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# PDA Letter

**Volume XLI • Issue #9**

**October 2005**

## In This Issue...





# Prefilled Syringes: Safety, Convenience, Compliance

**Thomas Schoenknecht, PhD, Bünder Glas GmbH;**
**Mathias Romacker, Bünder Glas GmbH**

Some view the injectables market as the traditional, more conventional side of drug delivery. As such, they do not tend to associate it with the level of cutting-edge science and technology that is readily linked with other delivery methods, such as advanced inhalers.

In reality though, the experience of those close to the injectables sector would lead them to take a quite different view. The number of injectable products is rocketing—not the least because injection is currently the only viable way of delivering many of them. As a consequence, demand for technologies that improve the production, administration and experience of receiving injectable products is strong.

The first products presented in prefilled syringes were heparins, launched in Europe by Sanofi and Rhône Poulenc-Rorer in the early 1980's. At that time, the prefilled syringes market was viewed as a relatively insignificant niche area within the huge injectables market. Therapeutically, prefilled syringes were limited to a narrow range of applications in a few vaccines and anticoagulant products. Their use was also limited geographically to Europe.

Initial interest, during the 1980's and 1990's, was sparked primarily by the clear advantages prefilled syringes have over traditional vials and ampules. The procedure for using a prefilled syringe product often involves nothing more than removing the syringe from the packaging and injecting the formulation. In contrast, anyone administering a traditional injection from a vial might typically have to: read the required dose from the physician's dosing directions, withdraw from the vial slightly more formulation than is required, invert the syringe to allow any air bubbles to reach the top, depress the plunger slightly to expel any air and, finally, depress the plunger slightly further still to leave precisely the required dose, which they measure using the scale printed on the syringe barrel.

Prefilled syringes, with their single-use, disposable format, together with the fact that they eliminate several of the procedures required

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**Coming Next Month...**
**U.S. Regulatory Update**

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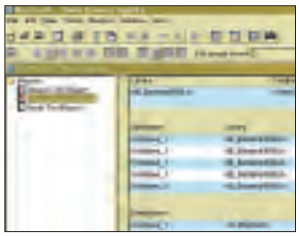

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## President's Message

**Robert Myers, President**

# Moving Things in the Right Direction

The future couldn't be brighter at PDA. In September, we named two highly qualified vice presidents and a new head of operations in Europe—all with strong PDA credentials.

**Richard Levy,** PhD, joined PDA as our new Senior Vice President of Science and Regulatory Affairs and **Robert Dana** joined as our new Vice President of Quality and Regulatory Affairs. I hope you will join me in welcoming these two long-standing PDA members as they adjust to their new roles as PDA staff. PDA and its membership are very fortunate to have two highly qualified and talented industry experts in these positions.

**James Lyda** rejoins PDA in Europe. Jim formerly worked at PDA in the 1990's as our VP of External and Regulatory Affairs and played an integral role in the creation of the PDA European office.

PDA also formalized arrangements for our first ever **PDA/EMEA Joint Regulatory Conference,** to be held in 2006. This is a true milestone for our Association and particularly for our members in Europe. The goal is to build this conference into a premier regulatory conference in Europe, as the PDA/FDA Joint Regulatory Conference in the United States. has become. Speaking of which, the 2005 PDA/FDA conference was held in September and broke all PDA records for attendance. Over 1,200 professionals attended the five-day event, which included the two-and-a-half day conference, exhibition, TRI courses and the Mycoplasma Workshop. We are confident that the PDA/EMEA Joint Regulatory Conference will become an equally valuable event for the industry.

Finally, PDA introduced a new **Audit Resource Center** as a successor to the Audit Repository Center. We are partnering with SynTegra, which will revamp and manage the Center, as well as introduce a number of user-friendly services.

## Editor's Message

**Walter Morris**

The *PDA Letter* has undergone a number of changes since I joined PDA in 2003, most notably the new look and feel.

If 2004 was devoted to finding a new look for the *Letter*, 2005 has been devoted to revamping the content. To accomplish this goal, it is critical that you, our members, become more involved in the process. As such, we have organized a *PDA Letter* Editorial Committee. Currently, five PDA members have been selected for the committee:

- **Vinod Gupta**, PhD, Director of Release Coordination QA, Organon
- **Gordon Kilgore**, VP, VAI Automation Inc.
- **Michael Awe**, previously with Pfizer
- **Gormlaith Browne**, Project Engineer, GE Healthcare Bio-Sciences
- **Elizabeth Martinez**, General Manager, Terra Farma

We encourage others to join, as well.

This group, along with PDA senior staff and I, have developed an editorial calendar for 2006. The feature stories for each issue will cover the topics listed below:

- January: Contractor Relationships
- February: Supply Chain
- March: Validation & Risk Management
- April: Compliance Systems
- May: Quality Systems
- June: Automation
- July/August: Aseptic Processing/Sterile Products
- September: Release Systems
- October: Pharmaceutical Development
- November/December: FDA/EMEA Update

With this calendar in place, I encourage all PDA members to consider submitting articles for publication. Of course, not every article can be published, but the more submissions we receive, the better the quality of the Letter will become. Of course, all authors must ensure that articles are their own original work, that they have not been previously published, that all borrowed material is properly cited, and that all copyrights are honored.

I sincerely hope you have found the new look of the *PDA Letter* to your liking and that you've seen improvement in the quality of articles within. As we move forward into 2006 together, I'm confident that the *PDA Letter* will only improve.

# 2006 PDA/EMEA Joint Regulatory Conference




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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.

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

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# Richard Levy, PhD, and Robert Dana, Named PDA VP's

## James Lyda to Head PDA's European Activities

On September 2, 2005, PDA named **Richard V. Levy**, PhD, its new Senior Vice President of Science and Regulatory Affairs and **Robert L. Dana** the new Vice President of Quality and Regulatory Affairs.

Like new President **Robert Myers**, Dr. Levy and Mr. Dana are long-standing PDA members and have served on various PDA committees and on the Association's Board of Directors.

"We are extremely pleased to welcome Rich Levy and Bob Dana to the PDA staff," said Robert Myers, PDA President. "Both are well established within the PDA community and have proven records of success. They strengthen the Association's ability to accomplish its mission to develop scientifically sound and practical technical information for the pharmaceutical and biopharmaceutical industries."

Dr. Levy brings to PDA a comprehensive understanding of the industry. He is recognized as a leader with a strong focus on research and analysis. Prior to joining PDA, Dr. Levy was a Corporate Vice President and General Manager at PAREXEL Consulting. He joined PAREXEL as Vice President of KMI's consulting services. Previously, Dr. Levy worked as the Director of the Viral and BioMolecular Technologies Business Unit for Millipore Corporation and served in a variety of senior research and development, regulatory and quality systems capacities within Millipore. He is trained as a microbiologist.

Dr. Levy began serving on the PDA Board of Directors in 1999. In 2003, he was chosen by the membership as PDA's Chair-Elect, and would have succeeded **Nikki Mehringer** as PDA Chair in 2006. He served as the PDA Treasurer in 2002 and 2003. Dr. Levy was the co-chair of the program committee for the 2005 PDA Viral & TSE Safety Conference, which drew a remarkable 360 participants.

**"I am very excited to join PDA and have the opportunity to work with the PDA staff under Bob Myers' leadership," said Dr. Levy. "I look forward to connecting with the global membership and the PDA community to address industry challenges and to proactively move the Association into new areas of scientific interest."**

"I am very excited to join PDA and have the opportunity to work with the PDA staff under Bob Myers' leadership," said Dr. Levy. "I look forward to connecting with the global membership and the PDA community to address industry challenges and to proactively move the Association into new areas of scientific interest. I am committed to ensuring that the high quality and integrity of the information, resources and services which PDA provides to the pharmaceutical and biopharmaceutical community is maintained and enhanced where possible."

