Science • Technology • Quality • Regulatory • Community

# PDA Letter

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May 2005


## In This Issue...





# EMEA Prepares for a Larger, More United Europe

**Victoria Dedrick, PDA**

### New Community Legislation, Enlargement Pose Great Challenges

Both the enlargement of the European Union on May 1, 2004, and new Community pharmaceutical legislation, effective by November 2005 present considerable challenges for the European Medicines Agency (EMEA) and its partners and stakeholders that comprise the full EU regulatory system. The EMEA works as a network, bringing together the scientific resources of the Member States to ensure the highest level of evaluation and supervision of medicines in the EU. In addition, the EMEA closely cooperates with international partners, particularly the U.S. FDA, contributing greatly to global harmonization.

Recent political, institutional, legislative and scientific developments in the EU will have a significant impact on the regulatory environment over the coming years. The scientific environment is changing dramatically with the introduction of new technologies and emerging therapies, such as gene therapy, pharmacogenomics, proteomics and xenotransplants. These developments need to be addressed within the context of continuing globalization.

The integration of ten new Member States (MSs) and their National Competent Authorities (NCAs), and the planned accession of a further two additional states in 2007, increases the complexity of operating an efficient regulatory system, whilst new legislation extending the scope of the Agency's activities increases pressure on its resources and on its ability to meet the expectations of stakeholders.

Political orientations such as the Lisbon strategy for economics, social and environmental renewal are important factors to increase the competitiveness of the pharmaceutical industry based in the European Union. The Lisbon strategy was agreed to by EU heads of state at the March 2000 annual spring meeting. The objective of the strategy is to make the European Union the most competitive and dynamic knowledge-based economy in the world by 2010.

One of the key issues for health authorities in the European Union over the next years will be their ability to adequately monitor medicinal products on the market, especially from a safety perspective. Recent worldwide withdrawals of

*continued on page 11*

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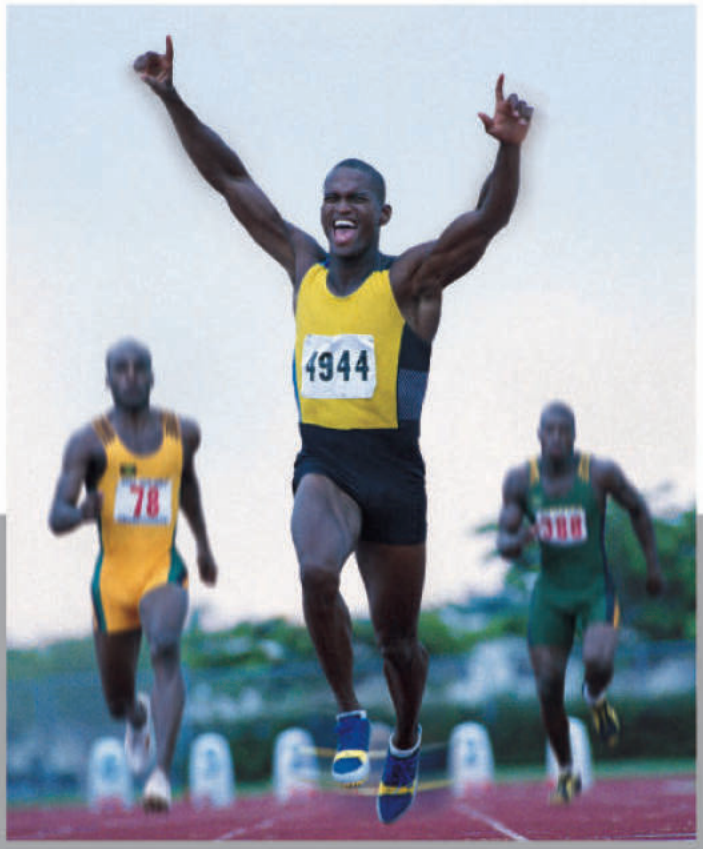


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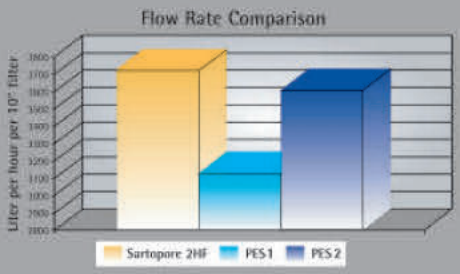


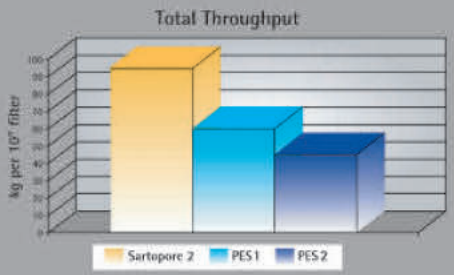


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| Conference | Tabletop Exhibits | PDA TRI Training Courses |
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| September 12-14, 2005 | September 12-13, 2005 | September 15-16, 2005 |

## Overview

The PDA/FDA Joint Regulatory Conference continues to be a much anticipated event and an essential part of continuing education in the pharmaceutical and biopharmaceutical fields. It has established a formidable reputation for providing the latest updates on regulation and guidance impacting:

- Pharmaceutical Manufacturing Science and Technology
- Quality Systems and cGMPs
- Drug and Process Development

This year the theme for the conference is *The Product Life Cycle: Quality by Design, Implementation and Continuous Improvement*, which will provide regulatory updates and implementation strategies across the product life cycle from drug development to post-marketing surveillance ensuring that safe and efficacious drugs are available in support of FDA's public health mandate.

## Who Should Attend

This conference will be of value to mid- and senior-level pharmaceutical and biopharmaceutical professionals, academics and regulators working in:

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- ✓ **Manufacturing Sciences**
- ✓ **Process Development**
- ✓ **Drug Development & Technology Transfer**

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- Receive the latest information from FDA on post-marketing surveillance for drugs and the role of the newly created and independent Drug Safety Oversight Board (DSB) which you can incorporate into your company's intelligence gathering

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# Leadership Update

On April 20, 2005 PDA announced that Neal Koller, President, is leaving PDA to pursue other opportunities.

"I am proud and honored to have served as president of PDA, the premier organization in the pharmaceutical and biopharmaceutical sector. I would like to express my sincere gratitude to the membership and staff, and wish the association the best of success," said Koller.

"On behalf of PDA, I'd like to thank Neal for his many contributions and his tireless efforts in support of the association, and wish him well in his future endeavors," said Nikki Mehringer, Chair of the Board.

Mehringer also announced the appointment of Bob Myers, President of Beacon Pointe Group, as PDA Acting President. Myers has extensive experience in leadership positions with PDA as a volunteer, including serving as the Chair of the Board from 2000-2001. Myers and Koller will work together to transition responsibilities.

PDA has begun a search to fill the open position of President immediately.

PDA staff is available to answer members' questions. Please contact Matthew Clark, Director of Marketing Services, Membership & Chapters by e-mail or call +1 (301) 656-5900.

# PDA's Sherman Named to FDAAA Board

On April 26, 2005 PDA announced that Gail Sherman, Vice President of Education & Director, Training and Research Institute, has been elected to the FDA Alumni Association (FDAAA) Board of Directors.

"I am very pleased to see Gail recognized by her fellow FDA alumni for her contributions to the Agency and continued support of FDA's mission," said Robert Myers, PDA President. "In the short time she has been with PDA, Gail has carried over this high level of commitment to the PDA community, helping to advance the Training and Research Institute as a leader in education, training and applied research in the pharmaceutical and biopharmaceutical sciences and associated technologies."

The FDAAA helps FDA alumni stay connected with major scientific and public health issues facing FDA and with each other through educational and other events, and a variety of volunteer service projects. These activities enable alumni to continue to support FDA's vital mission and stay active in efforts to improve public health throughout the United States and the world.

Sherman will serve a three-year term on the FDAAA Board.

**About FDAAA**

The Food and Drug Administration Alumni Association, Inc. is an educational, service-oriented organization founded in 2001 by a small group of FDA retirees and employees. The non-profit, non-lobbying organization is legally incorporated in the State of Maryland and has tax exempt status from the Internal Revenue Service. The Association also has a collaborative relationship with FDA under a Memorandum of Understanding.

# PDA Task Force Update: Computer Validation Management and Electronic Information Assurance

**George J. Grigonis, Jr., QA Edge, Inc.**

## 33 CVM TF Volunteers Hold 6 Meetings

The first meeting of the Computer Validation Modernization (CVM) Task Force (TF) was held in September 2004. The TF consists of 33 PDA members and staff from regulated companies, service and product suppliers, the PDA Training and Research Institute and the U.S. FDA. Already, the TF has met six times.

