Science • Technology • Quality • Regulatory • Community

PDA Letter

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In This Issue…

Parenteral Drug Association

Connecting People, Science and Regulation℠

A Risk-Based Approach to ERP Systems Validation

Subbu Vis, Director, ValiMation, Inc.

Overview

The regulated life-science industries are required by the regulatory authorities to provide evidence and associated documentation that computerized systems consistently provide the functionality required for their intended purposes. Due to this regulatory requirement, companies spend a great deal of time and resources ensuring that their computerized systems are fully validated and comply with the GxP regulations. With the age of highly integrated and complex computerized systems, the task of computerized systems validation (CSV) has proportionately become highly complex. It is, therefore, more important now for the computerized systems which automate a wide range of activities in a life-science organization to be validated by using logical, scientific, risk-based methods. To effectively conduct CSV across a life-science organization, a practical, scientific approach needs to be taken to ensure that critical systems, or those posing a high risk, are thoroughly validated, and that other lower-risk systems are validated appropriately (i.e. with less rigor). This is in line with the U.S. FDA's vision, as stated in multiple guidance documents, including *FDA Guidance for Industry – Part 11, Electronic Records; Electronic Signatures – Scope and Application*.

Reduction of the validation effort should not be the primary objective of taking a scientific/risk-based approach to CSV; rather, the approach should be used to direct the validation effort more towards the critical decision points of the system/functional area. The intent of this article is to apply risk-based approaches to the validation of an enterprise resource planning system.

System Introduction

The process of creating a new pharmaceutical product is a long cycle, starting from research, testing, forecasting, planning and development, and progressing to manufacturing, packaging, distribution, etc. Improvements in the process efficiency can be obtained by the implementation of an enterprise resource planning (ERP) system. Some of the basic requirements that an ERP system should satisfy for a

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2006 Annual Meeting

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Cover Art: Anaheim, Calif., home to the 2006 PDA Annual Meeting

Coming Next Month... Compliance Systems

Announcement and Call for Papers

PDA's 1st Annual Global Conference on Pharmaceutical Microbiology

Bethesda, Maryland ◆ October 30 – November 1, 2006

Call for Papers/Call for Exhibitors

Dear Friends and Colleagues,

The 2006 PDA Pharmaceutical Microbiology Program Committee invites you to submit a scientific abstract for presentation at PDA's 1st Annual Global Conference on Pharmaceutical Microbiology. We are looking for submissions on the following hot topics:

- Microbial control in closed and open systems
- Disposable systems
- Global harmonization
- Water systems
- Disinfectant qualification
- Environmental excursions
- Sterilization processes
- Environmental monitoring in sterile areas
- Environmental monitoring in non-sterile areas
- Filter performance and ratings
- Inspection readiness
- Isolator/barrier technologies
- Emerging and innovative technologies
- Risk analysis in microbiology
- Global pharmacopoeial topics
- Industrial practice for microbial ID – bacteria and fungi

****All submitted abstracts will be reviewed by the Program Planning Committee for inclusion in the meeting or for poster presentation.****

VISIT WWW.PDA.ORG/MICROBIOLOGY2006 TO SUBMIT YOUR ABSTRACT. ABSTRACTS MUST BE RECEIVED BY MAY 1, 2006 FOR CONSIDERATION.

Please include the following information in your abstract and follow the steps identified in the Precis Abstract Manager.

- Title
- Presenter's biography
- Additional authors
- Full mailing address
- E-mail address of the presenter and co-presenters
- Two-three paragraph abstract, summarizing your topic and the appropriate forum (case study, discussion, traditional, panel, etc.)
- Target audience (by job title/department)
- Audience take-home benefits
- Key learning objectives

Commercial abstracts featuring promotion of products and services will not be considered. Upon review by the program committee and after May 1, 2006, you will be advised in writing of the status of your abstract. PDA will provide one complimentary registration per presentation. Additional presenters are required to pay appropriate conference registration fees. All presenters are responsible for their own travel and lodging, with the exception of health authority speakers.

ATTENTION EXHIBITORS

PDA is seeking vendors who provide excellent products/services in support of this conference. Space is limited and is on a first come, first serve basis. To reserve your space, please contact Nahid Kiani at kiani@pda.org or 301-656-5900 x 128.

Celebrating 60 Years: PDA's Science Trailblazers

Walter Morris and Robert Myers, PDA

This year, in celebrating PDA's 60th anniversary, the *PDA Letter* is publishing a series of articles highlighting important contributors to the Association. In the January issue, we printed a "Past Leader Spotlight," featuring former PDA President Nathan Kirsch.

This month, we are pleased to recognize several of PDA's "Science Trailblazers"—those PDA members who helped introduce the Association and the pharmaceutical industry to a new scientific field that is now recognized as part of the foundation of our educational efforts. Narrowing the list down was difficult, as so many of PDA's past and current members are worthy of recognition for their scientific contributions. However, the following six scientists stand out because of their easily identifiable and valuable scientific contribution to the industry, length of service to PDA, the number of manuscripts contributed to the *PDA Journal of Pharmaceutical Science and Technology*, the PDA Honor Awards received and their roles as leaders in our organization.

We hope you enjoy this sampling of PDA "Science Trailblazers" and come to appreciate the key role they have played in building PDA's scientific heritage.

Kenneth E. Avis, D.Sc., University of Tennessee – Parenteral Manufacturing

Dr. Kenneth Avis for many decades was regarded as the foremost authority in parenteral manufacturing by academia, industry and regulatory authorities. Dr. Avis also had a long and distinguished history of working with PDA. He joined the Association in 1956 and was elected to the Board of Directors 1960. In 1968 and 1969, Dr. Avis was elected PDA President (the equivalent of today's PDA Chair). He remains the only academician to hold this office. During his term, PDA published its first membership directory and volume one of a series of bibliographies on parenteral drug literature.

Dr. Avis began contributing to PDA right away. He first published a manuscript in the PDA Journal in 1957; it was titled, "The Sterilization of Oleaginous Parenterals." At the time, he was an associate professor of pharmacy at the Philadelphia College of Pharmacy and Science, and the PDA Journal was officially titled, the *Bulletin of the Parenteral Drug Association*. Dr. Avis ultimately **published 19 manuscripts** in the PDA Journal, most of them coauthored with colleagues and students.

Dr. Avis' greatest contribution to PDA was his strong advocacy of the use of scientifically-sound aseptic technique in manufacturing and preparing parenteral products. In a 1959 commentary to the Journal called, "Current Misconceptions in Parenteral Manufacturing," Dr. Avis focused on the need for proper training of hospital pharmacists to produce parenterals. In a 1971 commentary, "Personnel Training: An Academic Approach," he discussed the value of post-graduate university training for pharmaceutical industry and regulatory agency professionals, as well as professional training for line operators without science degrees. This paper remains relevant even in the 21st century, having been cited by the U.S. FDA at a 2002 hearing of the Advisory Committee for Pharmaceutical Science.

In this regard, Dr. Avis played a major role in building the University of Tennessee's Department of Pharmaceutical Sciences. He served as the university's Director of Parenteral Medications in the Department of Chemistry and later became the Chairman of the new Department of Pharmaceutics in the College of Pharmacy. Today, the university still offers graduate and post-doc courses created by Dr. Avis.

In 1988, Dr. Avis was awarded PDA's most prestigious award, Honorary Membership. PDA TRI further honored Dr. Avis by naming one of its laboratories the Ken Avis Laboratory.

Irving J. Pflug, PhD, University of Minnesota – Heat Sterilization

Dr. Irving Pflug has been the authority on the science of industrial heat sterilization for over three decades. He has been a prolific contributor to the scientific literature on heat sterilization and other topics, publishing close to 250 manuscripts.

Dr. Pflug's involvement with PDA as an instructor of heat sterilization techniques resulted from contamination problems that occurred with certain parenteral products in the early 1970s, which ultimately led to the death of some patients. Contributing to the problem was the general dearth of experts in modern heat sterilization techniques in the industry. The ensuing uproar within the industry and the regulatory agencies prompted PDA to act. Under the direction of former president **Nathan Kirsch** (Schering-Plough) and PDA administrative secretary, **Solomon Pflag,** the Association reached out to Dr.

Pflug, requesting that he bring his extensive knowledge of modern heat sterilization science to the pharmaceutical industry.

In 1977, Dr. Pflug taught PDA's very first training course, titled "Microbiology and Engineering of Sterilization Processes." In 1978, PDA awarded a $4,000 grant to the University of Minnesota in honor of former Chair **Charles P. Schaufus,** which was used by Dr. Pflug to further develop the technical book and syllabus for the course. While initially intended to be offered for only one year, the course was taught through PDA for more than a decade. Dr. Pflug continues to teach the course around the country at company locations upon request and for general participants under the auspices of the Univeristy of Minnesota.