**Robert Dana** has over 38 years of experience in the pharmaceutical industry. He worked for Bristol-Myers Squibb as a Senior Director of Compliance Assurance Services, Director of Technical Evaluation and Service, and Technical Auditor, GMP. He also worked for Bristol Laboratories as a Manager of Product Development and as a Product Development Research Scientist. Dana has held diverse consulting roles in the areas of GMP and regulatory compliance, most recently as Founder and President of Elkhorn Associates, Inc., specializing in quality and regulatory compliance for the pharmaceutical and medical device industry.

With PDA, Dana served on the Board of Directors from 2001 through 2004. He also sits on PDA's Regulatory Affairs and Quality Committee and is the leader of PDA's Inspection Trends/Regulatory Affairs Interest Group.

"Having served as Science and Regulatory Advisor to PDA since April 2005, I look forward to working with PDA members and staff full time to help grow the Association and fulfill its mission," said Dana. "I am committed to ensuring that PDA continues to be a leading and influential contributor of information and resources for global regulatory and harmonization processes."

Dr. Levy will report directly to Robert Myers, and Mr. Dana will report to Dr. Levy.

### James Lyda Returns to PDA

**James Lyda** rejoined PDA in September as the head of PDA's European activities. Jim has a long and distinguished record of service to PDA. He joined the PDA staff in 1992, serving as the PDA Vice President of External and Regulatory Affairs until his departure in 2002. That year, Jim joined KMI, a division of PAREXEL International, which became PAREXEL Consulting in 2004.

# HAZARD AREA MICROBIAL MONITORING

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# PDA Resuscitates ARC as Audit Resource Center

## Association Signs Management Covenant with SynTegra

PDA has partnered with SynTegra, a pharmaceutical supply chain and patient safety solutions provider focused on ensuring the safe use and distribution of drug products, to revitalize its Audit Resource Center, the successor to the Audit Repository Center. The Audit Repository Center was established in 2000 to help the pharmaceutical industry more efficiently and cost effectively meet its audit requirements and facilitate the industry's move to higher levels of information technology management, integration and implementation.

"Companies providing computer products and services for regulated pharmaceutical operations are required to conduct product supplier audits, either by regulations or good business practices," says **Lance Hoboy**, VP of Finance and Strategic Planning for PDA. According to Mr. Hoboy, a global audit repository benefits both manufacturers and suppliers by serving as a clearinghouse for audit data and by standardizing the auditing process. It also helps avoid the cost and duplicate efforts associated with carrying out multiple audits of a particular company's computer products, since suppliers are audited several times a year.

"We're honored that PDA has selected us as the licensee responsible for relaunching and maintaining the Audit Resource Center," said **Thomas E. Menighan**, President of SynTegra. "This virtual center was created by and for stakeholders in the pharmaceutical industry responsible for maintaining the integrity of their manufacturing and distribution processes. The audit systems and techniques within the Audit Resource Center are synergistic with SynTegra's operational, regulatory and distribution management services," he said.

Menighan added, "In the next few weeks, we will be working with PDA staff, the PDA Industry Advisory Board and other stakeholders to optimize the content and benefits the audit process provides."

According to Menighan, Audit Resource Center users can look forward to several new features in the revamped storehouse, including a robust and easily navigable Web site with improved security, as well as highly advanced search functionality and information accessibility. Users will also have the option of either downloading audits securely from the Web site or obtaining them on a CD-ROM. In addition, SynTegra plans to increase the number of available audits over the next several months.

# Member Volunteer Opportunities

### PDA Nanotechnology Interest Group: Call for U.S.-Based Volunteer

PDA is seeking a member volunteer from the United States to serve as a U.S. liaison to the European Branch of the PDA Nanotechnology Interest Group, which formed in 2004.

PDA needs a representative from its U.S. membership to participate in the IG's activities. If you are interested to serve as PDA's U.S. liaison and want more details about the opportunity, please contact **Bob Dana at dana@pda.org**.

***More Member Volunteer Opportunities on page 28!***

### Task Force: PDA Technical Report No. 14 Industry Perspective on the Validation of Column-Based Separation Processes for the Purification of Proteins Update

Task Force members should have experience with production scale chromatography operations/validations. Most Task Force work will be done by e-mail and regular teleconferences. The expected duration of the Task Force is approximately one year. If you are interested in participating, please submit a short description of your job function and relevant experience to **Iris Rice,** Coordinator, Regulatory Affairs and Science, at +1 (301) 656-5900, ext. 119 or rice@pda.org.

# Nomenclature Standardization for "Large Pore Size" Virus-retentive Filters

**Kurt Brorson, PhD, U.S. FDA; Gail Sofer, GE Healthcare; Hazel Aranha, PhD, GAEA Resources**

What's in a label? (or name or number for that matter). A great deal, apparently. Some of today's clothing manufacturers are intentionally labeling clothes a size or two smaller than they really are, to cater to consumer's vain self-images.

Unclear nomenclature is unacceptable, however, in the more serious world of biotechnology. If a filter is counted on to remove viruses from biotech products by size exclusion-based mechanism, its rating or nomenclature must be crystal clear. For example, 18-26 nm Parvoviruses can not be assumed to be retained on/in a "large pore size" virus–retentive filter (designed to remove retroviruses and other larger viruses).

Virus filtration is a critical unit operation during the manufacture of recombinant proteins, monoclonal antibodies, and plasma-derived biopharmaceuticals. **Patrick Celis** (EMEA) remarked (Celis 2005) at the PDA/EMEA/FDA co-sponsored Viral and TSE Safety Conference that in his experience as a reviewer of marketing authorization dossiers that virus filters are one of the most common virus clearance unit operations in bioprocessing.

Viruses vary widely in shape and size; many can potentially compromise the safety of biologicals and biopharmaceuticals. Virus filters vary as well, the PDA Virus Filter Task Force (TR41) has noted that a majority can be broadly grouped as targeting "large" (Retroviruses, Reovirus, Herpes Simplex Virus) or "small" (parvovirus, HAV) viruses. The situation is a little more complex than this; "small virus" removal filters can also be used to retain the intermediate size (HBV, HCV) viruses as well, and some "large virus" filters can extend clearance to some of these medium size viruses as well.

To date, the naming of virus filters has been vendor specific. Among the parameters used by virus-filter manufacturers are average pore size measurement (Asahi Planova 35N, 20N, 15N), type of virus retained (Millipore Viresolve NFR, NFP), size of virus retained (Pall Ultipor DV50 and DV20), nominal molecular weight cutoff (MWCO; dextran or protein; Pall Filtron Omega 300K and 100K), and MWCO of proteins (Millipore Viresolve 180 and 70) that can pass through the membrane (Carter and Lutz, 2003; Aranha, 2001). Some end users, particularly newer and less experienced professionals, may find this naming system ambiguous and confusing. A single rating system would promote transparency by placing filters into "baskets" where a minimum level of clearance of particles of defined size can be achieved. New entrants into the virus filter market will be generally expected by end users to achieve this level of performance.

In 2002, PDA convened a virus filter task force comprised of industry professionals, regulatory groups and filter manufacturers with the purpose of developing a common nomenclature and a standardized test method for classifying and identifying viral-retentive filters. Additionally, the task force was charged with the development of a technical report on virus filtration.

