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# PDA Letter

Volume XLV • Issue #7

www.pda.org/pdaletter

July/August 2009


## In This Issue:




PDA Parenteral Drug Association

*Connecting People, Science and Regulation®*

# New Era for PDA Journal Begins

**Walt Morris, PDA**

July 2009 will be remembered as a historic one for the *PDA Journal of Pharmaceutical Science and Technology*, as both a new editor begins the task of guiding the 63-year-old publication and a new, powerful website launches, which will forever change the way readers interact with the publication.

It took some time to find the right person to take over the editorial operations of the Journal, and, following months of intense screening of many qualified applicants, PDA believes it has found an excellent editor in Professor **Govind Rao,** PhD, University of Maryland, Baltimore County (UMBC). Dr. Rao teaches Chemical and Biochemical Engineering and serves as the Director of UMBC's Center for Advanced Sensor Technology. He holds a BTech in Chemical Engineering from the Indian Institute of Technology, Madras, India, and earned his PhD in Chemical Engineering from Drexel University. He joined UMBC as a faculty member in 1987, the same year he earned his doctorate.

Dr. Rao brings valuable expertise, along with extensive industry connections, to the task of helping PDA maintain one of the best society journals in the pharmaceutical/biopharmaceutical industry. His research has focused on applications of fluorescence spectroscopy to bioprocess engineering, and his lab has developed next-generation sensors for low-cost, non-invasive monitoring of oxygen, pH and $pCO_2$ in bioreactors. In addition, novel sensors for glucose and glutamine have been developed, which have led to a paradigm shift in bioprocess technology, as they collectively enable High Throughput Bioprocessing. Dr. Rao's lab also has focused on developing novel applications of Green Fluorescent Protein in Bioprocessing. Its unique fluorescent properties and ease of use in a variety of culture systems have provided new insights into heterologous protein production. Recently, the lab has started developing the next generation of sensors based on surface plasmon coupled fluorescence.

Dr. Rao has been honored with several prestigious awards. These include the Presidential Young Investigator Award from the National Science Foundation, Outstanding Teaching and Research Awards from UMBC, the Van Lanen Award from the American Chemical Society, the Gaden Award from Biotechnology & Bioengineering, the University System of Maryland Regents Award for Excellence in Research and he has been named a 2003 Innovator of the Year by the Maryland Daily Record. In addition, he holds several patents and these have

*continued on page 17*

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***The 2009 PDA/FDA Asia-Pacific Pharmaceutical Supply Chain Conference was the first meeting under the MOU between PDA and the SIFDS.***

***Coming Next Issue:***
***A 10 Year View of Harmonized Regulations***

# Editor's Message

## PDA's Future Course Becomes Clearer in July

I've used this space several times over the last 10 issues to keep the membership informed of the latest regarding their member benefits. Since last September, every PDA publication except for the Letter has made the leap into the 21st century, becoming solely electronic products. We just announced the conversion of the Technical Reports in the June *PDA Letter*.

With the final transition of the *PDA Journal of Pharmaceutical Science and Technology* from a print product to a powerful online research tool about to be completed, we felt it was appropriate to dedicate the cover of this issue to the momentous event. Last August, the project of selecting an online solution fell to me in my role as Director of Publishing, and it has been a thrill.

Adding to the excitement is the fact that my boss, PDA Sr. VP of Scientific and Regulatory Affairs, **Richard Levy**, has served as the Journal's Acting Editor. While I spent a significant amount of my time and energy on the website project, Rich worked tirelessly searching for a new permanent editor and simultaneously managing the Journal's editorial process. Honorable mention goes to **Salil Desai** at the University of Iowa, who was able to continue serving as Assistant Editor for 12 additional months following **Dr. Lee Kirsch's** departure. Salil was invaluable in keeping the Journal on track and helping with the website project. Just as my project is wrapping up, Rich's 12-month odyssey ends when he hands the keys to the Journal over to the new Editor, **Dr. Govind Rao**.

With all of these exciting changes, it is clear that the Shanghai Municipal FDA has picked a great time to begin collaborating with PDA. At the PDA/FDA Joint Regulatory Conference last September, PDA entered an MOU with the SHFDA which calls for information sharing, meetings and an office to conduct business. In June, PDA staff helped host the PDA/FDA Pharmaceutical Ingredients Supply Chain Conference in Shanghai, the first meeting under the MOU. The "News & Notes" section of this issue includes a report on the opening of the office. We dedicated the cover art to this event, because clearly, it will have a positive impact on PDA's activities for years to come. In addition, the issue includes a 4-page "Faces & Places" from the Shanghai events.