Dr. Pflug **contributed 11 manuscripts** to the PDA Journal, beginning in 1975 with "The Effect of Holding Time in Parenteral Solutions on the Outgrowth of Bacillus Stearothermophilus Spore." His latest manuscript was published in the PDA Journal in 2005, entitled "Variability in the Data Generated by Laboratories Measuring D-Values of Bacterial Spores." Three of his writings are referenced in PDA's first and most important technical report, TR#1: *Validation of Steam Sterilization Cycles* (1978).

In 1999, PDA bestowed Dr. Pflug with its highest award, Honorary Membership. He continues to consult with PDA on certain technical report projects. Dr. Pflug is currently Emeritus Professor of Food Sciences and Nutrition at the University of Minnesota.

Theodore H. Meltzer, PhD, Capitola Consulting Co. – Membrane Separation

With more than 40 years of experience in the field, Theodore Meltzer's name is linked to the science of membrane separation. His dedication to this important science has earned Dr. Meltzer four patents. He has served as a consultant on filtration and high-purity water preparations in the pharmaceuticals, biopharmaceuticals and semiconductors industries. His contributions to PDA are many, but none may be greater than his ability to pull together top thought leaders in his field to contribute to PDA's educational offerings.

Perhaps no PDA member has written quite as prodigiously on their area of expertise as Dr. Meltzer. Over his long career and participation in PDA, Dr. Meltzer has **authored or coauthored 24 manuscripts** in the PDA Journal, starting in 1971 with a paper called "The Bubble Point in Membrane Characterization." His latest manuscript, entitled "Choosing the Appropriate Membrane Filter – Test Requirements" (coauthored with **Maik Jornitz, et. al.**) was published in 2005. Dr. Meltzer's other collaborations on manuscripts involve a number of PDA leaders, including: **James Agallaco, James Akers, Kunio Kawamura, Russell Madsen** and **Ronald Tetzlaff**.

Dr. Meltzer also served on the PDA task forces that developed Technical Reports No. 40: *Sterilizing Filtration of Gases* (2005), No. 26: *Sterilizing Filtration of Liquids* (1998), and No. 23: *Industry Survey on Current Sterile Filtration Practices* (1997). In addition, Dr. Meltzer has coauthored a series of "Filtration Handbooks" for PDA/DHI with Maik Jornitz. In 2003 and 2004, they won the PDA Distinguished Author Award for their books, *Filtration Handbook: Integrity Testing and Filtration Handbook: Liquids*, respectively.

In 1996, Dr. Meltzer was honored with PDA's most prestigious award, Honorary Membership.

Julius Z. Knapp, Consultant – Particulate Inspection

Julius Knapp was the first PDA Member, if not the first in the world, to bring automation to the sterile injectable inspection process while working for Schering Corporation. Following PDA's attempt to develop a machine with Emhart Corporation in the 1970's, Mr. Knapp worked within Schering and successfully developed a high-speed electronic inspection machine; he now holds 15 patents in this area.

Mr. Knapp's experience includes 27 years as Director of Research and Development Engineering at Schering-Plough Corporation. There, he developed particulate inspection systems for parenteral products which improved product quality and simultaneously reduced product cost. He also developed a methodology to evaluate and validate manual and machine particle inspection systems—both now widely used in the pharmaceutical and biopharmaceutical industries.

Over the course of his distinguished career, Mr. Knapp has **authored or coauthored 15 manuscripts** in the PDA Journal. His first was published in 1980 and was titled, "Generalized Methodology for Evaluation of Parenteral Inspection Procedures." He continued publishing in the 1990's, including a three-part series on a new coincidence model for single particle counters coauthored with Lee Abramson. His latest manuscript was published in the Journal in 2000. ➤

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PDA's Latest Partnerships to Benefit the Membership

Henry Kwan, PhD, to Serve as PDA's Senior Chapter Liaison

Long-time PDA member Henry Kwan, PhD, has agreed to assist PDA as Senior Chapter Liaison. In this capacity, Henry will dedicate part of his time and all of his experience to assist PDA Chapter operations and to improve communications with PDA Headquarters. He will focus primarily on supporting Chapters in North America and the Asia-Pacific region, with Georg Roessling, PhD, responsible for the European Chapters. Henry plans to attend most Chapter events in the coming months and will contact Chapter leaders shortly to discuss their needs.

Henry remains committed to serving as a consultant to the pharmaceutical and biotechnology industries on product development, process design, troubleshooting and regulatory submission through his firm, Kwan Consulting, LLC. He can be reached at kwan@pda.org or +1 (301) 768-6257.

PDA Partners with UMBI to Foster Workforce Training and Education Programs

In conjunction with the University of Maryland Biotechnology Institute and the university system of Maryland, PDA has entered into a memorandum of understanding to develop a joint good manufacturing practices training program. The new GMP training and biomanufacturing program will provide workforce training and education to the pharmaceutical and biotech industry. For more information or if you are interested in serving on the advisory committee, please contact Gail Sherman, Vice President, Education and Director, PDA Training and Research Institute, at +1 (410) 455-5800 or sherman@pda.org.

PDA Partners with Learnwright to use PharmaTrain®

PDA and Learnwright, Inc., reached an agreement to utilize Learnwright's ***PharmaTrain Training Management System*** technology to deliver online training services to pharmaceutical and biopharmaceutical professionals worldwide.

"This agreement enables PDA to offer just-in-time training through a reliable, secure online platform," said Gail Sherman, PDA VP of Education. "It allows us to expand our development and delivery of regulatory compliance training courseware, e-learning programs, and reference documents and literature, including CD-ROM and video-based materials."

PharmaTrain is a comprehensive system used to manage training activities that is securely hosted on the Internet and can be accessed easily anywhere, anytime through PDA's website.

Celebrating 60 Years: PDA's Science Trailblazers, continued from 7

In 1986, Mr. Knapp conducted an analysis of the three available methods of particle contamination measurements and the lack of agreement between them for the PDA Research Committee. Based on this work, PDA sponsored two international meetings to achieve practical solutions for the problems that were outlined. The first meeting in 1987 was called the "International Conference on Liquid Borne Particle Inspection Metrology" and the second in 1990 was called the "International Conference on Particle Detection, Metrology and Control."

Today, Mr. Knapp is a member of the PDA task force working on Technical Report No. 37: *Visible Particle Methodology and Standards*, which is still under development. Mr. Knapp won the PDA Distinguished Service Award in 2000 and the PDA Gordon R. Personeus Award in 2003 for his special contributions and service to PDA.

Bengt Ljungqvist, PhD, and Berit Reinmuller, PhD – Contamination Control

PDA members best know the Swedish scientific team of Drs. Ljungqvist and Reinmuller for their remarkable contributions in the advancement of contamination control science.

Their affiliation with PDA began in the early 1990's, when PDA was strengthening its ties with scientific parenteral associations in Europe. As members of the Nordic Association of Contamination Control (R^3-Nordic), Drs. Reinmuller and Ljungqvist worked with PDA leaders and leaders of A^{3}P (France) and the Parenteral Society (United Kingdom) to reach a "Memorandum of Understanding" promising to promote communication and the mutual exchange of technical information in health care products. PDA and R3-Nordic members continue to enjoy "secondary membership" benefits.

Ever since the events that brought the Nordic Association and PDA together, Drs. Reinmuller and ➤

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12 PDA IGs Scheduled for 2006 PDA Annual Meeting

Kathleen Greene, Novartis

Twelve of the sixteen PDA Interest Groups will meet at the 2006 Annual Meeting in Anaheim. Interest Group meetings provide a great opportunity to learn what's happening in the specific areas they address and provide a forum to discuss specific items of importance with your peers. If you are struggling with a specific issue, have a technical problem for which you'd like to get input from other experts in the field, or just want to learn more about a specific topic, an Interest Group meeting is the perfect place for you.

In addition to an opportunity to network and interact with your peers and get some solid input on technical issues or concerns, Interest Group discussions provide other benefits, as well. Podium presentations and interactive panel discussions by subject-matter experts help you remain aware of current activities, trends and expectations in your specific area of interest. Each Interest Group focuses on different topic areas and has different deliverables. You might be involved with developing a PDA Technical Report on a specific topic, or have the opportunity to participate in developing PDA's comments on proposed new regulatory guidance. Possible future benefits could include topic-specific training and online discussion groups for Interest Group members.