Based on a reported 53- to 64-nm diameter (Bamford and Ackermann, 2000; Coetzee and Bekker, 1979; Coetze et al., 1979) and its previous successful use in testing size exclusion properties of large-virus filters, the PDA virus filter task force arrived at a consensus that the coliphage PR 772 could serve potentially as a model to standardize nomenclature for large-pore-size virus filters.

After extensive discussions, a "large virus" filter test method was drafted by the PDA task force. The committee agreed that the purpose of the method was to provide a common nomenclature system for large virus filters. The purpose was not to test filters at maximum or worst case operating conditions, nor to compare filters from one filter manufacturer to the other, nor be a substitute for process validation for the purpose of regulatory compliance. The general method applied to "large virus" nanofilters made from all filter manufacturers participating in the task force. It pre-specified ➤

***Authors' Note:*** *Views expressed in this article reflect those of the authors and do not constitute official positions of the U.S. FDA or the U.S. Government. Discussion of individual filters does not constitute an endorsement of filter brands or manufacturers by the U.S. FDA or the U.S. Government.*

permissible ranges for relevant operating parameters based on industry practice, published literature, and filter manufacturer recommendations. The bracketed ranges were intended to allow testing at conditions recommended by the filter manufacturers that are realistic for commercial operations. The committee assumed that operating conditions for filters from one filter manufacturer would not be the same for filters from other filter manufacturers. When conducting tests of their individual filters, manufacturers pick parameter set points (+/- reasonable limits) for their specific protocols from the bracketed acceptable operating ranges in the general document.

In Fall 2004, the filter method was prototyped in a third party lab (CDER/FDA) in collaboration with three filter manufacturers (Pall, Millipore, and Asahi Kasei). Each filter manufacturer provided from 3 different QC released lots intended for process scale manufacturing.

This paper summarizes activities of the Nomenclature Standardization Task Force including background characterization of the bacteriophage PR 772 and testing of Pall Ultipor VF DV50, Millipore NFR and the Planova-35 filters.

### Why use a bacteriophage instead of a mammalian virus for nomenclature standardization?

When virus filters clear their targets primarily by size exclusion, their performance is dependent on spatial constraint. Therefore, it is logical that any virus (either mammalian or bacterial) in the same size range should be applicable as a surrogate for preliminary evaluation of the performance capabilities of filters. From a practical standpoint, bacteriophages are far easier and safer to work with (see Table 1).

For several decades, bacteriophages have been used as surrogates for mammalian ➤

**Table 1.**

| | |
|---|---|
| **Physical Characteristics** | • Icosahedral<br>• Size per<br>– Early TEM reports (Coetzee et al., 1979)–53nm (probably inaccurate)<br>– International committee on the taxonomy of viruses (Bamford and Ackermann, 2000)- 64nm<br>– Dynamic light scattering (Lute et al., 2004)- 82nm |
| **Logistic Considerations** | • *E. coli* host used to propagate PR 772 is non pathogenic; BSL 1 lab<br>• Easily cultivated to high titers;<br>– crude preparations: ~ $10^{10}$ pfu/ml<br>– CsCl purification ~ $10^{13}$ pfu/ml<br>• Easy to enumerate using the agar-overlay plaque assay; titers obtained post 18-24 h incubation<br>• Little loss of infectivity upon storage at 4°C for 2-4 months<br>• Monodispersed after two months at 4°C (storage time: 3 months) |
| **Genetic Sequence** | • Genome size ~15kb<br>• 32 open reading frames of at least 40 codons.<br>• 97% identity to the genome of *Tectiviridae* family prototype phage PRD1. |
| **Bioinformatic Analysis** | • Overall gene order of PRD1 and PR 772 highly conserved<br>– it has been possible to assign putative functions to almost all gene products<br>• No identifiable undesirable DNA sequences (e.g., virulence factor, antibiotic resistance)<br>– phage-host system is suitable for routine laboratory work |
| **Other** | • CsCl procedure eliminates almost all contaminating nucleic acids, a concern for QPCR assays.<br>• Availability of genome sequence also provides a powerful tool for quality control of the phage preparations<br>• Distinguishable from other *Tectiviridae* phages by HaeIII and RsaI endonuclease digestions. |

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viruses in size-based removal applications, such as medical and environmental applications (Aranha and Brandwein, 1999). Phages have also been used by filter manufacturers to evaluate the size exclusion properties of their viral removal filters (Aranha-Creado et al., 1997, Brough et al., 2002, Oshima et al., 1996).

Final regulatory submissions use validation data with mammalian model viruses. End users may process development and optimization studies to evaluate the potential performance and logistic feasibility of proposed viral clearance steps. These studies are not part of any regulatory claim, thus, appropriate size bacteriophages can be considered for these studies. Similarly, the PDA nomenclature will not exclusively serve as a regulatory claim, so the use of bacteriophages is warranted in this context as well.

### Characterization of bacteriophage PR 772

PR772 had not been extensively characterized prior to its selection by the task force. Some TEM studies (Coetzee et al., 1979; Coetzee and Bekker, 1979), limited sequencing (Bamford and Ackermann, 2000) and filtration studies (Aranha-Creado et al., 1997, Brough et al., 2002, Oshima et al., 1996) had been performed, but not enough to support using it for the standardization of virus filters. A subset of the task force (KB and HA) decided to more extensively characterize PR772 and published the findings in the scientific literature (Lute et al., 2004). Key goals included:

- Developing standard and easy to perform preparation methods
- Gaining a better size estimate by dynamic light scattering (DLS)
- Determining aggregation status of various types of preparations (DLS).
- Determining pre-filterability through 100 nm filters.
- Measuring the stability of infectivity and monodispersion upon storage at 2-8°C.
- Determining its genomic sequence.
- Developing an identity test.
- Determining if it can be freeze/thawed

In each case, PR772 proved to be suitable for its intended use; CsCl gradient purified preparations are easy to make, high titer, stable and monodispersed. The hydrodynamic diameter was measured by DLS at 82nm, a figure that is likely to be much more accurate than the TEM measurements from the 1970's (53nm) which are known to be artifact prone (Earnshaw et al., 1978). Further, DLS measures the hydrodymanic behavior of particles in solution (Chu, 1991), a measurement more representative of the actual behavior of a virus during filtration. Table 1 lists PR772's characteristics which are described in more detail in Lute et al. (2004) and Brorson et al. (2005).

### Design of experiments and results of the task force concerning the "large virus" virus-retention filters

In Fall 2004, representatives of three filter manufacturers (Pall, Millipore and Asahi Kasei) traveled to CDER headquarters to assist in prototyping the method. The method, detailed in PDA's TR41 (PDA virus filter task force, 2005), sets acceptance criteria for virus retention (LRV > 6log10), protein passage (>95% passage of IVIG) and integrity/installation testing (must pass vendor test). Three membrane lots or spinner series were tested; each vendor passed as described in table 2 below. It should be noted that not only did the Viresolve NFR, Ultipor DV50, Planova 35N meet the PR772-LRV6 rating, but all filters exceeded the rating by an impressive 2-3 log.