Initial meetings of the TF focused on establishing a working charter and project plan. The scope of this TF is to define:

- A "Current Good System Practices" (CGSP) framework that considers available bodies of knowledge and courseware devoted to software and systems engineering,
- An outline for courseware development that places CGSP in a regulatory context as a primer to a CGSP framework and,
- The necessary PDA infrastructure to deploy and sustain the framework for efficiently and effectively implementing computing environments used for business and regulated operations.

To date, the TF produced a curriculum outline that recognizes computing compliance as a combination of technology processes, enterprise reform and risk management. This multidimensional view breaks away from traditional approaches that are project-centric, paper-oriented and typically attempt to force fit antiquated "waterfall" engineering concepts to computing solutions and projects.

Members of the EIA Task Force meet at PDA's Headquarters in Bethesda, Md. in March

A new kind of thinking required to stay current with emerging technologies and IT concepts embraces current good system practices. Such practices are matched to today's computing options and deliver low-risk and reliable solutions designed to fit business needs. CGSP are those collective activities for evolving, engineering, servicing and using computing hardware and software in a way that ensures confidence that computing environments are, and remain, fit for their intended purposes as business solutions.

The core suite of courses for this curriculum will introduce CGSP in the context of meeting computing needs of the life sciences company, simultaneously meeting compliance expectations to satisfy laws and regulations applicable to computer use. This suite will also address key aspects of enterprise reform (business transformations) that: enable a process-centric way of thinking; apply risk management to corporate assessments of a computing environment's fitness for use; and consider cost of ownership, system reliability and performance.

The TF is identifying courseware electives that focus on "how to" details for engineering, quality and metrics work. Electives include:

- Writing testable requirements
- Managing the testing process
- Commercial-off-the-shelf-based systems engineering practices

Members of the CVM Task Force meet on an unseasonably warm February day at PDA's Headquarters in Bethesda, Md.

- Key steps to useful metrics and process improvement
- Conducting meaningful reviews & assessments
- Managing test outsourcing
- Specifying, selecting and managing IT service providers

These are but a few examples of courseware being investigated.

The Computer Validation Modernization TF's work on the curriculum will identify what has to be developed and what can be offered from available courseware through partnerships to deliver education to the industry and regulators.

### EIA TF Has 25 Volunteer Members

The first meeting of the Electronic Information Assurance (EIA) Task Force (TF) was held in October 2004. The TF consists of 25 members, from regulated companies, service and product suppliers and the FDA. Already the TF has met five times.

The TF's first few meetings focused on establishing a charter and project plan. The scope of this TF is to define: a framework for an EIA program that builds upon GERM [Part 1 Good Electronic Records Management (GERM), Item No 19003, published jointly by PDA and ISPE] principles; and a PDA infrastructure needed to deploy and sustain the framework as an industry road map.

To date, the TF has produced a framework for the assessment of electronic information that treats electronic information as an asset that has a life cycle. Information is created, used and modified, and subsequently retained for a finite period, after which the information is destroyed. Each life cycle phase has a major focus that is characterized by key practices. The practices are intended to ensure that electronic information retains the properties of: integrity, authenticity, confidentiality, availability and non-repudiation. The framework also recognizes the importance of supporting practices that cut across all life-cycle phases and are fundamental to organizational thinking that enables EIA. For example, practices and related key activities cover:

- Information quality
- Security
- Information technology
- EIA program quality & measures
- Enterprise policy & procedure management
- Risk assessment and management
- Enterprise semantics

The TF set up smaller subgroups focused on researching references and practices (e.g., standards-based technical, procedural and administrative safeguards) applicable to the various life cycle phases and supporting activities. The TF intends to amass a comprehensive and useful knowledge base of such practices. To that end, a subgroup is engineering a database tool to help describe the practices and relate them to relevant life cycle and supporting activities. The TF's ultimate objective is to enable PDA to keep the knowledge base current and future-proof.

### Participants Welcomed

For more information on how you can participate in these Task Forces please contact George Grigonis, Sr. Systems Consultant, QA Edge, Inc., at grigonis@comcast.net.

George Grigonis leads both the CVM and EIA Task Forces. He also was the leader of PDA Task Forces for Supplier Auditing and Part 11. The Supplier Auditing Task Force resulted in PDA Technical Report #32 for supplier auditing and the establishment of the Audit Repository Center. The Part 11 Task Force developed three publications: *Good Electronic Records Management, Part 1; Complying with 21 CFR Part 11, Part 2;* and *Models for Systems Implementation and Evolution, Part 3).*

### CVM Task Force Members

Mike Ambrose, CimQuest
Carylon Apperson-Hansen, Cleveland Clinic Foundation
Warren Campbell, Consultant
Patrice Clark, Booz Allen Hamilton (BAH)
Virginia Corbin, Waters Corp.
John English, TECHNIP BioPharm
Skip Garrison, ValSource
Rita Geiger, Infostrength
Greg Gogates, CRF Box
Harvey Greenawalt, IT&E
George Grigonis, QA Edge, Inc.
Peter Halas, WWC
Steven Henderson, SEC Associates
Wells Horton, Proctor & Gamble
Russ King, Infostrength
Chris Laiacona, BASF
Fernando Lopez, AstraZeneca
Marc Mercer, Cephalon
Marylin Monocol, IBM
Paul Motise, U.S. FDA
John Murray, U.S. FDA
Alex Pawluk, Cephalon
Philip Piasecki, Novartis
Michele Pontinen, BAH
Gail Sherman, PDA
John Sicurella, Avecia
Nausika Sullivan, IBM
Carla Welsh, Merck

### EIA Task Force Members

Carolyn Apperson-Hansen, Cleveland Clinic Foundation
Haruhiko Araki, Hitachi
Laura Carter, SEC
Richard Dolejan, Schering-Plough
Steven Frampton, 3M
Rita Geiger, Infostrength
Tom Golden, BioMimetic
George Grigonis, QA Edge, Inc.
Birgitta Hedin, AnorMED
Vien Hua, Sanofi-Synthelaboratory
Marilyn Kibler, IBM
Russ King, Infostrength
Victoria Lander, NuGenesis
Paul Motise, U.S. FDA
John Murray, U.S. FDA
Paul Noble, IDS Scheer AG
Brenda Nuite, Kimberly-Clark
James Pace, QA Edge, Inc.
George Smith, U.S. FDA
Stephen Weil, IBM
Gordon Workman, BAH

# USP Update

**Roger Dabbah, PhD**, USP

The USP convention of 2005 was successfully completed with a number of resolutions adopted by the Convention. Thirteen resolutions were adopted covering a wide range of topics and issues. The resolutions can be viewed on the USP Web site at www.usp.org.

A number of Resolutions are relevant to PDA members:

- Resolution 1 on "Public Monographs and Reference Materials" deals with the elimination of barriers to expanding and updating public monographs in USP-NF in collaboration with appropriate stakeholders and to develop reference materials for all legally marketed therapeutic products in the US;
- Resolution 2 on "Integrity and Safety of Therapeutic Products" relates to the development of packaging, shipping, distribution, and storage standards and practices to ensure integrity and safety of therapeutic products through the distribution and dispensing system
- Resolution 3 on "New Science and Technology" directs USP to work with appropriate stakeholders to track emerging sciences and technologies for their impact to the public health and patient care by the development, when appropriate, of information, best practices, and standards
- Resolution 6 on "USP International Presence" is designed to increase the impact of USP public health programs internationally and to provide assistance in improving regulatory mechanisms and building capacity to monitor drug quality for countries without appropriate resources; and
- Resolution 7 on "International Harmonization" indicating that USP will continue its effort to harmonize compendial standards with the Pharmacopeial Discussion Group (PDG) and other pharmacopeias.

The Convention also elected a Council of Experts (COE) with about 40 committee chairpersons. Early in April, the COE will elect members of each Expert Committee.

The March –April 2005 *Pharmacopeial Forum* [30 (2)] has been published and includes a number of interesting items. It contains the Second Interim Revision Announcement (IRA) to USP 28-NF 23 that essentially consists of changes to 71 monographs of Dissolution for delayed and extended release tablets and capsules, transdermal systems and a few tablets that will have a delayed official implementation of April 1, 2006. Also included in the IRA are changes in <701> Disintegration, < 711> Dissolution, and <724> Drug Release with these changes on a delayed implementation date of April 1, 2006.

The in-process section of PF includes proposal for 19 new USP monographs, three for dietary supplements and five for NF monographs. Proposals for new General chapters include three for USP, <345> Assay for Citric Acid/ Citrate and Phosphate, < 1065> Ion Chromatography, and <1226> Verification of Compendial Procedures, and one for dietary supplements, <2030> Supplemental Information for Articles of Botanical Origin.

The Stimuli to the Revision Process section of the same PF includes a number of must read papers. These are:

- "Common Pharmaceutical Calculations in USP Monographs" by B. Davani, et al, of the USP staff
- "HPLC Column Classification" by B. Bidlingmeyer et al, represents the recommendations of the USP Working Group on HPLC Columns which will facilitate the selection of HPLC Column by analysts performing a USP test
- "RSD and Other Variability Measures of the Lognormal Distribution" by Charles Tan from Merck; and "The USP Revision Process: Recommendations for Enhancements" by R. Bishara et. al., members of the USP project Team on Compendial Process Improvements (PT-18).