Active participation in Interest Groups also exposes you to industry trends and events. There is no additional cost to join an Interest Group, nor is there a limit to how many Interest Groups you can join.

We look forward to seeing you at one or more Interest Group meetings at the PDA Annual Meeting.

Interest Group Sessions at the 2006 PDA Annual Meeting

Monday, April 24, 4:00-5:15 p.m.

Quality Systems

Vaccines

Packaging Science

Process Validation

Microbiology/Environmental Monitoring

Pharmaceutical Water Systems

Tuesday, April 25, 4:15-5:30 p.m.

Biotechnology

Lyophilization

Clinical Trial Materials

Visual Inspection of Parenterals

Facilities and Engineering

Inspection Trends/ Regulatory Affairs

Celebrating 60 Years: PDA's Science Trailblazers, continued from 8

Ljungqvist have been active and strong contributors to PDA. Over 15 years, they have **published eight manuscripts** in the PDA Journal—the first titled "Some Aspects on the Use of Biotest RCS Air Sampler in Unidirectional Air Flow Testing" in 1991. Their latest manuscript, "Modern Cleanroom Clothing Systems: People as a Contamination Source," was published in 2003. In addition, the two scientists have published three books through PDA-DHI on contamination control since 2001.

Drs. Ljungqvist and Reinmuller perhaps are best know for the "limitation-of-risk" (LR) method of airborne contamination control in cleanrooms. They have written numerous manuscripts on the method, including one published in the PDA Journal in 1995, "Hazard Analyses of Airborne Contamination in Clean Rooms—Application of a Method for Limitation of Risks." This method has had a major impact in the industry and has even influenced the shape of the U.S. FDA's 2004 guidance, *Sterile Drug Products Produced by Aseptic Processing—Current Good Manufacturing Practice*.

Dr. Reinmuller and Ljungqvist both work for Kungliga Tekniska Hogskolan in Stockholm. In 1996, the two scientists were awarded PDA's Distinguished Service Award.

PDA plans to recognize these individuals at the 2006 PDA Annual Meeting.

Acknowledgements

PDA thanks the following people for their help on this article: **Russell Madsen,** The Williamsburg Group LLC; **Ann Nicholas,** University of Minnesota; **Dr. Irving Pflug**; **Kristen Evans,** U.S. FDA; **Richard Friedman,** U.S. FDA; **Brenda McGee,** University of Tennessee; **Nathan Kirsch,** ret.

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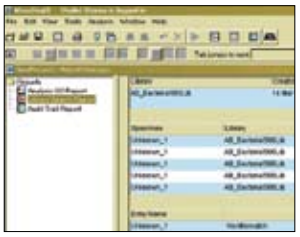

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25 YEARS ADVANCING SCIENCE

PDA Risk Management Task Force Update

Hal Baseman, ValSource, LLC

In the spring of 2005 the PDA Science Advisory Board authorized the formation of a task force to review risk management practices for aseptic processes. The Risk Management Task Force (RMTF) consists of a diverse group of members, representing large and small pharmaceutical and biopharmaceutical companies, medical device companies and the U.S. FDA. The charter of this team is to present concepts and approaches to managing risk, making risk decisions, evaluating events, developing plans and assuring compliance related to the aseptic processing of sterile products. RMTF activities will culminate in the issuance of a technical report, targeted for early 2007.

RMTF has developed an approach, which is now being transcribed to a written technical report. The task force hopes to present this approach to the PDA membership within the next year. The report will focus on key product attributes which are impacted by aseptic processing steps and that are a risk to patient safety. These attributes are pyrogenicity (or unacceptable endotoxin levels) and lack of sterility (or lack of sterility assurance).

The objectives of the technical report will be to provide awareness of risk management approaches, to suggest a practical approach to risk management, and to establish an understanding of the benefits and utility of risk management in aseptic processing-related decision making. Risk management is a method for obtaining information and reducing uncertainty. It can and should be used to assist in decision making for process development and planning, for qualification, validation and improvement, for investigation and problem solving, and for evaluation and demonstration of compliance. A key element of the approach is the use of risk management as an effective way to improve aseptic processes through the reduction of risk.

RMTF is aware that there are many other risk management documents, articles, publications and standards published or in development. The value of the PDA Technical Report will be in its practical approach to using risk management specifically for aseptic processing of sterile products. The technical report will present an overview of risk management background, concepts, definitions and standards, along with a set of models which can be used to identify, quantify, evaluate and report risk. Examples of risk management events and suggested process steps which have an impact on aseptic processing risk will be provided. Additionally, these process steps will be cross-referenced to the six quality systems.

The use of risk management can facilitate, but does not replace, the obligation to comply with regulatory requirements, and does not replace appropriate communications between industry and regulators.

In the next few months, RMTF plans to present additional information and updates. We welcome comments and input from interested parties regarding this article, the concepts and approach presented, and/or any matters related to the development of the technical report or to the risk management of aseptic processes. If you wish to contact us, please feel free to do so through PDA or directly to RMTF co-chairs.

For More Information

For more information on this task force and technical report, contact **Harold Baseman** at halbaseman@adelphia.net, or **Iris Rice** at +1 (301) 656-5900 or rice@pda.org.

Hal leads PDA's Process Validation Interest Group, which will be meeting at the 2006 PDA Annual Meeting on Monday, April 24, 4:00-5:15 p.m. (see page 8 for more information on IG sessions at the Annual Meeting).

PDA Risk Management Task Force Members

Co-Leader: **Hal Baseman,** *ValSource LLC*

Co-Leader: **Tim Ramjit,** *Schering-Plough*

Kris Evans, *FDA*

Bill Harclerode, *Abbott*

Thomas Genova, *GBSC (Centacor)*

Nanette Londeree, *Bayer HealthCare*

Sam Kim, *Eli Lilly & Company*

Jeff Hartman, *Merck & Company*

Michael Long, *AstraZeneca*

Bill Miele, *Pfizer*

Charles Tomonti, *J&J Cordis*

Marlene Raschiatore, *Wyeth*

Jorge Ferreira, *WGI*

Ruhi Ahmed, *BioMarin Pharma.*

Iris Rice, *PDA*

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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

Recommended Reading

Technical Report 38, Manufacturing Chromatography Systems Post-approval Changes: (ChromPAC): Chemistry, Manufacturing and Controls Documentation

This Technical Report, prepared by the PDA ChromPAC Task Force, addresses post-approval changes to drug substance manufacturing processes for chromatography systems and outlines in change tables the recommended test documentation in support of the changes.
Item no. 01038; PDA Member: US $75, Nonmember: US $150

Technical Report 40, Sterilizing Filtration of Gases

This technical report is designed to assist the reader in the selection, qualification, and validation of an appropriate filtration process. This report is a complement to PDA Technical Report No. 26.
Item no. 01040; Member: US $75, Nonmember: US $150

Technical Report 41, Virus Filtration

The new PDA Technical Report on Virus Filtration addresses virus removal filters, explains how they work, their selection, characterization and validation. If you use virus filters in your bioprocessing, then this new technical report is a must for you.
Item no. 01041; Member: US $75, Nonmember: US $150

Technical Report 42, Process Validation of Protein Manufacturing

This Technical Report (TR) focuses on validation of biopharmaceutical processes used to manufacture therapeutic proteins and polypeptides produced from recombinant or non-recombinant cell-culture expression systems. Selected principles may also apply to other product types, such as proteins and polypeptides isolated from tissues and body fluids. The TR provides practical guidance for compliance with CGMP's and ICH guidance's for the validation of biopharmaceutical processes to the drug substance stage.
Item no. 01042; Member: US $75, Nonmember: US $150

Encyclopedia of Rapid Microbiological Methods, Volume 1, **Editor: Michael J. Miller, PhD**

Microbiologists and management alike are working together to remove the perceived barriers concerning RMM implementation within many companies. This three volume encyclopedia focuses on regulatory and compendial initiatives currently in place that will help pharmaceutical microbiologists begin the journey of implementing RMM in their facilities and also describes the many rapid methods currently available.
Item no. 17220; Member: US $275, Nonmember: US $339

Environmental Monitoring, Volume I, Volume II and Protocol CD, **Editor: Jeanne Moldenhauer**

These two volumes, with more than 50 chapters written by subject matter experts worldwide, describe methods for developing and operating an appropriate, sustainable microbiological program both in the lab and during production. Numerous useful protocols are included on CD.
Item No. 17239; Member: US $480, Nonmember: US $599