Given the successful standardization of "large pore size" virus retention filters the PDA/FDA task force will move on to standardize nomenclature of "small pore size" virus-retention filters. Because of technical issues associated with small virus filters, the task force assumes that a proscriptive approach of rigidly applying this design as a template for the future small virus filter study is not warranted. The committee also realizes that additional filter manufacturer specific flexibility may be needed in these future studies. The next task force meeting will take place at the PDA/FDA joint conference in September 2005. ➤

**Table 2. Summary of prototype testing of the filter method at FDA/CDER in fall 2004**

(Table from KB's presentation at the April 2005 PDA Annual Meeting in Chicago)

| Filter | n= | Integrity/ Installation | PR772 Retention (log10) | IVIG Passage |
|---|---|---|---|---|
| Planova 35N | 9 | + | > 8.7 | + |
| DV50 | 6 | + | > 9.2 | + |
| NFR | 6 | + | > 9.1 (5)<br>7.8 (1) | + |

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### Conclusions

PDA and CDER have successfully developed and promulgated a "large virus" filter nomenclature standard based on retention of PR772, a bacteriophage. The task force is now working on the standardization of "small pore size" virus-retention filters.

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## About the Authors

**Kurt Brorson,** PhD, is a staff scientist in the Division of Monoclonal Antibodies, CDER, FDA. **Gail Sofer** is a regulatory director for GE Healthcare. **Hazel Aranha** is the president of GAEA Resources. Both Gail and Kurt co-chaired PDA's Virsu Filtration Task Force which drafted Technical Report No. 40: Virus Filtration. Hazel participated in the Task Force.

# Regulatory Compliance: A Strategic Tool

**Siegfried Schmitt, PhD, Amersham Health**

"GMPs for the 21st Century" and "A Risk-Based Approach to Validation" are just two of the major initiatives being reviewed by the regulators and are aimed at giving the concept of validation a complete overhaul. The reasons for doing so are manifold and have been reported previously. What has been covered in little detail is how industry should—or could—respond to the challenges presented by these new paradigms.

There is a need to break from the traditional mold of performing validation, which inevitably will introduce new risks as well as new opportunities. It is time to review existing practices, and this would best be approached in a holistic manner with an open mind for all types of suggestions and the ability to think "outside the box."

In practical terms, this means addressing regulatory compliance as a strategic tool, endorsed and understood by top management, giving it due attention and support. In order to achieve this ambitious goal, compliance has to be seen as value-added and based on cost/benefit considerations. It would be unwise not to leverage the benefits of other ongoing initiatives in industry, also aiming at improved performance and quality levels, whilst at the same time reducing cost. To achieve this, cross-functional teams need to establish strategies, determine how synergies can be achieved, and develop the tools and concepts that should be applied to achieve the desired outcome.

These concepts include Six Sigma, Lean Manufacture and The Capability Maturity Model, to name a few. A common misconception is that these are easy-to-understand methodologies, which can be quickly implemented and applied with the help of a few consultants. This will almost certainly create a negative result. These tools are highly sophisticated, have been developed over many years, and have their own unique strengths and weaknesses. For that reason, most experts are familiar with only one of these tools, and they fail to discover the synergies that can exist between them and to understand that one tool cannot provide the solution to all problems.

Training records, a popular and recurring theme in inspection reports, are a good example of how these techniques can be used to help to support validation. Typically, manufacturers maintain training records manually on paper. Some of the disadvantages of manual records are: lack of ownership for the records, outdated or inaccurate records, time-consuming storage and retrieval, and lack of a defined and enforced process.

A Six Sigma team was deployed to help assess the problem and find remedial solutions. An initial assessment found errors in more than half of the records. One obvious solution—storing and managing the records in a document management system with work-flow capability—showed that it would improve the Six Sigma levels to about one error per 100 records. The advantages of applying Six Sigma to the project were: a defined strategy for establishing root causes, evaluating solutions, and most importantly, delivering hard data on cost and time savings along with data on the actual failure/error rates. This project rigor and the information on cost elements are often absent from traditional validation projects.

The Six Sigma team on its own cannot deliver a compliant solution, as it takes the knowledge and expertise of quality assurance or validation personnel to define the validation requirements for any given solution. In our specific case, this covered requirements for electronic records and electronic signatures along with the necessary validation documentation.

There are many other areas in which it would be advantageous to apply specific tools to validation projects. For example, applying the Capability Maturity Model to validation outsourcing provides decision-makers with benchmarking tools, addressing both the service supplier and the in-house validation capabilities. Based on the information provided by these tools, a firm can avoid serious issues of over demand by the company or oversupply by the outsourced provider.

It is timely that PDA is going to publish the "*Validation Handbook for Managers*," which combines many examples of the most popular techniques and tools in one volume, supplemented by many references and written in a language that can be easily understood by management. This book is not only aimed at management, it is also a valuable reference resource for the validation expert looking for tools and solutions in the never-ending quest to satisfy regulatory compliance requirements.

# PDA Calendar of Events for North America

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## Conferences

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

**November 3-4, 2005**
**Aseptic Processing Guidance**
Las Vegas, Nevada

**April 24-28, 2006**
**PDA Annual Meeting**

**May 8-10, 2006**
**2006 Training Conference**
Philadelphia, Pennsylvania

**September 11-15, 2006**
**PDA/FDA Joint Regulatory Conference**
Washington, D.C.

## Training

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

### *Laboratory Courses*

**October 4-5, 2005**
**Validating a Steam Sterilizer**

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

**October 31-November 4, 2005**
**Rapid Microbial Methods**

**November 7-9, 2005**
**Cleaning Validation**

**December 1-2, 2005**
**Environmental Mycology Identification Workshop**

**December 8-9, 2005**
**Developing and Validating Cleaning and Disinfection Programs for Controlled Environments**

### *Course Series*

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

**November 29-December 1, 2005**
***Career-long Learning*™**
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**February 6-8, 2006**
**Lake Tahoe Course Series**
Incline Village, Nevada

## Chapters

**October 4, 2005**
**PDA Southern California Chapter**
**Combination Products and USP Update**
Irvine, California

**October 20, 2005**
**PDA Midwest Chapter**
**Dinner Meeting**
Northbrook, Illinois

**October 20, 2005**
**Rapid Microbiological Methods**
**PDA Canada Chapter**
Quebec City, Canada

**October 21, 2005**
**PDA Southeast Chapter**
**Golf Social**
Raleigh, North Carolina

**November 1, 2005**
**PDA Metro Chapter**
**Vendor Night**
Clark, New Jersey

**November 10, 2005**
**PDA Mountain States Chapter**
**Speaker Dinner**

**November 17, 2005**
**PDA Delaware Valley Chapter**
**Vendor Show**

**November 17, 2005**
**PDA West Coast Chapter**
**Dinner Meeting**

**November 17, 2005**
**PDA New England Chapter**
**Dinner Meeting**

**December 1, 2005**
**PDA Metro Chapter**
**Dinner Meeting**
Clark, New Jersey

**December 6, 2005**
**PDA Capital Area Chapter**
**Dinner Meeting**
**Parametric Release**
Gaithersburg, Maryland

# Europe/India/Asia Pacific/Middle East

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## EUROPE

**October 24-25, 2005**
**The Universe of Pre-filled Syringes - 2005**
Munich, Germany

**November 10, 2005**
**PDA and PDA Europe**
**PDA Nanotechnology Conference 2005**
London, England

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

**November 30-December 2, 2005**
**PDA Training & Research Institute Laboratory Course**
**Practical Aspects of Aseptic Processing**
Basel, Switzerland

**December 7, 2005**
**PDA and the PDA France Chapter**
**Biosimilars/Extractables & Leachables**
Paris, France

**October 10-11, 2006**
**PDA/EMEA Joint Regulatory Conference Course Series**
London, England

**October 12-13, 2006**
**PDA/EMEA Joint Regulatory Conference**
London, England

## INDIA

**October 7, 2005**
**PDA and the PDA India Chapter**
**Microbiology for Pharmaceuticals and Cleanrooms**
Mumbai, India

## ASIA/PACIFIC

**November 24, 2005**
**PDA Australia Chapter**
**Annual Meeting and Holiday Dinner**

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

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

## MIDDLE EAST

**December 27, 2005**
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**Annual Meeting**

**May 17-18, 2006**
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**Quality Tools for the 21st Century**
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*Volume II and Volume III are to be released in December 2005.