Finally, Richard Levy writes in the "Science & Technology Snapshot" about another PDA initiative that will influence the Association's activities—the Paradigm Change in Manufacturing Operations (PCMO) project.

I've been with PDA for nearly six years, and I can honestly say that the last has been the best. It is an exciting time to work for the Association; I hope it is the same to be a member!


# PDA Letter

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# SIFDS/PDA Shanghai Joint Development Center Unveils Office

**PDA and SIFDS discuss future collaborations following ceremony**

Officials from the Shanghai Institute of Food and Drug Safety (SIFDS), a branch of the Shanghai Municipal Food and Drug Administration (SHFDA) and PDA, celebrated the grand opening of a new office for the SIFDS/PDA Joint Development Center (SHJDC). The opening comes just nine months after PDA and SIFDS inked a Memorandum of Understanding that outlined a cooperative arrangement to facilitate information exchange and sharing.

**Tang Minhao,** Deputy Director, and **Yan Liang,** Director of Legal and International Affairs, of the SHFDA, **Xu Lai,** Director of the SIFDS and **Robert Myers** and **Richard Levy** from PDA participated in the grand opening ceremony.

PDA President Robert Myers said at the ceremony, "Working with the SHFDA and the SIFDS is in line with PDA's vision to be the foremost global provider of science, technology and regulatory information and education for the pharmaceutical and biopharmaceutical industry."

Afterwards, Myers said, "It was truly an exciting moment for me to be witness to the opening of the SHJDC office, coming at the conclusion of our first two-day meeting in partnership with the SIFDS. I'm confident that this collaboration will continue to grow and contribute to the enhancement of quality and technology in China's pharmaceutical industry for years to come."

The opening ceremony came on the heels of the *2009 PDA/FDA Asia-Pacific Pharmaceutical Supply Chain Conference* and TRI Courses, the first joint meeting held between PDA and the SIFDS under the September 8 Memorandum of Understanding. On June 15 and 16, pharmaceutical professionals from industry and the SHFDA gathered to hear presentations on best practices in pharmaceutical supply chain manufacture and control. This event also marked the last in a series of meetings PDA and the U.S. FDA held worldwide on the topic beginning in September 2008 in Washington, D.C.


Following the SHJDC opening ceremony, PDA, SIFDS and the SHFDA officials met to debrief on the two-day meeting and to plot the future course of the collaboration.

The overall impression of the meeting was positive. SHFDA official Tang Minhao expressed his satisfaction with the meeting, noting it established a solid foundation for the future. He indicated that the Chinese government was committed to providing support for future PDA programs with the SHFDA.

PDA Senior Vice President Richard Levy stated, "Based on our successes so far, we agreed to expand our educational efforts for 2010 by co-organizing two meetings with TRI courses, one focused on manufacturing sciences and the other on quality and regulatory issues of interest to China. PDA's **Wanda Neal's** leadership in managing the meetings in cooperation with the SIFDS staff will contribute to our success next year, as it did in 2009."

SIFDS' Lai noted that the PDA and her organization demonstrated seamless assistance and cooperation in setting up and executing the supply chain conference. The SHFDA would like to continue to discuss the overall cooperative program and further areas of collaboration, she said.

Joining Minhao, Lai and Liang from the SHFDA at the ceremony was **Yi Chengdong,** PhD, Deputy Director. Other PDA representatives were **Robert Dana,** Senior Vice President; Training and Education, **Nahid Kiani,** Vice President, Membership Services & Sales; and **Hal Baseman,** PDA Board of Directors. A representative of the U.S. FDA, **Steven Wolfgang,** PhD, Consumer Safety Officer, also attended the festivities and spoke at the meeting.

**[Editor's Note:** See "Faces & Places" for photos from the Conference, the Ceremony, and PDA's visit to SHJDC, pp. 40-43.]

# NASA "Nano" Satellite to Solve Effects of Long-Term Space Travel

**Emily Hough, PDA**

The National Aeronautics and Space Administration (NASA) has launched a "nano" satellite that will provide a way to develop potential countermeasures to the detrimental effects of long-duration space travel. The PharmaSat "nano" satellite, which was launched on May 19 at the NASA Wallops Flight Facility, provides a way for NASA to study of how microbes may become resistant to the drugs used to treat sick astronauts on long-duration space missions.