Filtration Handbook: Liquids, **Authors: Mark W. Jornitz & Theodore H. Meltzer**

This book presents an illustrated lecture series dedicated to training industry professionals. Based primarily upon technical papers from peer-reviewed journals, this training guide provides comprehensive training that is invaluable to filtration professionals at all levels.
Item no. 17208; Member: US $200, Nonmember: US $249

Hosting a Compliance Inspection, **Author: Janet Gough**

Here is the guidance you need to host a compliance inspection. This book provides a common-sense approach for assessing an incoming inspection and preparing for it. Companies can keep themselves in a state of readiness for any inspection and here is how to do it.
Item no. 17192; Member: US $130, Nonmember: US $159

Microbial Risk Assessment in Pharmaceutical Clean Rooms, **Authors: Bengt Ljungqvist and Berit Reinmuller**

This monograph clearly explains the Limitation of Risk Method (LR-Method). When a systematic risk analysis is performed and sampling locations are selected and evaluated in a rational manner using this method, comprehensive monitoring will reduce the number of microbiological samples necessary and provide quality improvement.
Item no. 17175; Member: US $80, Nonmember: US $99

The Manager's Validation Handbook: Strategic Tools for Applying Six Sigma to Validation Compliance, **Author: Siegfried Schmitt**

This book is dedicated to modern methodologies and tools that delivery the best validation practices, processes and results, while achieving compliance with regulatory requirements for the healthcare industry.
Item no. 17234; Member: US $200, Nonmember: US $249

A Risk-Based Approach to ERP Systems Validation, continued from cover

pharmaceutical company are:

- Regulatory and quality
- Demand management
- Batch history/lot tracking
- Inventory status
- Distribution

An ERP system typically interfaces with a broad spectrum of a facility's functional areas as shown in Figure 1.

Validation Approach

Important Considerations: The following factors typically affect how a system like the ERP system is validated:

- Scale and complexity of the system
- History of the software package

Quality of the vendor providing the software package

In addition, companies should focus on the critical aspects of the system, because it is impractical to spend the time and money needed to validate every single feature of such a system. Likewise, it is important to identify the compliance data associated with the system, because not all of the data handled by the ERP will be considered compliance data.

Typically, ERPs consist of multiple modules, not all of which interact with compliance data or perform compliance-related functions. It is important, therefore, to understand the compliance functions and the interactions of the various modules with compliance data.

Lastly, the system usually consists of various functional areas/departments in an organization that utilize various aspects of the system. It is important to understand the human interactions with the system and its compliance data.

Step 1–Business Process Understanding: To completely understand the various human and system module interactions, a clear business process flow map needs to be generated. This can be achieved by interviewing users about their current responsibilities and the processes used by their departments. A flow map provides a better picture of the business across the different departments and identifies the critical decision-making points throughout the information flow. Once the overall process map is obtained along with the requirements of the system, the effort can be refocused on the processes that handle compliance data directly or indirectly. For example, the finance department routinely interacts with the ERP system of most organizations. While finances are very critical to any organization, the department usually has no impact on compliance data, and thus, from a validation point of view, their interactions may be omitted.

Step 2–Identifying Compliance Data/Compliance Processes: Once a thorough understanding of the business process and requirements of the overall system are obtained, the boundaries of the validation effort need to be established. This can be done by narrowing down the scope to the aspects of the system that have a high compliance impact, e.g., those software modules and human interactions that have a direct/indirect impact on the compliance data (See Figure 2, page 20). ➤

continued on page 20

Learn More at the 2006 PDA Annual Meeting

Subbu Vis is Senior Project Manager at Valimation, Inc. He will be speaking about the use of risk-management techniques in validating ERP systems at the 2006 PDA Annual Meeting in the Quality Science track, Tuesday, April 25, 2:00-3:30 p.m. The session, moderated by **Kathleen Greene** (Novartis Corp), is titled "Risk-Based Quality Management." Other speakers in the session include **Siegfried Schmitt,** PhD, GE Healthcare and **Lisa McChesney-Harris,** PhD, Protocol Link, Inc.

Other PDA Resources on This Topic

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

On-Demand Recording

- **Integrated Risk Assessment for Compendial Water Systems**

For more information, or to purchase this on-demand recording, call Vicky Acosta at +1 (301) 656-5900 ext. 158.

Publications

- **PDA Technical Report No. 42: *Process Validation of Protein Manufacturing*** *(item #01042)*
- ***Microbial Risk Assessment in Pharmaceutical Clean Rooms*** *(item #17175)*
- ***The Manager's Validation Handbook: Strategic Tools for Applying Six Sigma to Validation Compliance*** *(item #17234)*

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

Figure 1: Typical Departmental Interfaces with ERP Systems

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

Conferences

March 2-3, 2006
2006 PDA Pharmaceutical Anti-Counterfeiting Forum
(Conference and Exhibition)
Bethesda, Maryland

March 27-28, 2006
Cold Chain Management
(Conference and Exhibition)
Bethesda, Maryland

April 24-28, 2006
2006 PDA Annual Meeting
(Conference, Courses and Exhibition)
Anaheim, California

April 26-27, 2006
Workshop on Biotech Process Validation
Anaheim, California

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

June 26-28, 2006
PDA Emerging Manufacturing and Quality Control Technologies Conference
(Conference and Exhibition)
San Diego, California

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

October 23-24, 2006
Prefilled Syringes and Drug Delivery Systems
(Conference and Exhibition)
Bethesda, Maryland

October 30, 2006
PDA's 1st Annual 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

March 8-10, 2006
Cleaning Validation

March 15-16, 2006
Validating a Steam Sterilizer

March 28-29, 2006
Cross Flow Filtration Evaluations, Scaling and Practical Protein Purification and Separations

March 30, 2006
Process Development and Large Scale Implementation of Membrane Chromatography Devices

April 4-7, 2006
Pharmaceutical and Biopharmaceutical Microbiology 101

April 10-11, 2006
Developing and Validating Cleaning and Disinfection Programs for Controlled Environments

May 8-12, 2006
Aseptic Processing Training Program (session 2, week 1)

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

June 1-2, 2006
Environmental Mycology Identification Workshop

June 12-16, 2006
Aseptic Processing Training Program (session 2, week 2)

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

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Durham, North Carolina

April 27-28, 2006
PDA Annual Meeting Course Series
Anaheim, California

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

Chapters

April 5, 2006
PDA Metro Chapter
First Annual PDA Metro Chapter Day: Microbiology Update
Clark, New Jersey

June 12, 2006
PDA Canada Chapter
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Vancouver, British Columbia

Europe/Asia Pacific/Middle East

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

EUROPE

March 21-23, 2006
Practical Aspects of Aseptic Processing
Basel, Switzerland

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

September 27-28, 2006
Visual Inspections
Berlin, German

October 10-13, 2006
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London, England

ASIA/PACIFIC

November 13-17, 2006
2006 PDA Asia-Pacific Congress
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MIDDLE EAST

May 17-18, 2006
PDA and the PDA Israel Chapter
Quality Tools for the 21st Century
Eilat, Red Sea, Israel

A Risk-Based Approach to ERP Systems Validation, continued from page 16

This approach needs to be clearly documented in a formalized risk-assessment document that is revisited throughout the life cycle of the system.

Step 3–Establishing Risk Scenarios and Risk Indices: Above and beyond narrowing the scope of the validation to the compliance-related modules/processes of the system, a more detailed risk analysis should be performed to determine where certain testing/validation risks might be permissible. The risks taken should be clearly documented and analyzed for their risk index. In the case of the example in Table 1 (page 22), a modified failure modes and effects analysis (FMEA) table has been used to identify risks and their risk index ("risk index" in this example is the RPN, or Risk Product Number, which is described below). It is important to note that risks may be of several types, such as:

- System design risks
- System usage risks
- Business process risks
- Validation risks (the focus of this article)
- Part 11 risks

In the example in Table 1, the RPN is calculated as a product of the following parameters: RPN = S x D x O, where:

S = Criticality/Severity (Ex. 1): This is the most important parameter to be considered while performing a risk analysis. Criticality/severity is the seriousness of the consequence of a failure. For certain scenarios, a weighted risk index may be used, where, for example, RPN = S^3 x D x O.