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*Prefilled Syringes: Safety, Convenience, Compliance, continued from cover*

prior to administering a formulation presented in a vial, are significantly quicker and more convenient. Ease of use, in addition to simply making them more convenient, means that prefilled syringes are safer.

### Safety Benefits

The major safety benefit is the reduced likelihood of dosing errors—which can occur at each of the steps in the vial/ampoule procedure. The fixed dose in a prefilled syringe is filled mechanically and checked electronically during quality control.

In addition to reducing errors in the dose quantity, prefilled syringes reduce the risk of administering the wrong product because the syringe and packaging are clearly labelled with the drug name. For syringes filled at the point of administration, there is a period—between filling and giving the dose—when the syringe can be left full of drug but completely unmarked on a tray ready to use. This is a danger period since the identity of the drug in the syringe is typically known only to the person who filled it, and that information exists only in the memory of that person. If they are distracted during the danger period or are perhaps called away to an emergency and have to hand over to another person the job of giving the injection, there is a real risk of a mistake occurring.

Another safety benefit is the reduced risk of needle-stick injury. Accidents are more likely with traditional formats because the user is required to expose the needle tip for longer, while performing a series of actions requiring dexterity and concentration. The fact that prefilled syringes are single-use devices also eliminates the possibility of cross-infection arising from needle reuse. Prefilled syringes contain the precise amount of drug that is to be injected, but vials and ampules have to contain more liquid than the actual dose in order for the correct amount to be withdrawn. The excess formulation is wasted and, especially with expensive biotech products, elimination of wastage allows the manufacturer to make significant cost savings.

As demand increased and the range of viable applications of prefilled syringes broadened the market began to grow. Notably, the U.S. market, with its shorter history of prefilled syringes, was particularly keen on the advantages this format gave, to the extent that it is now exclusively an ready-to-fill syringe market.

The emergence of biotechnology drugs in the early 1990s gave demand for prefilled syringes a colossal boost worldwide and this product class today still represents the highest potential for future growth. In Europe, new drugs that have been presented in prefilled syringes include: erythropoietins, such as *Recormon* and *Eprex;* interferons like *Betaferon, Avonex, Copaxone* and *Rebif;* and rheumatoid arthritis drugs like *Enbrel* and *Humira,* to name just a few.

Crucially, biotech provided a late, but very profound, entry into the previously untapped U.S. market, where many of the aforementioned products, and many other biotech products, were developed and launched first—often in prefilled syringes.

### Increasing Focus on the Patient

The general trend in the wider healthcare sector, increasingly to place the patient more at the center of treatment strategies, rather than focusing purely on his/her disease, is having a considerable impact on the prefilled syringes sector and prompting new thinking.

The requirement from consumers for more convenient treatments is one of the factors driving the prefilled syringe market *en masse*. However, this demand for convenience also gives companies within the sector an opportunity to differentiate themselves.

Uppermost in the thoughts of many patients receiving injections are pain and discomfort. The needle is clearly the main component that determines how pleasant or unpleasant a patient finds the injection. Bünder Glas has identified three parameter sets that exert the greatest influence.

The first are the basic needle-quality characteristics, such as the requirement for a hook-free needle tip and smooth surface. These are achieved through a validated, reliable production process. Secondly, there are less critical, subtler factors such as the number of bevels at the needle tip, the angle of the bevels and the bevel length. Thirdly, the coating substance and method of application, for example siliconization, have been recognized as key in determining the pain of injection.

The increase in the number of prefilled syringes being used to self-inject, often at home, is in part a reflection of the trend towards more patient-centered treatments, but equally due to the application of prefilled syringes in new indications, such as rheumatoid arthritis and multiple sclerosis.

Prefilled syringe manufacturers are developing design features that take into account that in diseases such as these, the self-injecting ➤

# Seeing the Forest *and* the Trees: The Optimal Way to Successful Development

**Thomas Otto, Vetter Pharma-Fertigung GmbH & Co. KG**

In the pharmaceutical industry today, determining how an active substance is to be administered and appropriately packaged is absolutely crucial to the successful developing and marketing of a drug. Biologics often involve highly sensitive active substances that might be incompatible with an application system or a packaging component. Sensitivity to light and precipitation coming in contact with silicone oil are other challenges in dosage form development. And there is the validation process that must be conducted with great care to ensure that the drug and the packaging comply with international regulatory requirements.

Each step on the way, of course, is crucial to success. Packaging a drug in prefilled syringes, a process that began in Europe in the 1980s, offers numerous benefits: exact dosing, easy tracking from the manufacturer to the user, user-friendly administration, reduced waste and costs, and so on. Indeed, many of the problems and pitfalls that could threaten a drug on the market—counterfeiting, mix-ups and contamination, to name but a few—are handled before the drug actually hits the market. For one, prefilling syringes is preceded by an extensive decision-making process to decide what is the perfect form of administration for a particular drug. Extensive clinical testing and analyzing is then performed, including validation, before the drug goes into commercial manufacturing. And even then, changes can be made to remedy any potential problems. Prefilling requires a great deal of expertise, but it provides pharmaceutical companies with a drug to sell peace of mind later on.

## Invaluable assets

Vetter Pharma-Fertigung GmbH & Co. KG has the experience and the expertise to see both the forest and the trees in the entire drug-filling process. For more than 25 years now, it has been filling and packaging sterile liquid and lyophilized drugs using convenient, aseptically pre-filled injection systems including standard syringes, cartridge systems and its own patented dual-chamber application systems. In the fall of 2006, it will also have vials in its portfolio that will be used for clinical development and for swift market launches. This 1,600 employees-strong company has 15 years of experience in working with processes approved by the FDA, the EMEA and other authorities. Vetter currently holds over 127 patents to its name, including solutions to prevent counterfeiting and piracy.

*Prefilled Syringes: Safety, Convenience, Compliance, continued from 21*

patient is likely to be physically impaired in terms of the force he/she can apply and his/her degree of manual control. Relatively simple, though important, new features include a larger finger flange on the syringe barrel and a larger thumb plate on the plunger that makes the device easier to handle.

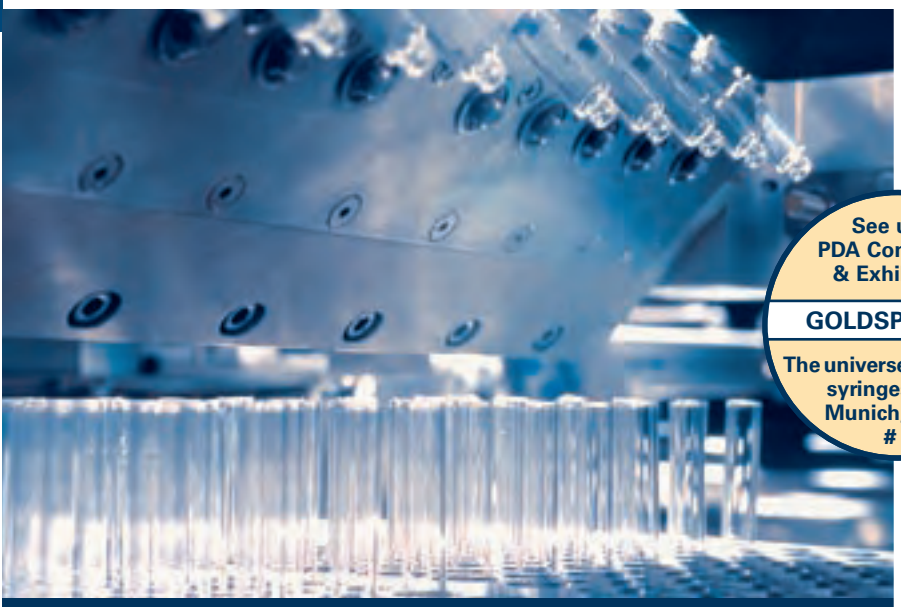
The need for prefilled syringe producers to innovate and make real breakthroughs has never been greater than in recent years. With the market for prefilled syringes estimated to have grown by more than 20% annually in the United States since 1999, to reach its current size of $200 million, and by round 8% annually in Europe to reach $1 billion, we appear to be rising to the challenge.