# PDA Interest Groups & Leaders

The following is a list of PDA Interest Groups (IGs). The list below includes the IG's name and contact information for each IG's leader, including the leader's affiliation and his or her e-mail address. More detailed information on PDA's Interest Groups and contact information is available on the PDA Web site at: www.pda.org/science/IGs.html.

## Aseptic Processing

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## Drug–Device Delivery Systems

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## Inspection Trends/Regulatory Affairs

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## Isolation Technology

*TBD*

## Lyophilization

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## Microbiology/Environmental Monitoring

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## Nanotechnology

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## Ophthalmics

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## Packaging Science

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## Pharmaceutical Water

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## Production and Engineering

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• European Branch

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## Quality Assurance/ Quality Control

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## Stability

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## Technology Transfer

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## Training

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## Vaccines

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## Validation

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## Visual Inspection of Parenterals

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*EMEA Prepares for Larger, More United Europe, continued from cover*

high-profile medicines have highlighted the need for a proactive approach to phamacovigilance, to be translated in adequate systems, methodologies and processes, providing the best protection for public health.

Another issue to be addressed by the international regulatory environment will be its ability to tackle the fall in innovative productivity despite a sharp increase in global R&D expenditure over the past decade. Appropriate measures will have to be taken in order to ensure that the pharmaceutical industry can take advantage of new pharmaceutical technologies in the manufacturing and analytical areas and can anticipate the implications of emerging therapies.

In addressing the above challenges EMEA will need to respond to:

- The additional responsibilities allocated to them in accordance with the new Community legislation
- New developments such as the perception of the safety of medicines and the environmental impact of the use of these medicines
- The assessment of new types of products
- Multilateral scientific cooperations.

EMEA has emphasized that all of its future developments should be increasingly handled in the context of continuing globalization. The Agency has further stated that these challenges should be regarded as new opportunities, which, through proactive initiatives should lead to enhanced protection and promotion of public health in an enlarged EU.

## The Road Map Process

On April 15, 2004, EMEA launched a consultation for a discussion paper, entitled "The European Medicines Agency Road Map 2010: Preparing the Ground for the Future," for partner and stakeholder consultation. Five workshops were organized and one discussion day. The partners included representatives from the EU regulatory authorities at the level of the EMEA Management Board, heads of agencies from the EU Member States including, at the time, the soon-to-be-added ten accession countries, and the various EMEA scientific committees. Stakeholders included professional associations, patient associations, academia, learned societies and industry associations. Comments received from 65 contributors from the EU and globally were taken into consideration for the elaboration of the final Road Map document that published in March 2005.

***EMEA has emphasized that all of its future developments should be increasingly handled in the context of continuing globalization.***

The EMEA Road Map addresses:

- The positioning of the EMEA over the coming years in a changing environment
- The consequent development of the Agency in such an environment and the objectives to be achieved
- The prerequisites that need to be fulfilled in order to allow the Agency to successfully achieve the objectives
- The future development of the Agency, finalization of its Road Map and an implementation plan to achieve its objectives

The key aspects of the Agency's vision for the coming years are to allow rapid access to safe and efficient medicines, provide for adequately informed patients and users of medicines, encourage and facilitate innovation and research in the European Union, tackle emerging public health challenges, prepare for developments in the pharmaceutical field, and reinforce the partnership between EMEA and the NCAs to establish a network of excellence at the EU level.

The Agency intends to strive to maintain and further strengthen its position as a regulatory authority that is public-health oriented, transparent in its operation, and committed to applying good administrative practices. The Agency will have to put in place a robust quality assurance system to guarantee the overall quality and efficiency of its operations. The major challenge for EMEA over the next few years will be its ability to meet the increasing expectations of its stakeholders.

## Objectives

The Road Map identifies the following as priority objectives to be achieved before the end of this decade:

1. *Top-quality scientific assessment*: The increasing complexity and cost of developing new active ingredients in today's globalized pharmaceutical industry demands a reinforced scientific advice process underpinned by a robust quality assurance system, including a strengthened peer-review system that can improve the consistency of scientific assessments. Consistency of the outcome of the scientific assessment should be key in such a quality assurance system. Globalization of development programs will drive the need for enhanced collaboration with non-EU Regulatory agencies, in particular the U.S. FDA, ideally leading to parallel reviews in key areas of scientific assessment. This will result in global development programs, especially for new innovations and technologies. Benchmarking with other non-EU

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regulatory agencies will become more critical.

2. *Timely access to safe, effective and innovative medicines*: EMEA needs to make gains in the operating efficiency of the centralized procedure and continue to assist international efforts to develop a global standard for the assessment of health care products. New Community legislation will provide several new legislative tools that will allow more rapid access for safe and effective innovative products to be placed on the market. Particular attention needs to be placed on identifying bottlenecks in the drug development process and what remedial actions can be taken.

3. *Continuous monitoring of medicinal products*: EMEA must implement a proactive approach to pharmacovigilance, the introduction of risk management strategies will enhance the continuous monitoring of products on the EU market. Exposure within a population of nearly 456 million remains an unknown. A strengthening of the collaboration with other non-EU regulatory agencies will be particularly important in the early identification of potential problems.

4. *Access to information*: The Agency intends to increase its profile with the outside world as an "approachable" informative and transparent organization. EuroPharm and EudraVigilance systems will be key channels for providing high-quality information about medicinal products. Implementation of transparency measures and other transparency tools stemming form the new legal provisions will result in the development of an *EU Transparency and Communication Strategy*, to be undertaken in cooperation with the NCAs and other stakeholders. Particular attention needs to be paid to the role of the pharmaceutical industry in the provision of information.

5. *Specific needs for veterinary medicines must be addressed and met.*

## Elements for Achievement

The Road Map identifies the following elements as critical to fulfilling the objectives:

1. *Provision of high quality scientific resources by the National Competent Authorities*: The continuation and strengthening of the provision of high-quality scientific resources by the NCAs to the EMEA is key to the success of the European regulatory system. The Agency will need to ensure the availability of a critical mass of highly specialized experts. The system could be further enhanced by the development of a network of centers of assessment/specialized centers to help face challenges and leverage expertise.

***In order to implement EMEA's vision, it will move toward establishment of a "Network of Excellence."***

2. *Availability of an adequate quality assurance system*: The requirements for good governance, good regulatory practices and integrated quality management must extend from EMEA toward its scientific committees and the NCAs, which are the provider network for scientific resources. The creation of an EU benchmarking system will assist in developing a coordinated approach that ensures all aspects of the scientific evaluation process are correctly applied.

3. *Availability of an adequate product development tool kit*: Initiatives should focus on addressing the encountered difficulties in the drug development stage to facilitate the process between basic research and the development of a commercial product. The best expertise available in the EU must be brought together to establish an adequate product development tool kit, without compromising the safety and efficacy norms of medicinal products.

4. *Availability of a high-quality IT infrastructure*: The Agency must take into account its new role as the coordinator to collect, harmonize, validate, evaluate and disseminate authoritative information on medicinal products. In doing so the aspect of globalization needs to be taken into account to ensure an alignment of IT architecture and procedural concepts to facilitate ease of use and harmonization.

5. *Availability of a high quality EMEA professional workforce*: It is critical to identify the areas of scientific competence where the Agency needs to strengthen its internal resources. A full training and competency program will be required. EMEA will have to critically examine and re-engineer existing business practices to maximize efficiency and provide sustainability within its new environment.

6. *Adequate workload and resource planning*: The issues of planning and workload need to be addressed, not only by the Agency, but also by the NCAs to ensure that there is coordinated planning and resource provision at the EU level.

## Implementation Plan

The EU regulatory system covers three main activities in relation to medical regulation, i.e. scientific assessment, monitoring of authorized medicines and harmonization of the technical requirements for the evaluation and supervision of medicines. However, the system still allows for different licensing routes for human and veterinary medicines although optionality has decreased with the recent extended scope of the centralized procedure.

In order to implement EMEA's vision, it will move toward establishment of a "Network of Excellence." EMEA feels that establishment of such a network will provide the best guarantees for the EU regulatory system to succeed. It has envisioned, as the Agency calls it, a two-pillar architecture:

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INNOVATIVE CLEAN ROOM PRODUCTS

- A national component of activities at the NCA level to allow the MSs to fulfill obligations (e.g., scientific assessment, monitoring of products and inspections).
- A European component in terms of contributions made by NCAs through the provision of scientific expertise to pan-European activities (e.g., centralized and decentralized licensing, arbitration, referral and harmonization activities, such as guidance development).