Ex. 1: Criticality/Severity Ratings

Rating	Description	Definition
1	Low	Very low effect
2	High	High effect
3	Critical	Hazardous effect

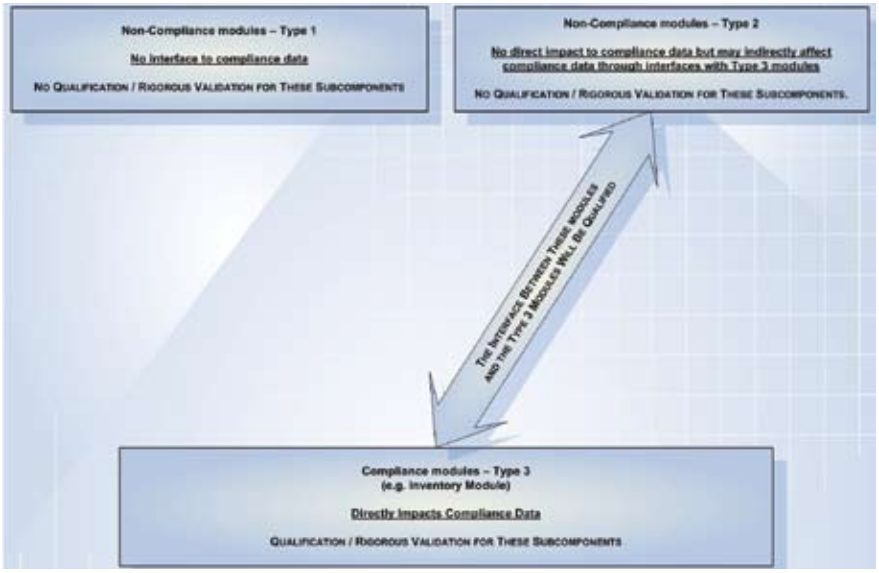
D = Probability of Detection (Ex. 2): It is the likelihood that the failure can be detected once it occurs.

Ex. 2: Probability of Detection Ratings

Rating	Description
3	Almost never
2	Medium
1	Almost certain

O = Frequency of Occurrence (Ex. 3&4): It is the probability or frequency of the failure/risk scenario occurring.

Figure 2: Narrowing Down Validation Scope



The rating of this parameter may be qualitative or quantitative. The difference in a qualitative and quantitative occurrence rating is illustrated in the examples below.

Ex. 3: Qualitative Occurrence Rating

Rating	Description
3	Very frequent
2	Frequent
1	Rare

Ex. 4: Quanitative Occurrence Rating

Rating	Probability of Occurrence
1 (very low)	1 to 10 per 10^4 to 10^6
2 (high)	11 to 50 per 10^4 to 10^6
3 (very high)	>50 per 10^4 to 10^6

Once the risk scenarios are identified, it is important to identify the cutoff factor of the RPN, indicating which risk scenarios need mitigation.

Step 4–Conducting the Validation Effort Using the Approach Defined in the Risk Assessment: Using the risk assessment, low-risk features of the software may be eliminated from testing. For instance, it is impractical and hardly necessary to test the screen navigation between the various screens of a large-scale system such as the ERP system. Since screen navigation has no impact on the data, errors can be easily detected. Such errors are highly unlikely for most mature ERP software products.

Similarly, data validation checks (e.g., boundary limits, format verification for data-entry fields, etc.) at a field level may be eliminated for all non-critical data, for the same reasons stated above. Instead, the risk assessment allows the validation effort to focus on the critical aspects of the system, including all the modules/programs identified as ➤

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A Risk-Based Approach to ERP Systems Validation, continued from page 20

those affecting compliance data, and all processes/actions identified as compliance-related processes.

Another approach to the validation effort is to conduct a thorough vendor audit/assessment of the software vendor providing the ERP solution. If the vendor passes the rigor of the audit with flying colors (by demonstrating a very strong quality-management system), a great deal of confidence may be obtained regarding the overall quality of the software package. This can further influence the extent of validation.

Step 5–Ongoing Risk Management: It is important to remember that the risk assessment is not a "one-shot" process. Since ERPs, the personnel and other systems that interact with them and the processes surrounding them are dynamic in nature, risk scenarios are likely to change throughout the life cycle of the ERP system. Risk assessments should be conducted periodically during the implementation of the system (for instance, it may be prudent to revisit the risk assessment at multiple phases of the implementation life cycle, e.g., planning, requirements, design, code/construction review and post-implementation). Once implementation is complete, risk scenarios should be revisited whenever changes to the system occur. It is also important to tie in the facility's problem-reporting system with risk management. New bugs or problems associated with the system may point to additional risk scenarios that were previously not considered. The findings of earlier risk assessments should be reviewed periodically to ensure that the assumptions and circumstances upon which they were founded are still valid.

Summary

Risk analysis has been extensively used in automotive, aerospace, defense and business sectors, and is one of the key objectives of FDAin their "GMPs for the 21st Century" initiative. Risk assessment helps in improving quality, safety and productivity, while cutting costs. FDA recommends that decisions relative to validation and other regulatory requirements such as 21 CFR Part 11 be made on the basis of: (1) predicate rule requirements, (2) impact on product quality, safety and record integrity and (3) a justified and documented risk assessment. The driving force in this recommendation is to not just make the validation efforts easier and cost-effective, but also more focused on the high-risk/highly critical aspects of the organization.

Table 1: Example of a Modified FMEA Risk Assessment Table

Category	Risk Scenario/Risk Effects	Assessment of Risk S	O	D	RPN	Mitigation Strategy	Residual Risk
System Design	The workstations are accessible to unauthorized personnel.	3	2	1	6	The security for the whole facility is controlled by a validated swipe card mechanism which allows access only to authorized employees. Furthermore the system possesses logical security that prevents unauthorized access.	Acceptable
System Usage	The system allows an active Purchase Order and an inactive Purchase Order to have the same Purchase Order Number. The user may confuse the new PO with an old, inactive PO.	3	1	2	6	The Purchase Orders are deleted after 5 years and the probability of this risk is very low. There is sufficient documentation to authorize the deletion of active POs. Once the PO is deleted, the old PO number is available for the system, but the old PO cannot be used in any transaction. No mitigation is required.	Acceptable
Business Process	The sample size used for testing incoming material may not be an actual representation of the entire lot.	2	2	3	12	The SOPs for sampling will be revised to include appropriate sampling quantities based on the size of the entire lot.	Acceptable
Validation	Data validation at a field level will not be tested.	1	2	1	2	Data validation was not tested at the field level as the frequency is low and the probability of detection is very high. Only important fields underwent both positive and negative testing. Moreover, the system has been in production for 2 years and no data validation related issues were reported through the Help Desk.	Acceptable
Validation	Only the GMP modules of the system have been validated.	1	1	1	1	A thorough analysis of the system and the business process was made, demonstrating no impact to compliance data and compliance processes. No mitigation needed.	n/a

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Regulatory Briefs

United States

FDA Warns Consumers About Overseas Rx

FDA is warning health care professionals and consumers that filling their prescriptions abroad may have adverse health consequences because of confusion with drug brand names that could inadvertently lead consumers to take the wrong medication for their condition. An FDA investigation has found that many foreign medications, although marketed under the same or similar-sounding brand names as those in the United States, contain different active ingredients than in the United States. Taking a different active ingredient may not help, and may even harm the user.

For the complete announcement, go to www.pda.org/regulatory/RegNewsArchive-2006.html.

FDA Publishes New Rule, Companion Rule and Guidance on cGMP for IND Phase 1

FDA is proposing to amend its current CGMP regulations for human drugs, including biological products, to exempt most investigational Phase 1 drugs from complying with the requirements in FDA's regulations. FDA will instead exercise oversight of production of these drugs under the Agency's general statutory CGMP authority and investigational new drug (IND) application authority. Simultaneously with the publication of this direct final rule, FDA is making available a guidance document setting forth recommendations on approaches to CGMP compliance for the exempted Phase 1 drugs. The action falls under FDA's "Critical Path" initiative.

The companion proposed rule provides the procedural framework to proceed with standard notice-and-comment rule making if the direct final rule receives significant adverse comment and is withdrawn. The comment period for the companion proposed rule runs concurrently with the comment period of the direct final rule. Any comments received on this companion proposed rule will also be treated as comments on the direct final rule and vice versa.

The guidance (once finalized) and the regulation it complements (once finalized) represent the Agency's effort to proceed with its plans to formally lay out an approach to aid manufacturers in implementing manufacturing controls that are appropriate for the stage of development. The use of this approach recognizes that some controls and the extent of controls needed to achieve appropriate product quality differ not only between investigational and commercial manufacture, but also among the various phases of clinical studies. Consistent with the Agency's CGMP for the 21st Century initiative, manufacturers are also expected to implement, where applicable, controls that reflect product and production considerations and evolving process and product knowledge and manufacturing experience.

The comment period for the rule and the companion rule closes on April 3. The rules become effective on June 1.

For more information and links to the rules and guidance, go to www.pda.org/regulatory/RegNewsArchive-2006.html.