*Note: This is an abridged version of an article which appeared in www.ondrugdelivery.com, and is printed with the authors' permission.*

## About the Authors

**Thomas Schoenknecht,** PhD, is the Director of Product Development/Product Management at Bünder Glas and the Chair of the PDA Prefilled Syringe Special Interest Group. He will discuss prefilled syringe trends in the pharmaceutical industry at the PDA conference, "The Universe of Prefilled Syringes 2005," in Munich, Germany. **Mathias Romacker** is the Director of Business Development for Bünder Glas.

**PDA's "The Universe of Prefilled Syringes 2005," Oct. 24-25, will cover methods, materials and technologies; safety; manufacturing; and regulatory. Besides Bünder Glas, a number of companies are sponsoring the event, including Vetter Pharma-Fertigung GmbH and West Pharmaceutical Services. A complete list of sponsors, the conference agenda and registration are available at www.pda.org.**



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# Regulatory Briefs

## Europe

EMEA publishes Practical considerations on the impact of the new pharmaceutical legislation on Marketing Authorisation Applications via the Centralised Procedure and Centrally Authorised Medicinal Products for Human Use, which addresses the phasing in of Regulation (EC) No 726/20041 and Directive 2004/27/EC2 to medicinal products for human use authorised or applied for via the centralised procedure. It provides an overview of those key-procedural elements affected by the new legislation, which will have an impact on ongoing applications or existing marketing authorisations, as appropriate. For general regulatory guidance on the interpretation and implementation of the new pharmaceutical legislation, please refer to the updated Notice to Applications published by the European Commission as well as to relevant guidance documents / operating procedures published on the EMEA Web site.

For more information, go to www.pda.org/regulatory/RegNewsArchive.html.

## United States

### FDA Requests Feedback on 503(b)

Section 503(b) of the FD&C Act sets forth the Federal standard used to classify drugs as prescription or OTC, and it describes when and how to switch a drug from prescription to OTC status. FDA's interpretation of section 503(b) of the act has not been explicitly set forth in any of the regulations that discuss the process by which FDA classifies (or re-classifies) drugs as OTC or prescription. To address this concern, FDA is asking for comments on a number of ➤

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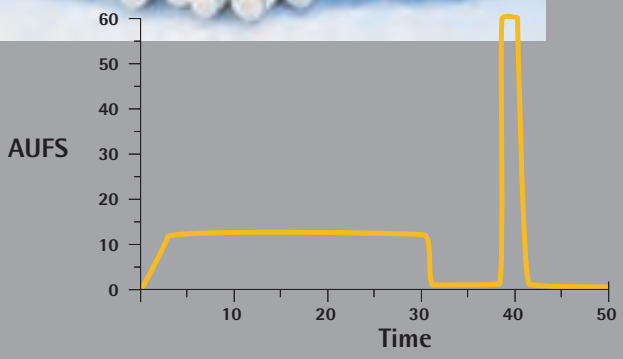


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questions by November 1, 2005, including:

A. Should FDA initiate a rulemaking to codify its interpretation of section 503(b) of the act regarding when an active ingredient can be simultaneously marketed in both a prescription drug product and an OTC drug product?

B. Is there significant confusion regarding FDA's interpretation of section 503(b) of the act?

C. If so, would a rulemaking on this issue help dispel that confusion?

To see the remaining questions and for a link to the Federal Register announcement go to www.pda.org/regulatory/RegNewsArchive.html.

### Question-Based Reviews for Generic Drugs

CDER's Office of Generic Drugs is developing a question-based review (QbR) for its Chemistry, Manufacturing, and Controls (CMC) evaluation of Abbreviated New Drug Applications (ANDAs) that is focused on critical pharmaceutical quality attributes. The QbR is a concrete and practical implementation of the underlying concepts and principles outlined by the FDA's cGMPs for the 21st Century and PAT initiatives. It will transform the CMC review into a modern, science and risk-based pharmaceutical quality assessment. OGD wrote a white paper on the QbR that discusses 1) what QbR is, 2) why QbR is necessary, 3) how QbR was developed, and 4) what the benefits of QbR are.

For more information, go to www.pda.org/regulatory/RegNewsArchive.html.

# Thermal Validation Solutions

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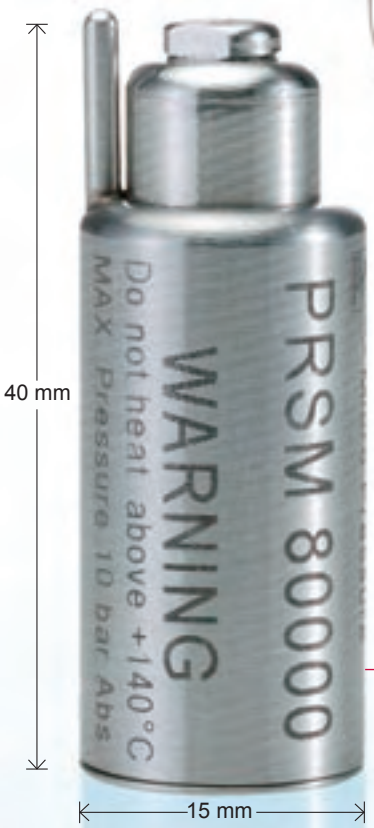



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# Basel Pharmalunch: "Think Global Eat Local"

Basel and the surrounding region represent one of the largest single concentrations of pharmaceutical professionals in the world. Hence, the Swiss Society of Pharmaceutical Sciences, in cooperation with PDA, the PDA Central Europe Chapter and the Technology Training Center, mutually agreed to provide a neutral and casual meeting place once a month for discussing burning issues in the pharmaceutical world and to network not only with fellow professionals in the PDA community (industry, academia and government), but also with the health care community at large.

Following each meeting, details will be posted to the Web site of the Swiss Society, www.sgphw.ch. For organizational purposes, registration should be done at: www.pharmtech.unibas.ch/modules/pharmalunch/.

We would also like to announce the October lunch, which will be held on Friday, October 28 at 12:00 with Dr. Petra Dörr, Head, International Affairs, Swissmedic. The topic to be discussed: "International Cooperation Initiatives of Swissmedic."

We hope that you will become a regular!

# Member Volunteer Opportunities

## Task Force: Audit Program for Filter Manufacturers

We are currently recruiting members for a task force to develop an audit program and a centralized audit repository for filter manufacturers. The task group, composed of operating company personnel and filter manufacturers, will establish standardized CGMP auditing procedures, auditor training/qualification requirements, a documentation process, and a system for sharing and distribution of the audit reports. The resulting audits will be maintained in the repository and be available for purchase by firms as needed. This will substantially reduce the costs of auditing for both the audited firm and the firm conducting the audit.