## "Nano" Satellite

***When it comes to "nano" satellites, don't think particles at the atomic or molecular scale. Rather, think bowling-ball scale. That's right, the "nano" satellites NASA has been launching this year are as big as bowling balls and can weigh anywhere from 10 to 110 pounds.***

Photo Credit by: NASA/Wallops Flight Facility

Already transmitting data, the "nano" satellite contains a controlled environment microlaboratory packed with sensors and optical systems that can detect the growth, density and health of yeast cells and transmit that data to scientists for analysis.

According to **Dave Niesel**, PharmaSat's co-investigator, it is believed that the antimicrobial resistance of the yeast will be altered compared to ground controls as the result of their adaptation to the microgravity environment.

Niesel said that although still in process, "the data collected to-date is exceptionally good."

"NASA hopes to continue to use, these small spacecraft 'incubators' for pharmaceutical and other biological experiments in the future," said **Bruce Yost,** the PharmaSat Mission Manager.

The scientific objectives for this mission include:

- Providing life support, such as sugars the yeast can consume, and environmental control, such as temperature, for yeast growth in 48 independent micro-wells
- Administering three groups of growing yeast with the an antifungal agent at three distinct dosage levels, and one control yeast group with no antifungal dosage
- Tracking the yeast population density and health in each microwell before, during and after administering the antifungal by using an optical density sensor and Alamar Blue (an agent that turns the yeast varying shades of blue and pink as they consume the sugars)
- Transmitting the yeast population and health data and PharmaSat's system status data to Earth for analysis
- Measuring and determining the effect microgravity has on yeast resistance to an antifungal agent

Science & Technology Snapshot

# Introducing PDA's PCMO Initiative

**Richard Levy, PhD, PDA**

PDA is well known for the quality and usefulness of our technical reports, technical books and the PDA *Journal of Pharmaceutical Science and Technology,* and for the value and timeliness of our various training courses and events. In order to ensure that these offerings continue to meet the needs of our global members and industry during a time of decreasing resources and dramatic changes to the foundations of quality control/quality assurance and GMPs, we—members of our Board of Directors and our Advisory Boards, along with staff—have developed a new initiative called the "Paradigm Change in Manufacturing Operations," or PCMO℠ for short.

The goal of the PCMO project is to provide an overarching framework for and prioritization of topics for technical reports and other documents and/or training events in order maximize the value of these PDA deliverables to pharmaceutical manufacturers of Investigational Medicinal Products (IMPs) and commercial products. By virtue of the framework's structure, the resultant menu of deliverables will facilitate the implementation of the guidelines from the International Conference on Harmonisation (ICH) on Pharmaceutical Development (ICH Q8, Q11), Quality Risk Management (ICH Q9) and Pharmaceutical Quality Systems (ICH Q10).

Accordingly, the PCMO follows the product lifecycle concept and has the following broad strategic intent:

- Enable an innovative environment for continual improvement of products and systems
- Integrate science and technology into manufacturing practice
- Enhance manufacturing process robustness, risk-based decision making and knowledge management
- Foster communication among industry and regulatory authorities

What PCMO means specifically for PDA is that we will be cataloguing our existing technical reports according to how they fit into the PCMO architecture. Once existing documents and ongoing task force efforts are placed into the framework, missing topics will be identified and a menu of needs developed. PDA will then establish and support additional task forces to met those needs, which will, in turn, create new publications, courses and meetings that support the PCMO objectives. These deliverables will in turn facilitate the transfer of knowledge and spark communication among the experts from industry, academia and regulators, as well as experts from the respective ICH Expert Working Groups and Implementation Working Groups.

It is important to note that PCMO is not meant to duplicate the work of other organizations in helping industry utilize the new guidances. Rather, it is a way for PDA to demonstrate how our existing documents help in this effort and for us to better focus our future efforts on this important and worthy goal.

After the PCMO concept was fully vetted by the Board of Directors, it was presented to our advisory board leaders who met at the 2009 PDA Annual Meeting. Program Advisory Board Chair **John Geigert,** PhD, President, BioPharmaceutical Quality Solutions, wrote about that meeting and the presentation of PCMO in this spot in the June issue. [**Editor's Note:** See the June Science & Technology Snapshot for more on the advisory board leadership meeting, June *PDA Letter,* p. 10.]