FDA Amends Rules on Content and Format of Drug Product Labeling

FDA is amending its regulations governing the content and format of labeling for human prescription drug products (including biological products that are regulated as drugs). The final rule revises current regulations to require that the labeling of new and recently approved products include highlights of prescribing information and a table of contents. The final rule also reorders certain sections, requires minor content changes, and sets minimum graphical requirements. These revisions will make it easier for health care practitioners to access, read and use information in prescription drug labeling. The revisions will enhance the safe and effective use of prescription drug products and reduce the number of adverse reactions resulting from medication errors due to misunderstood or incorrectly applied drug information. For both new and recently approved products and older products, the final rule requires that all FDA-approved patient labeling be reprinted with or accompany the labeling. The final rule also revises current regulations for prescription drug labeling of older products by clarifying certain requirements. These changes will make the labeling for older products more informative for health care practitioners. This rule is effective June 30, 2006.

In addition, FDA is developing a series of guidances on selected sections of prescription drug labeling, as well as guidance on how to implement the new requirements. FDA previously published two of these guidances for public comment: *Clinical Studies Section*

of Labeling for Human Prescription Drug and Biological Products – Content and Format and *Adverse Reactions Section of Labeling for Human Prescription Drug and Biological Products – Content and Format.*

The guidances are intended to help applicants and reviewers do the following: (1) select information for inclusion in the "Adverse Reactions" and "Clinical Studies" sections of prescription drug labeling, (2) characterize information selected for inclusion in these sections, and (3) organize and present the information, including use of graphs and tables, within these sections.

FDA received comment on both guidances when each was published previously. For the guidance on adverse reactions, the Agency received 14 comments from nine pharmaceutical firms, a trade organization, a pharmacy professional society, a health insurance company, a medical publishing company and a consumer. In response to these comments, the Agency made a number of revisions to the draft guidance. Most significantly, the final guidance makes recommendations on how to make the most clinically important information accessible to health care practitioners. It provides recommendations on how to characterize and organize information, and it clarifies the recommended criteria for determining when to include low-frequency adverse events in the "Adverse Reactions" section.

Regarding the guidance on clinical studies, the Agency received seven comments from six pharmaceutical firms and one trade organization. In response to these comments, the Agency has made revisions to the draft guidance. The final guidance provides several examples of the types of studies that can be included in the "Clinical Studies" section. The final guidance also provides clarification as to when it is appropriate to include comparative data.

Links to these documents are available at www.pda.org/regulatory/RegNewsArchive-2006.html.

CDER Office of Generic Drugs Moves

The Immediate Office of Generic Drugs has moved to:

Metro Park North 4 (MPN 4)
HFD-600
7519 Standish Place
Rockville, MD 20855
Main number: 240-276-9310
Fax number: 240-276-9327

Europe

EMEA Adopts First Positive Opinion for a Similar Biological Drug

The European Medicines Agency (EMEA) has adopted the first positive opinion for a similar biological medicinal product.

The product, Omnitrope, is manufactured by Sandoz GmbH and contains somatropin, a recombinant-DNA growth hormone. It is intended for the treatment of growth disturbance and growth hormone deficiency in children and adults.

The Agency's scientific committee, the Committee for Medicinal Products for Human Use (CHMP) adopted the opinion at its meeting in January 2006. The Committee considered that, in accordance with European Union requirements, Omnitrope has been shown by studies demonstrating comparable quality, safety and efficacy to be similar to a reference medicinal product already authorized in the EU, namely Genotropin.

The European Commission and EMEA have worked actively over a number of years to put in place a legal and regulatory framework for similar biological medicinal products. The first guidelines on quality, non-clinical and clinical issues were adopted by the CHMP in December 2003. A general regulatory guideline on similar biological medicinal products was adopted in September 2005.

Further guidelines, including guidance on specific classes of products, are planned for adoption during the first quarter of 2006. A conference was held in Paris in December 2005 as part of the public consultation process.

Chapter Contacts

The following is a list of the PDA Chapters, organized by the regions of the world in which they are located. Included are the Chapter name, the area(s) served, the Chapter contact person and his or her e-mail address. Where applicable, the Chapter's Web site is listed. More information on PDA Chapters is available at www.pda.org/chapters/index.html.

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The Qualified Person at the 2006 PDA/EMEA Joint Conference

London • October 12-13

Anders Vinther, CMC Biopharmaceuticals A/S and PDA Board of Directors

The first ever PDA/EMEA Joint Conference will be held in London, England, Oct. 12-13, 2006. With the participation of many senior level representatives of the European Commission, EMEA, national agencies and the industry, the 2006 PDA/EMEA Joint Conference is widely anticipated to be *the* pharmaceutical event of the year in Europe. The topics to be covered include: the regulatory framework in Europe, contractor management, investigational medicinal products, EU harmonization, starting materials and the role of the qualified person (QP).

The qualified person is a particularly important topic, because the U.S. FDA does not have a requirement for a QP and the expectations for the QP in Europe are changing. The role of the QP is specified in the European GMPs (Eudralex Volume 4, Part I, including Annex 16). PDA Board Director Kathleen Greene (Novartis) and AstraZeneca's Nigel Hodges will moderate the QP session at the 2006 PDA/EMEA Joint Conference. The focus will be on the legal basis, routine duties and obligations of the European QP.

The session will also explore different types of QPs and contrast the QP to the role of quality professionals in other countries. Over the past few years, there have been some significant and wide-reaching changes to the role of the QP and currently the changes to the European legislation are still being discussed and implemented. Some of the issues of interest are: the role of the QP in relation to GMPs for clinical trials (Annex 13) and API certification and importation from third countries. The session also will cover how the QP manages international quality regulations for global supply chains and how oversight and adequate assurance can be maintained. Come and hear about how different QPs work, and meet the regulators who will participate to discuss the most recent legislation changes and the expectations of the QP.

2006 PDA Annual Meeting: *Pharmaceutical Manufacturing Science in the 21st Century: From Innovation to Implementation*

John Geigert, PhD, 2006 PDA Annual Meeting Program Committee Chair

Worldwide changes, an ongoing commitment of regulatory agencies to bring the GMPs into the 21st century, and the emphasis on manufacturing science, risk management, quality systems and process analytical technologies, emphasize the need for industry, regulators and academia to pull together and find common workable solutions for the issues facing us.

The 2006 PDA Annual Meeting in Anaheim, California, April 24-28, 2006 provides the ideal opportunity to do just that. By creating a platform for continuous improvement, the meeting focuses on what PDA does best—*connecting people, science and regulation*℠.

This three-day meeting will highlight multiple case studies in three major tracks designed to uncover and outline new concepts, and help refine skills:

- **Manufacturing Science – Includes advances in barrier systems, facility design, PAT implementation and applied manufacturing science**
- **Biotech Science – Includes alternative production systems, process validation of cell-culture bioreactor processes and cleaning validation science**
- **Quality Science – Includes three full sessions on rapid microbiological methods and risk-based quality management**

Learning Beyond Conference Sessions

Adding to the unique learning experience of the 2006 PDA Annual Meeting are keynote sessions lead by three exceptional speakers: **Susan Desmond-Hellmann,** MD, President, Product Development, Genentech; **Norbert Hehme,** GlaxoSmithKline VP, Flu Manufacturing Strategy; and **Barry Cherney,** PhD, Expert Biologist, CDER/FDA.

The meeting also offers PDA Training and Research Institute courses, exhibits offering the latest in scientific technology to improve regulatory compliance and manufacturing environments, multiple networking opportunities, and a career fair featuring employers from all over the world.

About the Author

John Geigert, PhD, is the President of BioPharmaceutical Quality Solutions. Besides helping PDA put together the program for the 2006 PDA Annual Meeting, Dr. Geigert is Co-Chair of PDA's Biotechnology Advisory Board.

After the Annual Meeting, More Learning Opportunities

Training and Research Institute Courses

April 27-28, 2006 | Anaheim, California

In conjunction with the 2006 PDA Annual Meeting, the PDA Training and Research Institute is offering courses aimed at keeping you compliant and ahead of the curve on validation and risk-management issues.

New Course!

Development of Qualification & Validation Protocols - A Risk Management Approach

April 27, 2006

New Course!

Elements of Risk Management

April 27-28, 2006

New Course!