Phase 1 of the implementation plan will be an enhancement of the overall quality of the EU Regulatory System. A major focus point will be to increase the quality of regulatory activities throughout the EU. This will enable all EU regulatory authorities to maintain/further strengthen their systems both in terms of their national activities and their contribution to European-level activities.

An important component will be the availability at the EU level of top-quality scientific expertise. A strengthening of the scientific competencies at the EU level is vital for the application of one scientific standard for the different licensing routes and to keep the NCAs abreast of the constantly developing state of the art.

A first step will be the establishment of an EU-wide inventory of available scientific expertise covering all aspects of medicines regulation. Such an inventory will not only be a reliable source of information for the EMEA, but for all EU regulatory authorities. This inventory will be analyzed to determine missing/insufficient expertise at the EU level.

Adequate workload and resources planning at the EU level is another important step. Effective planning of workload and adequate (re-) allocation of resources is paramount to successfully address difficulties currently encountered in the system. Current difficulties typically involve the scientific review, referral procedures, classes of products, emerging safety concerns, the national pharmacovigilance systems, and the conduct of Good Clinical Practice (GCP) inspections in the framework of the centralized procedure (whereby a policy of routine inspections in the context of marketing authorization applications can currently not be implemented).

***An important component will be the availability at the EU level of top-quality scientific expertise.***

Of major importance for ensuring that the quality of expertise is maintained and further developed, is the provision of high-quality training to the experts involved in the different aspects of human and veterinary medicines regulation. The strengthening of the competence development at the EU level requires the establishment of an EU Competence Development Strategy in order to optimize the EU training activities.

The availability at the EU level of an adequate quality assurance system is of the utmost importance. It is also emphasized that the requirements for good governance, good regulatory practices and integrated quality management will extend from the Agency to the NCAs, who provide scientific resources to the networking model. To establish a coordinated approach to continuous quality improvement, the following is needed:

*1. Development of an EU Benchmarking System:* The EU benchmarking system should consist of high-level indicators, supported by specific performance indicators to achieve the best practice standards. These proposals will ultimately result in a regular cycle of benchmarking between all EU Regulatory Authorities.

*2. Strengthening of Existing Peer-Review Systems:* As with all quality assurance systems, it is important that a reinforcement of quality assurance in the field of medicines approval will add to the overall quality of the scientific assessment. Peer-review systems are already in place at the EU level for any scientific assessment carried out by a limited number of parties (e.g., rapporteur/co-rapporteur for the centralized licensing process, reference member state for the decentralized procedure, and activities undertaken by the supervisory MS in the context of inspections). The system could benefit from a further strengthening in this respect. This should lead to a higher quality output and an increased scientific and regulatory consistency of the EMEA Scientific Committees' conclusions of the scientific review processes.

*3. Continuing Organizational Improvements:* New Community legislation will provide for a series of changes in the field of medicines regulation with the particular aim of making effective and safe medicines faster available to patients and users of medicines. A particular challenge will be a common approach at the EU level towards transparency and communication. In addition, a culture of continual process improvement needs to develop, leading to efficient procedures and avoiding duplication, hence ensuring the best use of the available resources.

Phase 2 of the implementation plan addresses the future organization of the EU regulatory system. The design of the future organization of the EU regulatory system, as a consequence of the most appropriate balance between the trends for the next years and the

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**Microbiology**
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- Become more efficient and accurate with fungal identification

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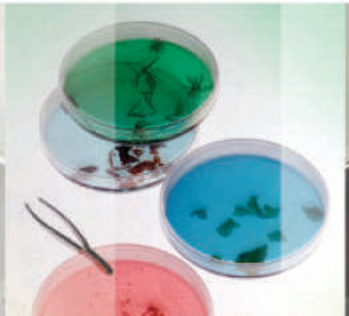
- Identify most common locations for environmental molds and yeasts


## *Baltimore, MD*

**Session 1: February 24-25, 2005**
**Session 2: June 2-3, 2005**
**Session 3: December 1-2, 2005**

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need for high-quality scientific expertise and output of the regulatory processes, requires a thorough reflection on the most efficient use of expertise available to the EU for the next decade. Two important questions need to be addressed in this respect:

1. How can the most efficient resource planning be best achieved, after careful identification of the necessary resources?
2. How can the workload between the NCAs be shared best, while avoiding unnecessary duplication of work, and what mechanisms should be put in place?

Further discussions among the EU regulatory authorities are needed on what the optimal organization of the future EU regulatory system should look like. The following considerations could be taken into account during these discussions: different possibilities to implement the concept of centers of assessment; selection of such centers; long-term consequences of partitioning the work through polarization; equality of NCAs in performing tasks; and finances for the future system.

### The EMEA Secretariat

One of EMEA's main responsibilities through its scientific committees is to deliver science-driven and consistent regulatory opinions on any aspects related to human and veterinary medicinal products.

In order to achieve this, the EMEA provides technical and administrative support to its scientific committees and coordinates within the EU regulatory system networking model the European scientific resources made available by the NCAs to the Agency, as well as any additional expertise necessary for the fulfillment of its responsibilities.

To adequately complete its tasks, EMEA will, as required in the new legislation, expand the scientific role of the Secretariat. The EMEA Secretariat will have a complementary role to that of the experts from the NCAs, hence avoiding any duplication of work and overlap between the activities performed by the Secretariat and the work undertaken by the scientific committees' members and experts. The Agency will further develop as a center of quality control. Well-defined roles and responsibilities will be established with full respect of the new legislative provisions. This will also include clear guidance to the pharmaceutical industry with respect to the Secretariat/pharmaceutical companies and scientific committee members and experts/pharmaceutical company interactions.

***To adequately complete its tasks, EMEA will...expand the scientific role of the Secretariat.***

In summary, in order to implement the EMEA's vision in terms of the extended role of the EMEA Secretariat, the following will be undertaken:

1. Establish clear roles and responsibilities for the EMEA Secretariat and the scientific committees members and experts, including the interaction with the pharmaceutical industry, taking into account the new Community legislation and the outcome of audits of the scientific committees.
2. Analyze what further organizational changes should be introduced at the level of the EMEA in order to allow the Agency to successfully address the different challenges it will face.
3. Implement, where relevant, a reorganization of EMEA, taking into account the outcome of such analysis.
4. Adapt EMEA's recruitment and competence development program to the new needs stemming from the implementation of new Community legislation and the EMEA "Road Map" project.

### The EU IT Strategy

The EU telematics systems correspond to the following key phases in the regulatory life cycle of medicinal products:

1. *EudraCT* is a database containing information on all ongoing and completed clinical trials in the EU.
2. *E-Submission* is a system permitting the electronic submission, validation and evaluation of applications for marketing authorization, eventually including full electronic work flow and tracking.
3. *The Communication and Tracking System*, is a system supporting the mutual recognition or decentralized procedure (it should be noted that the development of this system falls under the auspices of the Heads of Medicines Agencies).
4. *EudraVigilance* is a family of systems for electronic reporting, validation, processing and dissemination of information related to adverse drug reactions, both during clinical trials and in authorized use.
5. *EuroPharm* is a database containing authoritative information on all medicinal products authorized in the EU.
6. *The GMP database* is a system for electronic reporting, storage and dissemination of information on the outcome of GMP inspections, authorized manufacturing sites and

*continued on page 20*

# PDA Calendar of Events for North America

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

## Conferences

**September 11-14, 2005**
**PDA/FDA Joint Regulatory Conference, Courses and Exhibition**
Washington, DC

**October 20-21, 2005**
**2005 PDA Visual Inspection Forum**
Bethesda, Maryland

**February 2006**
**PDA International Congress**

**April 2006**
**PDA Annual Meeting**

## Training

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

### *Laboratory Courses*

**May 16-20, 2005**
**Aseptic Processing Training Program (Week 2)**

**May 25-27, 2005**
**Cleaning Validation**

**June 1-3, 2005**
**Practical Aspects of Aseptic Processing**
Basel, Switzerland

**June 2-3, 2005**
**Environmental Mycology Identification Workshop**

**June 13-17**
**Aseptic Processing Training Program (Week 1)**

**July 11-15, 2005**
**Aseptic Processing Training Program (Week 2)**

**July 26-29, 2005**
**Pharmaceutical and Biopharmaceutical Microbiology 101**

### *Lecture Courses*

**May 23-24, 2005**
**Sterile Pharmaceutical Dosage Forms: Basic Principles**

**August 8, 2005**
**Maximizing SOPs–An Untapped Resource of Training Solutions**

**August 9–11, 2005**
**Biotechnology: Overview of Principles, Tools, Processes and Products**

**September 26-27, 2005**
**Computer Products Supplier Auditing Process Model: Auditor Qualification**

**October 6-7, 2005**
**Fundamentals of D, F and z Value Analysis**

### *Lecture Courses*

**August 8, 2005**
**Maximizing SOPs - An Untapped Resource of Training Solutions**

**September 15-16, 2005**
**2005 PDA/FDA Joint Regulatory Conference**
Washington, D.C.

**September 26-27, 2005**
**Computer Products Supplier Auditing Process Model: Auditor Qualification**

**November 29-December 1, 2005**
***Career-long Learning™***
New Orleans, Louisiana

### *Course Series*

**October 24-26, 2005**
**Medical Device Course Series**
Denver, Colorado

## Chapters

**May 9-10, 2005**
**PDA and the PDA France Chapter**
**Similar Medicinal Biological Products**
Lyon, France

**May 12, 2005**
**PDA Metro Chapter**
**Real Quality**
Clark, New Jersey

**May 19, 2005**
**PDA Midwest Chapter**
**Dinner Meeting**
**Parenteral Product Development/Technology Transfer**
Northbrook, Illinois

