eakins & Associates, Chair), **Jim Rittenburg** (Authentix), **David Schonecker** (Colorcon) and **Bob Dana** (PDA), assembled a first rate roster of speakers, including **Scott Gottlieb**, MD, Deputy Commissioner for Medical & Scientific Affairs, FDA, who gave the keynote Address. Dr. Gottlieb's speech is available at: www.fda.gov/oc/speeches/2006/pda0303.html.

The conference also heard from **Arif Alikhan**, Vice Chairman and Executive Director of the U.S. Department of Justice Task Force on Intellectual Property who spoke on the Department's efforts in enforcing and protecting intellectual property rights. The presentation stimulated the audience into providing a lively Q&A session. In general terms, the main thrust of the questions and comments from the audience was the disparity in the sentencing guidelines for pharmaceutical counterfeiting and those for trafficking in narcotic drugs. **Jeffrey Gren,** Director, Office of Health and Consumer Goods, U.S. Department of Commerce, emphasized the role of global cooperation in fighting counterfeit drugs and the Department of Commerce's international activities such as working with authorities in India and China.

The range of individual authentication and track & trace technologies available as anti-counterfeiting tools such as special inks and holograms and RFID and 2D matrix bar codes were reviewed in depth by experts in the field. A round table session provided an arena for these experts to debate the relative merits of the technologies, in particular the usefulness of RFID versus 2D matrix bar codes at the product container level. The number of different views expressed on RFID was in keeping with the slow progress seen in implementing RFID by the pharmaceutical companies.

Covering a new topic for PDA, the meeting represented a commitment to explore new areas of high interest to the membership that combine technology, regulatory and quality issues. The meeting brought speakers and exhibitors from companies and government that had not been previously associated with events organized by PDA. The attendees were very impressed with the quality of the speakers and encouraged PDA to continue to maintain an active interest in the area of pharmaceutical counterfeiting.

Bob Myers (right) and Michael Eakins (left) welcoming Dr. Gottlieb

About the Author

Michael N. Eakins, PhD, is a Principal Consultant for Eakins & Associates. He chaired PDA's 2006 Anti-Counterfeiting Forum and is working with PDA and the program planning committee on a future event on the topic. He is also the Chair of the 2007 PDA Annual Meeting, scheduled for March 19-23, 2007, in Las Vegas.

The Foundation for Business Success – the 2006 PDA/FDA Joint Regulatory Conference, continued from page 33

And of course, after a busy day at the conference, you will have the opportunity to relax with friends and colleagues at several networking activities including the gala event celebrating FDA's 100th and PDA's 60th anniversaries. Stay tuned for special event details.

On behalf of the PDA/FDA Conference Program Committee, I would like to invite you to join us for what promises to be an outstanding conference. You will take home current, pertinent and relevant information that will enhance your career as well as your understanding of emerging FDA and industry thinking on *The Foundation for Business Success: Continuous Improvement Throughout the Product Life Cycle.*

Vice President's Message

Gail Sherman

PDA Supports FDAAA Scholarship Fund

Bob Myers (third from right) poses with other scholarship fund contributors

I am pleased to discuss this month the U.S. FDA Aumni Association (FDAAA) and PDA's relationship with the association.

Founded in 2001, the FDAAA is dedicated to serving those who have supported and continue to serve the consumer protection mission of the FDA. The FDAAA has several goals, a few of which are: educate the public about FDA's vital work; promote interest among America's youth in national service careers and public health opportunities at the FDA; assist FDA in recruiting alumni with specialized expertise and institutional knowledge during critical situations; and consult with foreign governments in need of expert advice on establishment and operation of national regulatory programs. In regards to the third goal, several members of FDAAA volunteered and assisted during the Hurricane Katrina catastrophe. Additionally, FDA alumni have also worked with the Agency on issues of international importance in countries such as Jordan, Russia and Bahrain.

On April 5, 2006, the Association conducted its fourth annual meeting with a tribute to the FDA Centennial—the 100th anniversary of the 1906 Pure Food and Drugs Act. During this program, we heard from **Donald Kennedy**, PhD, former Commissioner of FDA, and **Andrew von Eschenbach**, MD, current acting Commissioner. Both had interesting comments and remarks about where the Agency has been, and the forward thinking of the Agency. Additionally, we heard from an industry panel, including the CEOs from Medtronic, Schering-Plough Corporation and CV Therapeutics on issues facing the FDA and the industry in the current FDA environment. There was also discussion about education across the board, and more importantly, the lack of emphasis on science education from grammar school forward, and the impact of this on recruitment and hiring of qualified scientific staff both in the industry and the Agency. One of the CEOs discussed the lack of training in product development which is so critical to the pharmaceutical industry today.

So what is PDA's relationship to the FDAAA you ask? This year the FDAAA wanted to do something special to recognize the centennial of the FDA. We made several suggestions and recommendations and came to the conclusion that one of the best things that we could do as an organization was to establish the FDAAA Scholarship Fund. Two of our very active Board members (**Bob Sauer**, ret CVM and **Jim Benson**, ret CDRH and once an FDA Commissioner) went out on a search for the best program and college/university to endow. They presented their findings to the Board, which then selected the School of Pharmacy at Temple University in Philadelphia for the FDAAA scholarship. The Temple program, a Masters of Science in Regulatory Affairs/Quality Assurance, meets the career requirements of professionals involved in regulatory and QA departments of the pharmaceutical industry. The scholarship fund has, to date, collected more than $40,000 (U.S.) from the FDAAA members and supporters. We congratulate future students in the Temple program, and encourage teaching in the sciences to promote a stronger scientific community both in the industry and regulatory arenas.

PDA is a sponsor of the FDAAA Centennial Scholarship Fund. **Bob Myers**, PDA's President, was recognized by the FDAAA for PDA's support of this endowment. Other sponsors of the initial program included PhRMA Foundation, Consumer Healthcare Products Association and Pfizer. The "fishbowl" set out during registration collected over $1,000 (U.S.) from members at the annual meeting.

And, by the way, my former FDA Center (CBER) is 104 this year, having celebrated its centennial in 2002!

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