Statistical Tools Supporting Quality Risk Management and Analysis (ICH Q9)

April 28, 2006

Cleanroom Management

April 27-28, 2006

Preparing for FDA Pre-Approval Inspections, cGMP & Post-Market Inspection

April 27-28, 2006

PDA Workshop on Biotech Process Validation

April 26-27, 2006 / Anaheim, California

After a long period without significant change, Biotech Process Validation is evolving rapidly. The FDA initiative on GMPs for the 21st Century, ICH Q7A and Q8 and PAT are examples of some of the initiatives that have had influence on process validation guidance. This workshop will provide you with a unique opportunity to get an update on current developments, review helpful case studies, and give you a platform for many productive discussions with your colleagues that will contribute to your success.

For more information or to register, visit www.pda.org/validation2006.

Networking News…the 2006 PDA Annual Meeting

Catch Up with Your Colleagues in California!

PDA recognizes that a big part of your career success is not only *what* you know, but *who* you know. So along with the outstanding science presented during the 2006 Annual Meeting Conference and Courses, PDA will also be providing more opportunities than ever to network. Meet with friends and colleagues in one of many relaxed venues. Discuss the day's meeting, share ideas and experiences, and chat over breakfast, lunch or hors d'oeuvres. Strengthen and expand your professional network by enjoying time with your peers and making new contacts that might help or influence your career.

Take Time to Orient Yourself

Start off your Annual Meeting experience the right way. Spend Sunday afternoon with other conference attendees, representatives of the PDA Chapters representatives and the Annual Meeting Program Planning Committee for an informal reception to learn what is in store for you at this year's meeting. Connect with peers and plan your stay in Anaheim to maximize learning, networking, and of course, fun!

Sunday, April 23 | 3:00 p.m. – 6:00 p.m.

Learn the Latest at Lunch with Exhibitors

Grab a sandwich and a friend and tour the Exhibit Hall. It's informative, interactive and will give you the chance to evaluate and compare the latest pharmaceutical and biopharmaceutical technologies. Satisfy your hunger and your curiosity, while comparing notes with your colleagues. See next page for a complete exhibitor list.

Monday, April 24 | 12:30 p.m. – 2:00 p.m.

Interact with Interest Groups

Interest Group sessions provide one of the best networking experiences at PDA conferences and offer the perfect setting for having your questions answered by your peers. At this year's Annual Meeting, you can choose from 12 Interest Group sessions.

Monday, April 24 | 4:00 p.m. – 5:15 p.m.
Tuesday, April 25 | 4:15 p.m. – 5:30 p.m.

Enjoy an Evening Reception in the Exhibition Hall

Unwind with your peers at the end of the conference's first day, enjoy the refreshments and take another look around the exhibit booths. One ticket is included with your registration fee; you may purchase additional tickets for guests. Don't miss the prize drawings too!

Monday, April 24 | 5:15 p.m. – 7:30 p.m.

Dive into Hot Topics and Breakfast at Roundtable Discussion Sessions

Pick up your breakfast in the Exhibit Hall and take advantage of this chance to participate in a discussion group on one of four topics: Visual Inspection, Biologics, Prefilled Syringes or Risk Management. This informal, smaller forum promotes discussion, encourages participants to ask questions and is the ideal venue to meet others who share your interests.

Tuesday, April 25 | 8:00 a.m. – 9:00 p.m.

Explore Employment Options at the 2nd Annual Career Fair

If you are considering a career move, or if you're looking for new talent, this is the place to be. Employers from all over the world will come face-to-face with potential employees, in a private interview setting. Pack some extra copies of your resumé, just in case!

Tuesday, April 25 | 8:00 a.m. – 5:00 p.m.

See the Future Leaders of Our Industry at the Student Research Symposium

At this symposium, a select group of up-and-coming students will present their work, which was chosen based on its comprehensiveness and potential contribution to the advancement of the pharmaceutical and biopharmaceutical industries. Enjoy lunch and get energized by these young minds.

Tuesday, April 25 | 12:45 p.m. – 2:00 p.m.

Mark 60 Memorable Years as PDA Celebrates its Anniversary

We've taken out all the stops to create an unforgettable evening of celebration. If you're a longtime member, you'll enjoy a "stroll down memory lane" with a video presentation of people and places from PDA's past. This is the perfect event for new members to meet PDA's long-standing members and learn what the Association has meant to their careers and professional development, and why many have maintained their memberships for years. One ticket is included with your registration fee; additional tickets may be purchased.

Tuesday, April 25 | 6:30 p.m. – 9:30 p.m.

PDA Authors at Book Signing

Five authors will be on hand at the Annual Meeting to sign copies of their bestselling PDA/DHI Technical Books. Meet these subject-matter experts at the PDA exhibits hall booth for an opportunity to talk with them about their latest works. Author availability will be announced during the meeting.

Jeanne Moldenhauer, PhD
Michael J. Miller, PhD
Siegfried Schmitt, PhD
Ted Meltzer, PhD
Maik Jornitz

PDA
Parenteral Drug Association

2006 Annual Meeting

April 24–28 | Anaheim, California

Celebrating 60 Years of *Connecting People, Science and Regulation*SM

EXHIBITORS	Booth
AAIPharma	513
Accugenix, Inc.	516
Advanced Analytical	314
AES-Chemunex, Inc.	505
Allergan, Inc.	613
Althea Technologies	517
American Pharmaceutical Review / American Pharmaceutical Outsourcing / PAT	308, 310
American Stelmi Corporation	402
Applied Biosystems	204
Aptuit, Inc.	707
Aramark Cleanroom Services	209
Artel, Inc.	411
Asahi Kasei Medical America, Inc.	210
Aseptic Technologies	410
Associates of Cape Cod, Inc.	404
ATS Automation Tooling Systems	510
Baxter Healthcare Corporation	701, 703
Bayer Healthcare, LLC	604
Bio-Concept Laboratories	713
Biocorp	206
Biolog, Inc.	412
bioMerieux	200, 202
BioPharm International	102
BioProcess International/BioExecutive International	215
Bioscience International	306
Biotest Diagnostics Corporation	500
BioVigilant	104
BOC Edwards Pharmaceutical Systems	416
Boston Analytical Inc.	108
Cardinal Health	700, 702
Celsis International plc	217
Charles River Laboratories	600
Compli, LLC	610
Compliance Software Solutions Corporation	603
Contamination Control / Pharmaceutical Formulation & Quality (PFQ)	605
Contec, Inc.	106
Controlled Contamination services	606
Contract Pharma Magazine	614
CPS Pharma	512
Cryovac - Sealed Air Corporation	717
Domnick Hunter	211
Dresser Instruments/EBRO	309
Drumbeat Dimensions, Inc.	406
Duoject Medical Systems Inc.	611
Dupont Personal Protection	612
DuPont Qualicon	408
Eisai Machinery U.S.A. Inc.	417
Elan Drug Technologies	711

2006 Annual Meeting | Exhibitors and Sponsors

EXHIBITORS	Booth
EMD Chemicals Inc.	617
Genesis Machinery Products	507
Genomic Profiling Systems	414
Gerresheimer Group GmbH	317
Gram Laboratories, Inc.	705
Helvoet Pharma	212
Hyaluron Contracting Manufacturing	607
Irvine Analytical Laboratories	709
JM Hyde Consulting, Inc.	515
Lancaster Laboratories	100
Lighthouse Instruments, LLC	316
Marathon Products, Inc.	413
Masy Systems, Inc.	114
Microbiology International	608
MIDI, Inc.	602
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Moda Technology Partners	514
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Novatek International	101
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P3 Scientific, Inc.	312
Pall Life Sciences	300,302, 401, 403
PAREXEL Consulting	307
Pharmaceutical Systems, Inc.	103
Pharmaceutical Technology	511
Pilgrim Software Inc	214
PharmaSys, Inc.	216
PML Microbiologicals	400
Precision Pharma Services, Inc.	207
Protocol Link, Inc.	616
Raven Biological Laboratories	205
Remel, Inc.	409
Saint Gobain Desjonqueres	504, 506
Sartorius Corporation	501, 503
Sci-Tec, Inc.	315
Seidenader Equipment, Inc.	208
SL Pharma Labs, Inc.	601
STERIS Corporation	502
SynTegra LLC	715
Technical Safety Services, Inc.	704
TechnoFlex	615
Texwipe (ITW)	407
Title21 Software	415
Vectech Pharmaceutical Consultants, Inc.	509
Vectech Pharmaceutical Consultants International, Inc.	213
Veltek Associates, Inc.	301, 303, 305
Vetter Pharma-Fertigung GmbH & Co. KG	311

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Vice President's Message

Gail Sherman

Post-Conference Courses Offer Additional Quality Training

I am very proud to brag about the "quality" of our courses to be held at the 2006 PDA Annual Meeting: Pharmaceutical Manufacturing Science in the 21st Century: From Innovation to Implementation.