**May 20-21, 2005**
**PDA and the PDA India Chapter**
**PDA IndiaForum**
**Risk-based Validation**
Goa, India

**May 24, 2005**
**PDA Southeast Chapter**
**USP Course**
**USP Analytical Method Validation**
Raleigh, North Carolina

**June 2, 2005**
**PDA and the PDA Prague Chapter**
**PDA EuroForum**
**Contract Manufacturing and Technology Transfer**
Prague, Czech Republic

# PDA Calendar of Events for Europe/India/Asia Pacific

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## EUROPE

**May 9-10, 2005**
**PDA and the PDA France Chapter**
**Similar Medicinal Biological Products**
Lyon, France

**June 1-3, 2005**
**PDA Training & Research Institute Laboratory Course**
**Practical Aspects of Aseptic Processing**
Basel, Switzerland

**June 2, 2005**
**PDA EuroForum**
**PDA and the PDA Prague Chapter present**
**Contract Manufacturing and Technology Transfer**
Prague, Czech Republic

**June 6, 2005**
**PDA EuroForum**
**PDA and the PDA Spain Chapter present**
**Complete Stability Study for a Global Submission**
Barcelona, Spain

**June 13, 2005**
**PDA EuroForum**
**PDA and the PDA UK/Ireland Chapter present**
**Risk Assessment and Risk Management in Pharmaceutical Manufacturing**
London, England

**June 28, 2005**
**PDA EuroForum**
**PDA and the PDA Italy Chapter present**
**Rapid Micro TM 33**
Milan, Italy

**September 21-22, 2005**
**PDA Training and Research Institute**
***Career-lon g Learning™***
Basel, Switzerland

**October 17-18, 2005**
**PDA Conference on the Universe of Pre-filled Syringes**
Munich, Germany

**November 10, 2005**
**PDA and the PDA UK/Ireland Chapter present**
**Conference and Exhibition**
**Nanotechnology**
London, England

**November 24, 2005**
**PDA and the PDA Central Europe Chapter present**
**PDA EuroForum**
**Pharmaceutical Product Labeling**
Vienna, Austria

## INDIA

**May 20-21, 2005**
**PDA IndiaForum**
**Risk-based Validation**
Gao, India

**July 19-20, 2005**
**PDA IndiaForum**
**Q7A Update**
Mumbai, India

**September 16-17, 2005**
**PDA IndiaForum**
**Certificate of Suitability CEP**
Mumbia, India

**November 22-23, 2005**
**PDA IndiaForum**
**In-Licensing**
Mumbia, India

## ASIA/PACIFIC

**June 2005**
**PDA Japan Chapter**
**Training Course: Aseptic Processing**
Tokyo, Japan

**June 17, 2005**
**PDA Taiwan Chapter**
**Annual Meeting**
TBD

**November 2005**
**PDA Japan Chapter**
**Annual Meeting**
Tokyo, Japan

**December 2005**
**PDA Korea Chapter**
TBD

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7. *EudraNet* is a family of services to exchange and share information between the EU regulators securely, efficiently and reliably.

These systems are either already in operation (*EudraNet, EudraVigilance, EudraCT*) or are under construction. Responsibility for the management of the development and operation of most of these systems was conferred on the EMEA by the European Commission and the NCAs in 2001. EMEA's responsibility for several of these systems is also defined in the pharmaceutical legislation.

### Innovative Medicines

EMEA will use a two-pillar approach to facilitate the development of innovative medicines. A first pillar addresses improvements to the current regulatory licensing framework. In this respect the Agency will implement new tools provided by revised Community legislation. This mainly relates to a revised scientific advice procedure, the possibility for accelerated evaluation, and the granting of conditional approvals.

Improvements to the licensing framework likely will involve the following six areas of the process:

1. The scientific advice procedure: New Community legislation requests the EMEA Executive Director, in close consultation with the EMEA scientific committees, to establish the necessary administrative structures and procedures allowing the development of advice for the pharmaceutical industry, especially with respect to the development of new therapies. A revision of the scientific advice procedure will be undertaken, and additional features will be included to allow for a strengthening of the provision of scientific advice. To overcome delays in the clinical development of medicinal products for which orphan drug designation has already taken place; particular emphasis will be put on a further improvement of the protocol assistance process.

***EMEA has created an "Innovation Task Force" to focus on new medicinal products...***

2. An accelerated assessment procedure: The goal here is to shorten the scientific review to 150 days.

3. A conditional approval concept

4. The involvement of specialized expertise: New Community legislation provides for the establishment of Scientific Advisory Groups, which will be involved in the scientific evaluation process. EMEA will create Scientific Advisory Groups for each of the therapeutic domains for which the centralized licensing route will become mandatory.

5. The management of the compassionate-use procedure: New Community legislation provides the opportunity for the Agency to be involved in the compassionate-use concept by notifying the MSs of situations whereby a medicinal product, eligible for evaluation under the centralized procedure and fulfilling certain criteria, is made available under compassionate use provisions.

6. A rolling review pilot program: Would allow the submission of well-defined packages of responses (e.g., quality package, preclinical package, clinical package) as a reply to the list of questions adopted by the scientific committee.

The second pillar involves the stimulation of research and innovation. First, the Agency is looking to identify areas where further research is needed. Using its broad base of knowledge and extensive contacts with all stakeholders, EMEA can operate as a platform to bring all stakeholders together, including academia and patients organizations, to discuss what areas require further applied research.

Secondly, EMEA can initiate discussions among its scientific committees, academia and the pharmaceutical industry on innovative approaches for the development of medicinal products. This will be of particular importance in relation to the various novel therapies in development. These discussions could also explore if the regulatory requirements could be adapted without compromising the safety of patients. As a consequence, an ongoing dialogue on the development of new medicines would be started, resulting in a closer relationship between the academic research and the drug development by the pharmaceutical industry.

These initiatives being undertaken by the Agency will be incorporated into a formal package of measures. The EMEA Strategy on "Fast Track" will ultimately aim to provide for expedited approval of safe and effective breakthrough therapies for unmet medical needs, hence accelerating the availability of such innovative medicines.

### Need For New Technologies

New technologies or therapies include cell and gene therapy, xenotransplantation, nanotechnologies, anti-sense molecules, tissue engineering and pharmacogenomics. New approaches to manufacturing and control methods for these technologies need to be addressed.

EMEA has created an "Innovation Task Force" to focus on new medicinal products for which the Agency has no experience with respect to technical requirements and assessment. This task force will provide dedicated information on emerging therapies and technologies to the public via EMEA's

# Announcement and Call for Papers

## 2006 PDA Biennial Training Conference

May 8–10 • 2006 Ritz Carlton Hotel • New Orleans, LA

PDA is seeking presentation proposals for the 2006 PDA Biennial Training Conference. The attendees will include regulatory training professionals, training managers, quality professionals, human resource professionals, supervisors, technical trainers, and others who train within the international pharmaceutical, biopharmaceutical, and related industries. PDA will consider abstracts of a noncommercial nature, with potential to significantly contribute to enhancing the knowledge and skills of regulatory and technical trainers for acceptance.

**SUBMISSION DEADLINE: JUNE 15, 2005**

This conference will focus on training issues of significant value to pharmaceutical trainers whose responsibilities include regulatory training (GLPs, GCPs, QSRs, and/or CGMPs) and technical training. Abstracts outlining the latest trends in training, including but not limited to the following issues, are being sought:

- **Technical Training** (trainer qualification, OJT, effective procedures/SOPs, partnering with e-learning, cross training, measuring training impact, training in aseptic areas, etc.)
- **Training Theory & Design** (developing learning objectives, evaluation methods, stand-up presentation technique, developing e-learning, measuring training impact, facilitation techniques, participant-centered training, developing games, etc.)
- **Training Management** (influencing workplace learning, influencing senior management, training as a business goal, trainer qualification, from trainer to problem-solver, non-training solutions, training the top – CEOs, VPs, and busy directors, training vs. performance improvement, etc.)
- **Training Professional** (effective needs assessments, from trainer to problem solver, influencing workplace learning, business goals and training, diversity on the training floor, training outside North America, internal consultant, performance improvement professional, etc.)
- **Regulatory Updates/Trends** (GxP training techniques, ideas, or trends – GMP, GLP, or GCP), ICH trends, Clinical Trial Directive, Part 11 update, guidance documents, training trends, CFR as training tool, quality system approach, etc.)