In addition to experience in manufacturing, testing, and validating sterilizing-grade filters and auditing these processes, active participation and meeting attendance are required. The task force is expected to meet for four one-day face-to-face meetings per year with additional monthly teleconferences. The project should take approximately one year to complete.

If you are interested in participating, please contact **Iris Rice,** Coordinator, Regulatory Affairs and Science, at +1 (301) 656-5900, ext. 119 or rice@pda.org.

## Task Force: Validation of Tangential Flow Filtration

PDA is organizing a Task Force to update Technical Report 15: Industrial Perspective on Validation of Tangential Flow Filtration (TFF) in Biopharmaceutical Applications. The Task Force's mission will be to describe current validation practices for TFF with a focus on Process Validation. We are seeking volunteers who are working at biopharmaceutical companies in the areas of Process Validation and Process Development as well as representatives from suppliers of TFF equipment and membranes. The Task Force will have regularly scheduled monthly teleconferences of 1-2 hours.

If you would like to volunteer for this Task Force, please contact **Iris Rice,** Coordinator, Regulatory Affairs and Science, at +1 (301) 656-5900, ext. 119 or rice@pda.org.

# PDA India Chapter: A Big Step Forward

**Darshan Makhey, PhD, Nicholas Piramal and PDA India Chapter President**

The PDA India Chapter may be the youngest kid on the block, but it would be a grave error to underestimate its potential. The Chapter has a dream to provide the best training on current GMPs to the Indian pharmaceutical industry and to help it establish the new standards for everyone to follow.

The PDA India Chapter recognized early that in order to realize its dreams, it must first establish strong relationships among all constituencies that can contribute positively to our goals. And, it must learn from the experience of individuals and organizations that share its dreams.

The Chapter has already forged a strong alliance with the Drug Controller General of India and the Deputy Drug Controller, West Zone.

Today, the Chapter has now taken yet another historic step to forge strong partnerships. When it came to our attention that the government of India was working toward establishing an EU-Indian Pharmaceutical Expert Group—with an aim to rapidly bring international GMP and manufacturing standards to India, we immediately saw the opportunity to forge an alliance. To make this connection, I traveled to meet with his Excellency, **Praveen Goyal**, the Indian Ambassador to Switzerland.

Goyal was previously involved in interacting with the founders of the EU-Indian Pharmaceutical Expert Working Group, while maintaining a close network with the science and technology community in India. The EU-India Summit held recently in New Delhi, India, will approve the Expert Working Group in September 2005. Detailed information about PDA will be submitted to the EU. Goyal highly recommended the PDA India Chapter explore the possibility of setting up a training center with a qualified partner, like PDA's Training and Research Institute. He noted that the Indian government encourages such training institutions by giving preferential treatment and concessions to nonprofit organizations.

*Gautam Maitra, Ambassador Goyal and Dr. Makhey*

The Ambassador, who is expected to retire this year, has also agreed in to play an advisory role to the PDA India Chapter.

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# EMEA, FDA, NASA and the UK Health and Safety Participate in 2005 PDA Nano-Pharmaceutical Conference

## November 10 • London

**D.F. Chowdhury, PhD, Aphton Bio-Pharma**

The keynote presentation for this one-day event will be delivered by the U.S. National Aeronautics and Space Administration (NASA), **Meyya Meyyappan,** PhD. He is a founding member of the U.S. Interagency Working Group on Nanotechnology, established by the Office of Science and Technology Policy. Dr. Meyyappan's presentation is titled, "The Potential Applications of Nanotechnology in the Pharmaceutical Industry."

The keynote address is followed by a line-up of speakers who will provide delegates a good overview of state-of-the-art technologies and developments. Subsequent presentations include **Paul Milner**, PhD, co-ordinator of Project ELISHA (Electro-Immunointerfaces and Surface Nanobiotechnology, an EU project funded under the Nanotechnology Theme of Framework 6), who will discuss the issues surrounding the translation of laboratory research into real devices, and touch upon the characterisation of Nano-Bio products. **Zheng Cui,** PhD, Head of centres of Competence, Rutherford Appleton Laboratories, Oxford UK, will discuss the development and manufacture of advanced delivery systems using Micro and Nano fabrication technologies. Industry case studies will be provided by **Mark P. Billings,** PhD, Director of Research and Development, pSiMedica Ltd., pSivida Group, UK, who will discuss the development of Porous BioSilicon TM for tumor targeting and drug delivery.

The next session focuses on health, safety and toxicology issues surrounding nano-pharmaceuticals, and in particular nano-particles **Nakissa Sadreih**, PhD, Associate Director for Research Policy and Implementation, Office of Pharmaceutical Science, CDER, U.S. FDA will provide the closing presentation.

For more information and to register, visit www.pda.org. More information on the PDA Nanotechnology Interest Group can be found at www.pda.org/interestgroups/nanotech/nanotech.htm.

# PDA Inter-Chapter Conference

**Carina Sonnega, Consultant and PDA Spain Chapter**

During the 2005 PDA International Congress in Rome in March, a new initiative was born: the organization of an annual inter-chapter event involving the PDA Chapters for Spain, Italy and France. The Spain Chapter proposed the idea, which received very positive feedback from the other two Chapters.

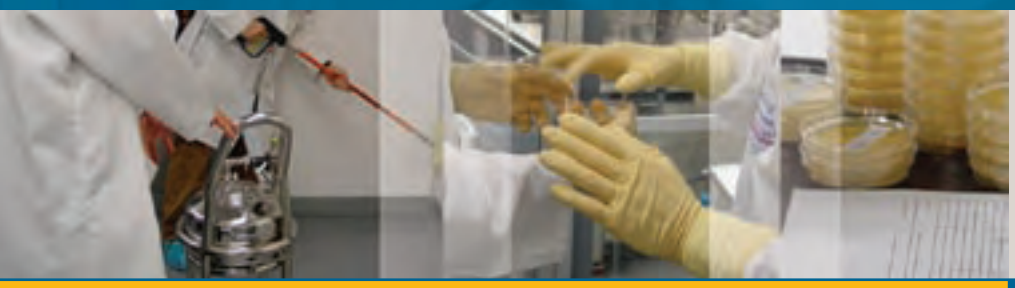
The initial aim of such an event will be to assist the Spain and France Chapters in their start-up phases (both of them having only been created last year, whereas the Italy Chapter has now existed for over four years). However, the ultimate goal will be to promote all three Latin countries that have a common pharmaceutical culture which is quite different from other European countries. In addition, PDA as a whole will benefit from such a joint event because it will attract people from all three countries involved, as well as from other countries, who want to learn more about the national regulatory requirements and procedures of Spain, Italy and France.

Meanwhile, several discussions and teleconferences have taken place between the representatives of the respective Chapters and PDA. These discussions have resulted in the establishment of a Core Organizing Committee, a preliminary agenda and a list of key topics that will be dealt with during the first two-day inter-chapter event, which is scheduled to take place in Barcelona in May 2006.

The Chapters are planning to schedule this event annually, with the location alternating between the three countries. Our next meeting will be held in Milan, Italy in September during the Rapid Microbiology Methods event, sponsored by the Italy Chapter. Further details of the program and speaker selections shall then be discussed. For those who have become curious after reading the above: the first official PDA announcement is scheduled to go out by the end of this year.

PDA Training and Research Institute *presents:*

# Developing and Validating Cleaning and Disinfection Programs for Controlled Environments



Please note date change!