Following the current trends towards quality systems and quality management, PDA has created a program on quality for the 2006 Annual Meeting in Anaheim, Calif., April 24-28. The three-track conference includes one on "Quality Science," and the post-conference TRI courses include four related to quality management:

- "Elements of Risk Management," taught by **Gregory Meyer,** Compliance Media
- "Statistical Tools Supporting Quality Risk Management and Analysis (ICH Q9)," taught by **Lynn Torbeck,** Torbeck and Associates
- "Development of Qualification and Validation Protocols – A Risk Management Approach," taught by **Hal Baseman,** ValSource, LLC
- "Preparing for FDA Preapproval Inspections, cGMP and Post-Market Inspections," taught by **Jeffrey Yuen,** Jeff Yuen and Associates

It is really exciting that the stars aligned, and we were able to find well-qualified experts who were available to be in Anaheim to teach these courses. All of our instructors for these courses are longtime PDA members, with histories of providing training and participating in interest groups and task forces.

TRI's remaining three courses build off of the Annual Meeting's Manufacturing Sciences track. These also are being delivered by long-term PDA members who have been TRI instructors for a number of years, including Theodore Meltzer, PhD, Capitola Consulting, and PDA Treasurer Maik Jornitz, Sartorius Corporation.

You can find descriptions of all these courses in our 2006 catalogue at www.pda.org/pdf/tri-courses/2006_coursecat.pdf.

The staff at TRI and I look forward to seeing you in Anaheim!

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Biennial Training Conference Courses: A New Approach to Training

Gail Sherman, PDA

The 2006 PDA Biennial Training Conference in Philadelphia, Pa., May 8-10, is fast approaching!

For this year's event, we have done something quite different with the post-conference courses. We wanted to be a bit non-traditional and provide our attendees with something additional to all that they would learn at the conference itself. To develop this new agenda, we used consulted with our new Training and Research Institute Advisory Board (TRIAB), which includes many seasoned professionals in the training community. Through several brainstorming sessions, the TRIAB agreed that the focus should be on the "business" of training—not necessarily the techniques to train or the rules and requirements surrounding training. The "business" of training includes those issues critical to why we do training, what it costs us to train, and how we get support as training directors and professionals in our companies. Six courses post-meeting courses will be offered:

- **The Manager's Role in Training: Making the Grade with the FDA**
- **The Evolution of Training: Keeping Pace with the Business and Regulatory Requirements**
- **The Business of Training: Earnings and Learnings**
- **Technical Training as an Integral Part of an Aseptic Operation Quality System**
- **cGXP Training for the 21st Century**

Five of these courses will be taught by TRIAB members. We are really excited about this change in focus and hope that you will be too! We are also offering two of our more traditional courses, both hits at previous meetings: **Maximizing SOPs – An Untapped Resource of Training Solutions** and **Regulation without Motivation: Spark a Change without Shorting Your Circuit**.

Please join us in Philadelphia for the premier conference about training, complete with great networking opportunities and fun while learning, as well as the additional training courses that will help you with your business practices. See you at the Liberty Bell!

You Came, You Asked, We Delivered!

What did we deliver? *New courses,* that's what! You may be surprised to learn that we actually *read* those surveys we ask you to fill out at our various lab and lecture courses.

As a result of your feedback in 2005, TRI is offering four new lab courses this year. Because these new courses were based on your input, we are sure that they will provide the maximum benefit to each of our members and the entire pharmaceutical, biopharmaceutical and medical device industries.

Our new lineup premieres on March 28th with the two-day lab course, **Cross Flow Filtration Evaluations, Scaling and Practical Protein Purification and Separations.** This course is immediately followed by the new one-day lab course **Process-Development and Large-Scale Implementation of Membrane Chromatography Devices.** These courses are designed to go hand in hand and are being offered back-to-back to make it easier for students to attend both.

Because we know many of you enjoy Baltimore's Inner Harbor during the summer months when the days are long and warm, we are offering two new courses. First, **Scott Sutton,** PhD, Vectech Pharmaceutical Consultants, has developed a new course to help professionals in our industry manage the volumes of environmental monitoring data generated during testing and manufacturing. Called **Environmental Monitoring Database and Trending Technologies,** this three-day course will cover software from Compliance Software Solutions Corp., Novatek and Microsoft. Last, but not least, we have a new four-day lab course scheduled for July 25-28 called, **Biomanufacturing Technologies,** which is designed to explain why and how bioprocessing is able to produce complex protein products starting from simple microorganisms and cells.

TRI started updating its laboratory offerings in 2005, with **Pharmaceutical and Biopharmaceutical Microbiology 101.** Because of the high demand for this course, we are again offering it twice in 2006 (April 4-7 and July 18-21).

All of these new courses mentioned above are hands-on, just like the rest of TRI's lab course offerings. There is also more information up on the website for each of these courses, just go to www.pdatraining.org to learn more! Or you can contact TRI at tri@pda.org with your questions.

March's Top 10 Bestsellers

From the PDA Publications Store

Environmental Monitoring, Volume I, II, and Protocol CD

Edited by Jeanne Moldenhauer, PhD

These two volumes, with more than 50 chapters written by experts worldwide, describe methods for developing and operating an appropriate, sustainable microbiological program both in the lab and during production. Numerous useful protocols are included on CD.

Item No. 17239
PDA Member $480
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Check out these titles and more from the PDA Publications Store.

1. **Environmental Monitoring, Volume I, II, and Protocol CD, edited by Jeanne Moldenhauer, PhD**
   Item No 17239, PDA Member $480, Nonmember $599
2. **Encyclopedia of Rapid Microbiological Methods, Volume I, edited by Michael J. Miller, PhD**
   Item No. 17220, PDA Member $275, Nonmember $339
3. **PDA Archive on CD-ROM - PDA Archive Retrieval Index (25% off)**
   Item No. 01101, PDA Member $395, Nonmember $590
4. **The Manager's Validation Handbook: Strategic Tools for Applying Six Sigma to Validation Compliance, by Siegfried Schmitt, PhD**
   Item No. 17234, PDA Member $200, Nonmember $249
5. **Technical Report No. 39, Cold Chain Guidance for Medicinal Products: Maintaining the Quality of Temperature-Sensitive Medicinal Products Through the Transportation Environment**
   Item No. 01039, PDA Member $75, Nonmember $150
6. **Technical Report No. 42, Process Validation of Protein Manufacturing**
   Item No. 01042, PDA Member $75, Nonmember $150
7. **Microbial Contamination Control in the Pharmaceutical Industry, edited by Luis Jimenez**
   Item No. 05630, PDA Member $145, Nonmember $179.95
8. **Good Manufacturing Practice Regulations, 21 CFR Parts 210-211, Sub-Parts B thru K Set of 10 programs – Shepherd training CDs**
   Item No. 11014, PDA Member $1500, Nonmember $1695
9. **Technology Transfer: An International Good Practice Guide for Pharmaceutical and Allied Industries, Mark Gibson, PhD**
   Item No. 17218, PDA Member $215, Nonmember $269
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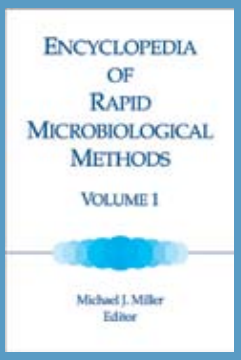

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2006 PDA/EMEA Joint Conference

LONDON, ENGLAND

CONFERENCE
AND EXHIBITION:
12-13 OCTOBER 2006

TRAINING COURSES:
10-11 OCTOBER 2006

MEET THE REGULATORS!

This is a unique opportunity to interact and network directly with those people who enforce regulation in the European Union.

Understanding the European GMP Environment

MARK YOUR CALENDARS FOR THE OPPORTUNITY TO MEET EUROPEAN REGULATORS IN PERSON! In continuation of PDA's tradition since 1986 of meeting annually with U.S. regulators at the PDA/FDA Joint Regulatory Conference, PDA is partnering with the European Agency for the Evaluation of Medicinal Products (EMEA) for the first time, to offer a similar conference in Europe. This conference will provide a forum to facilitate dialogue between top European health authorities and industry experts in an unbiased, science-based forum.

The aim of this conference is to increase understanding and awareness of European GMP expectations. Participants will include representatives from EMEA, member state health authorities and industry, who will share their expertise on recent developments in European GMPs and be available to meet and discuss topics with conference attendees.

SAVE THE DATE... Join us in London in October 2006 for the first ever PDA/EMEA Joint Conference!

FOR FURTHER INFORMATION PLEASE GO TO *www.pda.org*

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