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- Proposal title
- Target audience (by job titles, department and specialty areas)
- Session description
- Objective for the session
- Rationale: An explanation of how the participant and the organization will benefit from this session (<100 words)

Upon review by the program committee, submitters will be advised in writing of the status of their abstracts after **June 31, 2005**.

PDA will provide one complimentary meeting registration per presentation. Additional presenters will be required to pay appropriate conference registration fees. With the exception of regulatory speakers, all presenters are responsible for their own travel and lodging.

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Web site. It will implement the classification procedure for borderline products. In close cooperation with the EMEA scientific committees, the task force will initiate discussions with top quality experts in the NCAs, academia, learned societies and pharmaceutical industry, on all challenges related to new technologies. The Innovation Task Force is also tasked with establishing a "Strategic Plan for New Technologies" and ensuring that adequate competence exists in the EU regulatory authorities to handle new technologies.

### Generic and Nonprescription Medicines

EMEA's involvement in the field of generic and nonprescription medicines has been limited and restricted to the evaluation of products referred to the scientific committees in order to review emerging quality, safety and/or efficacy concerns for authorized products or classes of products, or to harmonize the product information of such medicines.

Discussions have already started with the pharmaceutical industry (in the field of both generic and nonprescription medicines) on the particular challenges EMEA will have to overcome to facilitate generics and nonprescription drugs. The Agency will look to benefit from the experience obtained by the NCAs in these fields. EMEA will closely follow all legal aspects in relation to the submission of generics and will ensure that appropriate guidance from its scientific committees is available for to biosimilar medicinal products.

### Herbal Medicines

New Community legislation on herbal medicinal products has significantly increased EMEA's role in this field. The most visible consequence has been the establishment of a new scientific committee for herbal medicines.

### Provision of Incentives for SMEs

New Community legislation provides for incentives to be given to small and medium-sized enterprises (SMEs) through the payment of reduced or deferred fees and through the receipt of administrative assistance. Administrative assistance can be offered in the form of translations of the product information, provided by the company in the English language, into all other EU languages; the provision of regulatory, legal and scientific advice on the preparation of the marketing authorization application dossier; and the publication of practical guidance on the different issues of relevance to SMEs.

### Interaction with the Agency's Stakeholders

In order to implement EMEA's vision in terms of interaction with its stakeholders, it is pursuing a multi-pronged strategy. The first prong involves manufacturers. First, the Agency wants to better articulate how it implements new Community legislation and improvements to its processes. Special focus will be place on communicating with manufacturers of generic, nonprescription and veterinary medicines. Second, EMEA wants develop a "Best Practice Guide" that clearly defines the interaction between the EMEA Secretariat and the pharmaceutical industry and between the EMEA scientific committees and the pharmaceutical industry.

The other prongs involve patients and health care professionals.

### International Collaboration

Finally, EMEA continues to place great emphasis on international collaborations. The Agency currently is active in the International Conference for Harmonisation and the World Health Organization, and works closely with the U.S. FDA and other health authorities around the world to align technical requirements.

The demands on EMEA for international cooperation are steadily increasing. The Agency has already been approached by non-EU countries that have shown interest in the networking model and want to know more about the benefits of the concept. Because of the demand for increased international cooperation, the EMEA will be obliged to introduce a further prioritization in its international cooperation. For 2005, priorities are being given to:

1. Preparing for the accession of Bulgaria and Romania in 2007 and for any other countries for which the EU will decide on future membership.
2. Refocusing the contribution to the ICH project, with priority for implementation and maintenance of existing ICH guidelines.
3. Strengthening the interaction with WHO in accordance with the new legal provisions (i.e. the scientific evaluation of medicinal products for human use intended exclusively for markets outside the EU).
4. Building on cooperation with operational Mutual Recognition Agreement partners with respect to GMP inspections in the context of an enlarged EU.
5. Reviewing the interaction with the U.S. FDA and exploring what further cooperation could be achieved in the framework of the Confidentiality Arrangements, including interaction with the U.S. Department of Agriculture, responsible for the licensing of veterinary biological medicinal products.
6. Exploring what further progress can be made in the EMEA's interaction with other non-EU Regulatory Authorities, such as the Canadian and Japanese Health Authorities.

# EMEA's 2005 Priorities: A Discussion with EMEA's Emer Cooke

**Gautam Maitra, PDA**

**In February, PDA European Director Gautam Maitra had the opportunity to interview the EMEA's Emer Cooke, Head of Sector-Inspections, about the Agency's priorities in 2005. The following is the interview in question-and-answer format.**

**PDA:** How is EMEA coping with the enlargement? How is the culture being developed and regulations enforced?

**Emer Cooke**: EMEA is very pleased to note that there has been a very smooth transition from 15 to 25 Member States in the context of EU enlargement, and in particular in the area of GMP supervision. This is due mainly to the efforts put in to the Pan European Regulatory Forum (PERF) preaccession program (1999 to 2003) by both EMEA and national authorities. GMP was highlighted as a priority area for all three PERF programs, thus providing the opportunity for new member states to work closely with existing member states, providing a structured forum for partnership; facilitating the implementation of the European legislation; providing a forum for the exchange of views; and promoting implementation techniques. In addition, representatives from all new countries were invited as observers to the ad hoc GMP inspectors meeting, the Quality Working Party meeting, and of course, the other scientific committees and working parties of the EMEA since April 2003, more than one year in advance of accession.

In addition several new member states have benefited from twinning programs and the Protocol of Europe Conformity Assessment Agreements (PECAs) in advance of accession. In view of the level of preparation, it is no real surprise that both EMEA and the new member states have adapted well.

The main impact on the EMEA inspector sector's activities has been the increase in the membership of the working parties and groups, with 42 agencies now being represented at the GMP and Quality Working Party meetings, and an increase in the pool of experts and inspectors available for work on behalf of the Community.

EMEA Head of Sector-Inspections, Emer Cooke

In July and September 2004, EMEA organized training sessions for assessors and inspectors participating for the first time in EMEA's activities, and new members also have the possibility to send participants to training courses for new assessors that are organized on an annual basis. With respect to the performance indicators for the centralized system, no impact has been noted to date.

**PDA:** What is the most important challenge for EMEA in 2005?

**COOKE**: EMEA's priorities are published in the EMEA's work program for 2005 and the Agency's Road Map (published in March) also gives a good overview of the areas on which EMEA will be focusing over the next five to ten years. From the general priorities perspective, I would like to quote from the three key priorities and suggest that you look into the work program and Road Map for further details:

**"1. Implementation of the new pharmaceutical legislation and EMEA long-term plan**

In 2005, the Agency will focus on preparation for the full entry into force of the new legislation in the last part of the year, with particular attention on provisions reinforcing safety of medicines, accelerating availability of medicines to EU patients and creating the right environment to stimulate research. These initiatives include implementation of the concept of risk management plans, expansion of the scope of medicines to be authorized through the centralized procedure, establishment of the accelerated assessment, conditional authorization, compassionate use procedures, as well as procedures for authorization of biosimilar and generic products and support to small and medium-sized enterprises. High importance will be given to initiatives aimed at increased communication and provision of information to patients, health care professionals and the general public.

**2. Optimization of the Agency's core business and existing activities**

Safety of medicines and improvement of the Agency's core activities will remain a priority in 2005. To provide for the safe use of medicinal products,

the Agency will reinforce its activities in the area of pharmacovigilance, in particular the EudraVigilance database and the implementation of the EMEA risk-management strategy for medicines for human use. The Agency will improve handling of referral procedures to provide faster opinions on questions related to safety of medicines.

The Agency will remain committed to managing effectively and efficiently its increased tasks and responsibilities ensuring that patients and users of medicines have access to safe and effective medicinal products within the timelines laid down in the legislation. The Agency will work for greater transparency of its operations and activities.

EMEA will further extend its capacity to provide scientific advice and the quality of that advice. It will strive to increase availability of veterinary medicines intended for minor uses and minor species.

**3. Implementation of the EU telematics strategy for the pharmaceutical sector**

EMEA was given the responsibility to implement the EU telematics strategy and projects agreed by the European Commission, Member States and the Agency, which once implemented, will increase efficiency of the network, provide better information to the users of medicinal products and will contribute to safe and effective use of medicinal products. The Agency plans to undertake further implementation and expansion of these projects in response to legislative requirements in 2005. As part of this plan:

The Agency will carry out additional work to considerably enlarge the original scope of the EuroPharm database of all medicines authorized in the EU. This will allow the general public to access information in the database in all languages, and it will include more information.

The Agency will continue to develop the EudraVigilance database and will add a new component on suspected unexpected serious adverse reactions from clinical studies.

EMEA will also prepare and design a database of manufacturing authorizations and good manufacturing practice certificates required under the new Directives."