*Baltimore, Maryland*

**December 8-9, 2005**

**PDA #324**

## Introduction

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## Benefits of Attending

- Reduce labor costs and disinfectant usage
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- Learn proper disinfectant rotation to reduce facility and equipment surface deterioration
- Decrease levels of viable and non-viable contaminants in your facility to lessen product contamination risk
- Ensure your cleaning and disinfection program complies with current regulatory guidelines
- Make your current training program more efficient and cost-effective

## Key Topics

- Contamination control in GMP/Class controlled environments
- Disinfection rotation issues
- Actually perform procedures within a Class 100/10,000 cleanroom
- Destruction of viable contamination
- Validation of disinfectants (in-situ, open container, antimicrobial effectiveness)
- Understand the regulatory guidelines with respect to cleaning and disinfection
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## For more information

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Manager, Laboratory Education
Tel: +1 (410) 455-5800
wamsley@pda.org

**Visit:** www.pdatraining.org

**For registration inquires please call +1 (301) 656-5900.**

## Vice President's Message

**Gail Sherman**

# Sharing TRI's Success with Others

2005 thus far has been a very successful year for TRI's training programs—both laboratory and lecture. Although we fretted over our fourth quarter early on, we have been amazed at the support and increased attendance at both existing and new programs offered during this time.

For example, in early September we offered a brand new course, "Fundamentals of Pharmaceutical Filters and Filtration" by experts **Maik Jornitz** and **Ted Meltzer,** PhD. Attendance was great! Attendance at our courses held in conjunction with the 2005 PDA/FDA Joint Regulatory Conference was off the charts compared to previous years, as well. In addition, many of our lab courses are fully subscribed. I attribute this success to the TRI staff, PDA marketing staff, our instructors and word of mouth from previous students.

So, having said that, all is not well everywhere. We had planned a lecture course series in New Orleans at the end of November, and I was so looking forward to my very first trip to the "Big Easy," but alas, that is not to happen. We had some serious soul-searching discussions with ourselves, trying to make the decision whether to cancel or move forward. The weather, the levies and the hotel chain made those decisions for us—at least as far as New Orleans. However, we opted not to cancel, but to move our venue elsewhere. So we are now holding the "New Orleans Course Series in San Antonio, Texas."

And you ask, how is that sharing TRI's success? As you may know, the PDA Foundation for Education, Training and Research has teamed up with Novatek and EMD Chemicals to help with the Katrina relief effort. In this light, all contributions will be donated to the Red Cross specifically earmarked for medicine and medical supplies so desperately needed for the victims of this tragedy. TRI has decided to pledge 5% of all tuition fees collected from the San Antonio Course Series to the Foundation for donation to the Katrina fund. So, for all of you who had planned to come to New Orleans, we will do this again when the city is ready to welcome us, but in the meantime, please join us in San Antonio, and know that while you learn, you are also helping the citizens of New Orleans get back on their feet again.

See you in San Antonio!

**To Contribute to the PDA Foundation for Education, Training and Research, Novatek International and EMD Chemicals Katrina Relief Fund, go to www.pda.org.**

# Interest in Molds is "Growing"

**James Wamsley, PDA**

Over the last several months, we have highlighted many of the new, improved, complementary and extremely popular courses that PDA TRI is offering. What has been overlooked, however, is the only true lab course series that PDA offers. PDA has offered two to three sessions of the *Environmental Mycology Identification Workshop* for several years, and the attendees called for more. So, in 2004, PDA offered its first *Advanced Environmental Mycology Workshop* to build on what students learned in the first course.

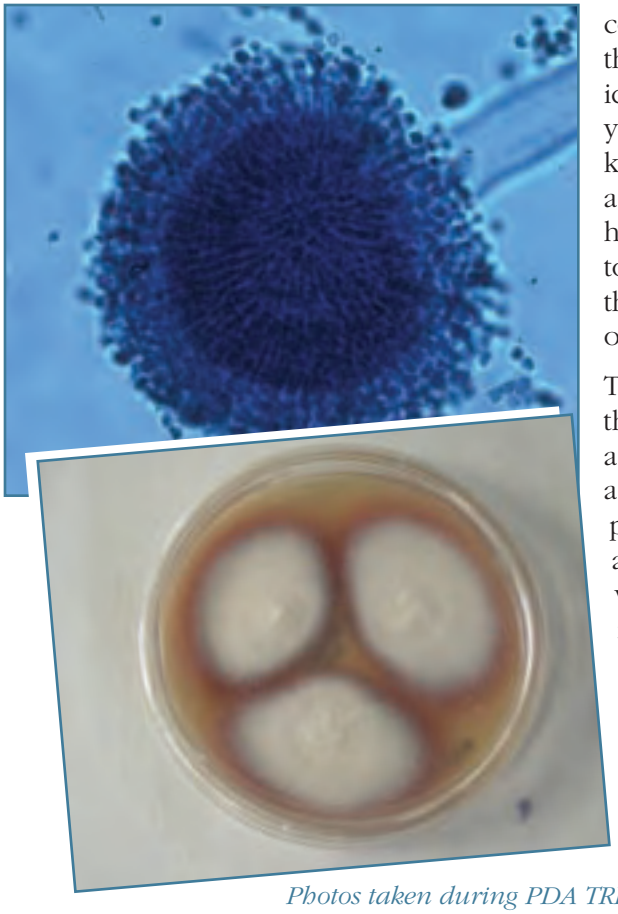
Why, you ask, would anyone want to spend three days looking at isolates of that fuzzy stuff that grows on your cheese (it's happened to everyone!)? It seems that many quality-control laboratories have decided to stop sending these environmental contaminates out for identification and instead, they are performing the identifications in-house in an effort to save resources and to improve overall efficiency of the manufacturing QC and release of product.

**John Brecker**, Decon Labs, Inc., designed this workshop to help those companies and individuals who have not had extensive training in identifying fungi—a subject often overlooked in higher-education scientific programs (including the one from which I graduated). The *Environmental Mycology Identification Workshop* gives participants a basic understanding of the process of identifying mold and yeast isolates, at least to the genus level, over a two-day period. Approximately 12 hours are spent in the laboratory, looking at macroscopic and microscopic features of several fungus cultures. Students learn distinguishing morphological characteristics of typical fungi found in routine monitoring, as well as techniques for isolation, culturing, and maintaining reference cultures. After the two-day lab course, each participant leaves with a good idea of where to begin back at his or her lab and is equipped with a flowchart for identification.

Apparently, that wasn't enough. We heard the call, "WE WANT TO SPECIATE!" Again, John sat down and designed a second course to build on what was learned in the first, as well as to introduce new techniques and even more isolates. The *Advanced Environmental Mycology Workshop* focuses more on the differentiation of species mostly based on microscopic morphological differences. Students also get a chance to work with some newer technology to help them achieve species-level identification. Students get a chance to work hands-on with a rapid identification system, as well as a microscope and digital camera for record-keeping. This three-day class is just as lab focused, with approximately 20 hours of lab time. In addition to the identification techniques, students learn CAPA, as well as disinfectant efficacy testing, and how they apply to fungi.

When asked, students had good things to say about both courses: they explained how these courses not only helped them learn more about identifying molds and yeasts, but also provided knowledge of new products and techniques that they had not yet been exposed to, and that are helpful in the ID process in their own labs.

These two classes are the unsung heroes at TRI, always quietly selling out, and always immensely popular among the attendees because of the value of identifying fungus in-house. So, if you've ever wondered exactly what that fuzzy stuff is on your cheese, sign up for the Mycology Workshop!



*Photos taken during PDA TRI's Environmental Mycology Identification Workshop in 2005*

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