***...the recent downturn does not suggest a trend, and in fact, the number of applications received by EMEA in 2004 was higher than ever.***

All this will be underpinned by an increase in focus on transparency and communication.

If we look at the more specific priorities outlined in the **chapter on inspections,** you will see that these mirror the general priorities.

I would like to focus on three of these to give you a flavor of the type and extent of work we have ahead of us for 2005. Apart from our core business activities, our major priority for 2005 is to prepare for the implementation of the pharmaceutical legislative review, in particular, the new requirements for GMP for starting materials and the setting-up of a database on manufacturing authorizations and GMP certificates. We have already worked on a community format for inspection reports, a community format for manufacturing authorizations and a community format for a GMP certificate. In addition, we have prepared a revision of the scope of the guidelines on GMP for active substances and a guideline of the grounds or triggers for inspections of active substance manufacturers (published in March). Work on the database has also begun, including an inquiry on existing member state systems to which the database will need to be linked. Work in the GCP area will continue to be focused on implementation activities relating to legislation on clinical trials and GCP, in particular the implementation of the second phase of the EudraCT database.

From an **international perspective,** we will be working to support ICH activities in the GMP areas, implementation of the various mutual recognition agreements, with particular emphasis on the new legislation and support to the new possibility for centralized opinions for medicinal products to be marketed outside of the EU, in cooperation with WHO, through our certification scheme.

**PDA:** What steps, if any, are being taken, as a result of the study in 2003 on hurdles to innovation? What is the status regarding centralized procedures?

**COOKE**: The Commission funded a study on innovation in the pharmaceutical sector in 2003. This was prompted, in part, by the fact that a significant reduction in the number of applications for marketing authorization had been noted in 2002 and 2003. At the time, there was significant concern in the regulatory community that this reflected a crisis in innovation with potentially very damaging long-term effects. The study, now published on the European Commission Web site, concludes that the recent downturn does not suggest a trend, and in fact, the number of applications received by EMEA in 2004 was higher than ever.

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# The EMEA Celebrates Tenth Anniversary

**Gautam Maitra, PDA**

PDA was invited to join the European Medicines Agency (EMEA) as it celebrated its tenth anniversary on March 11, 2005, in London. To celebrate, the Agency sponsored a conference called, "A Scientific Perspective on the Future of Medicines."

The conference was attended by a few hundred participants from all over Europe, and was just walking distance from the EMEA. It was very inspiring to look at the achievements of the past ten years, and it was incredible to see what the future holds for the Agency.

The breakfast session was very well arranged within the EMEA premises, with great networking opportunities and posters from the key departments on display. The session was very informal, giving participants the opportunity to have access to high level officials in the European regulatory scene.

Back at the hotel, following breakfast, the conference was divided into two sessions. The morning component was heavily concentrated on top-level regulatory issues, with speakers representing industry and government. The afternoon session was focused on science and technology. We were invited to the lunch press conference where EMEA Executive Director **Thomas Lönngren**, with selected staff, fielded questions from journalists.

"This is a celebration of ten successful years, with 15 member states and 15 cultures, and the future looks bright," Lönngren said. He went on to say that EMEA is dedicated primarily to public health and to ensuring that the regulatory system in Europe is science-based. Later he released the book, *Celebrating Ten years – Portrait of the European Medicines Agency*.

The message from European Commission Vice President **Günter Verheugen** was that the European regulatory system for medicines, with the Agency at its core, has become a success story. This view was echoed by the large number of speakers in attendance, including Luxembourg's Health Minister, **Mars Di Bartolomeo**, and the European Parliament Vice President, **Dagmar Roth-Behrendt**.

EMEA Executive Director, Thomas Lönngren

Speakers from the U.S. FDA and the Japanese Pharmaceuticals and Medical Devices Agency paid generous tribute to the Agency for its efforts in the field of medicines evaluation and commended the European way of regulating medicines and promoting public health.

A panel of internationally renowned scientists participated in the conference, entitled "A Scientific Perspective on the Future of Medicines," which focused on issues relating to HIV, vaccines, oncology, diabetes, pharmacovigilance, veterinary medicines and the patient perspectives on medicines regulation. Professor **Luc Montagnier**, President of the World Foundation for AIDS Research and Prevention, gave an update on research into vaccines against HIV/AIDS, while Professor **Paris Kosmidis**, President of the European Society of Medical Oncology, addressed expectations and developments in the field of cancer treatment. Trends in the treatment of diabetes were the topic of Professor **Eberhard Standl**, Vice President of the European Association for the Study of Diabetes, and **Munir Pirmohamed**, Professor of Clinical Pharmacology at the University of Liverpool, focused on how to handle pharmacovigilance in the future to improve drug safety and protect public health.

The Community authorization for veterinary medicinal products and its contribution to animal health in the EU was the theme of Professor **Paul-Pierre Pastoret** of the UK's Biotechnology and Biological Sciences Research Council. Concluding the scientific part of the conference, **Rodney Elgie**, President of the European Patients' Forum, gave the patients' perspective on the future development of medicines in Europe.

# Regulatory Briefs

## Europe

### EFPIA Welcomes the European Commission's Proposal for the 7th Framework Programme Including its Proposed Support for the "Innovative Medicines Initiative"

The European Commission launched an ambitious proposal for the new EU R&D Framework Programme 2007-2013. It proposes a significant increase in funds available for Research and Development and the creation of a European Research Council, both key elements in fostering the future of European research.

Such a public-private partnership would bring together European universities, pharmaceutical companies, small biotechnology companies and patient associations. This initiative would significantly enhance the science base in Europe and encourage more health research in Europe to improve the drug development process, leading to new innovative medicines and ultimately healthier societies in Europe and the world.

The European Commission last year requested the European Federation of Pharmaceutical Industries and Associations (EFPIA) to identify the main barriers to innovation in biomedical research. EFPIA established a multi-stakeholder consultation process, to identify these key barriers. Beginning in 2004 the stakeholders, led by the EFPIA Research Directors Group, identified four key bottlenecks that span the drug development process and laid the groundwork for how these could be addressed in practice. On that basis a European Technology Platform (ETP) for Innovative Medicines was established under the lead of EFPIA's Research Directors Group. If this Innovative Medicines Initiative is approved, EU funds would be awarded to the "best science" and directed to academia, clinicians and small biotech companies to carry out the key research that is a prerequisite to the development of effective new therapies, and enhancing Europe's competitiveness.

The main goals of the initiative are:

- To revitalize Europe's biopharmaceutical research capability and foster a strong and vibrant science base that is a prerequisite to developing new medicines
- To understand better the underlying mechanisms of diseases and thus to underpin the development of new and more effective medicines and therapies
- To foster competitiveness and science in the EU, creating significant economic value through biomedical leadership.

EFPIA's Research Directors Group (RDG) brings together the European Heads of Research from the world's leading pharmaceutical companies to address the issues facing research and development of biopharmaceuticals in Europe.

The proposal for the Seventh Framework Programme is available at europa.eu.int/comm/research/future/index_en.cfm.

### EFPIA Highlights EMEA's Success

Taking part in the celebrations of EMEA tenth anniversary, Brian Ager, Director General of EFPIA said that Europe can be rightfully proud of the creation of the EMEA—a policy vision made reality by the European Institutions and the Member States. "Industry's confidence in the functioning of the EMEA is witnessed by the constant flow of applications from companies and the consistently positive outcome of the annual performance review carried out between EMEA and EFPIA".

Brian Ager stressed that the research-based pharmaceutical industry contribution to society is twofold: economic and health. Neither of these is possible without innovation and the application of life science advances. Pharmaceutical innovation, however, is not easy and getting increasingly difficult. Four main "policy drivers" are needed to guarantee the research-based pharmaceutical industry's continuous quest for better therapies:

- A high-quality regulatory system for the approval of medicines: EFPIA welcomes progress achieved through the recent revision of the EU pharmaceutical legislation and looks forward to the EMEA future evolution as described in its road map for 2010.
- A strong science base: The science base is currently strong but perhaps lacks "critical mass."
- Sound intellectual property rights: Similarly, Europe's intellectual property regime puts us in a reasonable position globally.
- A fair and stable marketplace for medicinal products, which rewards innovation: This remains the main challenge. The EU scene is characterized by 25 fragmented markets, heavy cost containment measures and poor reward for innovation. Clearly this leads to a direct loss to Europe's research potential and also two other effects: wasteful parallel trade and significant patient access delays.

"None of this should distract us from the success of the EMEA", concluded Brian Ager.

**[Compiled from EFPIA press releases]**

# Dinner and Biotech Down Under

**Maha Nassar, SeerPharma Pty Ltd**

## PDA Australia Chapter Looks at the Future of Biotechnology at its March Dinner Meeting

The PDA Australia Chapter held its first dinner meeting of the year on March 10. Entitled "The Future of the Biotechnology and Pharmaceutical Industries in Australia," the meeting drew a crowd of over 80 participants.

Biotechnology is growing quickly in Australia, particularly in the research arena. With an increasing interest in biotech and how it is affecting the pharmaceutical industry, it seemed only appropriate that this subject be given due consideration.

An introductory note was provided by Chapter President **Greg Jordan** (Mayne Pharma), who in addition to introducing the speakers, outlined PDA's current initiatives and member benefits.

**Dr. Tony Coulepis**, Executive Director, AusBiotech (the industry body representing the Australian biotechnology sector), talked about the "Growth and Future Prospects for the Australian Biotechnology Industry" and provided the audience with an informative overview of core capabilities, tapped and untapped opportunities, and what needs to be done to further the prospects of the Australian Biotech and Pharma industries.

**Dr. Ashley Bates**, Head of Discovery Research, GlaxoSmithKline Australia, gave an interesting presentation on "The Role of Biotech in Pharma's Future." He discussed the challenges facing the pharmaceutical industry leading to an increasing trend of biotech-"big pharma" collaborations.

The PDA Australian chapter is holding its next dinner meeting on April 21. The meeting will focus on general validation and part 11 compliance issues.

Chapter members enjoy dinner and a presentation

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# Capital Area Chapter Awards First Scholarships

**Barry A. Friedman, PhD, Cambrex Bio Science Baltimore, Inc.**

The PDA Capital Area Chapter recently awarded its first joint scholarships with the University of Maryland Baltimore County (UMBC). This scholarship program represents the first-ever joint program offered by one of PDA's worldwide Chapters. The two scholarships, which are for the 2004-05 academic year, are designed to assist individuals who are considering biotechnology or pharmaceutical sciences as a career. This joint program is the first of several that the Capital Area Chapter plans to establish with area universities.

Applicants for these awards were initially screened by UMBC and a final selection made by the executive board of the Capital Area Chapter.

The awardees this year include **Jaime Miller** and **Erin Voss.** Jaime is a junior majoring in biochemistry. Upon completion of this degree, Jaime is considering a MD/PhD program at a local university. Erin is a senior majoring in biochemical engineering and is contemplating graduate school following completion of her undergraduate studies. Both awardees were the Capital Area Chapter's guests at the Wednesday, March 23 dinner meeting at the Holiday Inn in Gaithersburg, Maryland where they formally received their $5,000 (US) awards.

Chapter Leaders with the Scholarship Winners: Allen Burgenson, Bill Stoedter, Erin Voss, Jaime Miller, and Barry Friedman

At that meeting an announcement was made regarding the availability of scholarship applications for the 2005-06 academic year through UMBC. Students are invited to apply at UMBC through May 20, 2005.

Monies for these scholarships are derived from vendors that support each of our dinner meetings. These vendors participate with tabletop exhibits during our "Meet 'n Greet" hour that precedes dinner. The Capital Area Chapter would like to recognize the following vendors as contributors to these scholarships: **Accugenix, BD, Doe & Ingalls, Lancaster Labs, Millipore, PML Microbiologicals, Pall, Veltek and VWR.**

To learn more about the Capital Area Chapter, please visit their Web site at www.pdacapitalchapter.org or contact Barry Friedman, Chapter President, at +1 (410) 563-9200, ext. 285 or barry.friedman@cambrex.com.

# Chapters Contacts

**The following is a list of the PDA Chapters, organized by the area of the world they are located. Included are the Chapter name, the area(s) served, the Chapter contact person and their 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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# Views From the 2005 PDA International Congress–Rome

Italy Chapter Leaders with PDA's Gautam Maitra and Neal Koller

Lorella Chiapinell, MD, Sr. GMP Inspector, Italian Ministry of Health, talks about regulatory issues

The Italy Chapter Committee with PDA President Neal Koller

James Lyda and Italy Chapter VP Antonino Gianetto and Italy Chapter President Vincenzo Baselli


Carlo Pini, IMH, Michael Vivion, Executive Communications Group, and Mark Elengold, U.S. FDA answer questions

Hiltrud Horn, Horn Pharmaceutical Consulting


Lorella Chiapinelli, IMH, Joerg Neuhaus, GHA, and Paul Hargreaves, MHRA, answer questions

The Italy Chapter Committee during a work session

Pasquale Monteleone, Italian Ministry of Health, answers audience questions

# VP Message

## TRI Advisory Board Appointed

PDA recently established a Training and Research Institute Advisory Board (TRIAB) in order to help focus the TRI curriculum to best serve industry, academia and health authority audiences with practical training courses. TRIAB will establish instructional design criteria, oversee course development and guide the implementation of comprehensive training curricula and certificate programs as they relate to the needs of the PDA membership and the pharmaceutical and biopharmaceutical communities.

After several months of receiving volunteer information, TRIAB was appointed on February 1, 2005 by the Chair, **Bob Myers,** and myself. It should be noted here that the Chair has many years experience with PDA, having served as the Chairman of the PDA Board of Directors, and has been intricately involved in the establishment and early successes of TRI's training programs.

TRIAB currently has 12 members, appointed for one- and two-year terms, who represent many facets of the pharmaceutical and biopharmaceutical industries, including individuals with experience in scientific and training disciplines.

TRIAB has met three times thus far, twice by teleconference and at the 2005 PDA Annual Meeting. There have been many lively conversations about proposals for the new focus of TRI and about areas in which TRI activities and training programs should focus. TRIAB is planning a face-to-face meeting in May in Baltimore to designate priorities and develop timelines for its recommended programs. Moving forward into 2006 and 2007, TRIAB and the PDA New Products Committee (an internal committee of PDA staff) will be coordinating efforts to conduct training programs of greatest value to PDA's membership.

Currently the TRIAB has established three subcommittees in line with the PDA Strategic Plan. The subcommittees currently in place are looking at mechanisms to develop and implement e-learning, qualification and standards programs, and content development that will lead to new curricula for TRI. Volunteers are always needed for the subcommittees, so if any of our readers are interested in participating in the work of the TRIAB, please let me know.

I look forward to working with this group of dedicated PDA members as we develop, design and implement innovative training initiatives for PDA's members.

# FDA's Training Day at PDA TRI

James Wamsley, PDA

Friday, April 15, 2005 saw another first for PDA's Training and Research Institute. John Lindsay of Aseptic Solutions, Inc. and the co-coordinator of PDA's long-running *Aseptic Processing Training Program* developed a half-day course covering the fundamentals of facility design, velocity testing and airflow studies, for staff of FDA's Center for Drug Evaluation and Research. (CDER) The material for this hands-on course is also covered on the first day of the *Aseptic Processing Training Program.*

Student receives training from John Lindsay on the proper use of a velocity meter.

While the FDA employees are certainly familiar with the new Aseptic Guidance issued in September of 2004, they were able to "see in practice what they have been teaching in theory" Rick Friedman, CDER, pointed out.

Airflow and velocity over the vial descrambler is tested.

After a short lecture in the classroom they moved directly into the aseptic processing area (APA) at PDA TRI. From there the methods of testing the velocity of the air coming through the HEPA filter were covered, and students were able to perform abridged velocity testing using a hotwire velocity meter.

The difference in airflow from HEPA filter face and non-HEPA area is demonstrated.

After the velocity testing session was over, a liquid nitrogen fog generator was brought into the APA and cranked up so the students were able to see how the air actually moved around inside the clean room. With the fog held up to the filter face, the boundaries between laminar and non-laminar flow are able to be seen. Students were able to visualize using the fog that the boundaries established by flexible curtains in the APA between Class 10,000 and Class 100 areas may not necessarily be so cut and dry.

Using the fog generator, John demonstrated how air moves around some key areas along the monobloc filling line, specifically how aseptic connections should be made, where to stand when performing interventions, how to position yourself to promote the best airflow around you and the commodity you are working with. An interesting effect of how disruptive walking can be to the airflow within classified areas was demonstrated by having students walk at different paces through the fog to show that proper clean room behavior is absolutely necessary to maintaining an aseptic environment.

Students watch intently as the airflow between Class 100 and Class 10,000 areas is shown.

This training was delivered twice to 20 FDA employees. This training session marks another milestone in the long-standing relationship between the FDA and PDA. Feedback from both sides was great across the board, and we look forward to a continued relationship between FDA and PDA's Training and Research Institute.

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# The Quality Management System trusted by most life science companies!

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- Easy to use
- Fully configurable (no custom code required)
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- Unlimited applications on the same platform
- Comprehensive validation package
- Domain expertise

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TrackWise is the only software with out-of-the-box functionality and flexibility to implement your organization's cGxP applications: Deviations, CAPA, Complaints, Change Control, Commitments, Audits and more, with flexible workflows based on industry best practices. It's the only QMS solution that comes with a full-featured, built-in business rule engine, and with powerful query, reporting and trending capabilities! Add to this, proven, scalable and load tested web-based architecture.

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