In June, PDA had a unique opportunity to allow members of the ICH Steering Committee to review the PCMO program. To facilitate the review, PDA created the website www.pda.org/PCMO where we provided an introduction and a link to the project's dossier. The response from ICH was favorable. **Jacques Morénas,** Assistant Director, French Agency for the Safety of Health Products, who represents the Pharmaceutical Inspection Cooperation Scheme (PIC/S) as the Chairman, was on hand at the meeting and was so impressed by the program, PIC/S has since added a link to the PDA PCMO site onto their homepage (www.picscheme.org/links.php). The website is now available for public viewing and includes a link for those wishing to get involved.

Most recently, PDA Director **Lothar Hartmann,** Head of External Relations, Global Quality, F. Hoffmann-La Roche, and I met with U.S. FDA's **Rick Friedman,** Director, and members of his staff at CDER's Division of Manufacturing and Product Quality at their offices to discuss the PCMO project. The attendees showed interest in the project, and their comments and recommendations will be considered as we move from discussion to implementation later this year.

We are very excited about the Paradigm Change in Manufacturing Operations project. As we roll out the project, look for additional articles in the *PDA Letter* and in the PDA Journal.

# PDA Survey *Results*

## Cleaning Validation Sampling Recovery Practices

**Destin LeBlanc, Cleaning Validation Technologies**

The PDA conducted an online survey on the topic "Cleaning Validation Sampling Recovery Practices" during the fall of 2008. This is the fourth in a series of surveys the PDA has conducted on cleaning validation practices. The survey was designed by a team comprised of **Destin LeBlanc,** Cleaning Validation Technologies, **Liz Dallison,** Pfizer, **Jennifer Carlson**, Genentech, and **Paul Pluta**, Institute of Validation Technology.

The results of the survey are summarized below. Some of the responses in the results totaled more than 100% because more than one response was allowed per respondent. Note that while there were a total of 30 valid participants, not all responded to every question. Unless otherwise specified, the percentages are based on those who responded to that specific question. In addition, some questions had the option of "Other", with the opportunity to write in a response. "Other" responses we considered to be informative have been described in the summary below.

### Survey Participation

Of those 30 respondents who indicated their country, 53% were from North America, 30% were from Europe and 17% were from other locations.

Participation by *department* was as follows: 37% from Validation, 17% from Quality Assurance, 17% from Quality Control/ Analytical Support, 3% from Technical Service, 3% from Production/Manufacturing, 0% from Engineering, 0% from Regulatory, and 17% from "Other" departments.

By *facility type*, 73% were part of a multinational company, 13% were contract manufacturers, 7% were part of a regional company, and 7% were the sole manufacturing location for their company. There were no responses from virtual companies.

### Product Type Manufactured

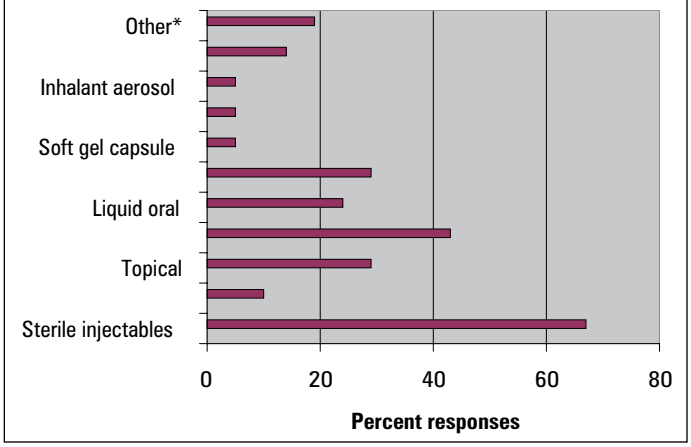
By *type of product*, 68% made finished drugs, 37% made APIs, 7% made combination drug/device products, and 13% made finished diagnostics.

By *facility function*, 36% were commercial manufacturing facilities, 11% were clinical manufacturing facilities, 50% made both commercial and clinical products, and 4% had "Other" functions.

By *manufacturing method for APIs*, 75% used biotechnology processes, 33% used organic synthesis, and 8% used natural products extraction.

Product types for *finished drug* manufacture are given in Figure 1.

**Figure 1: Types of finished drug products**

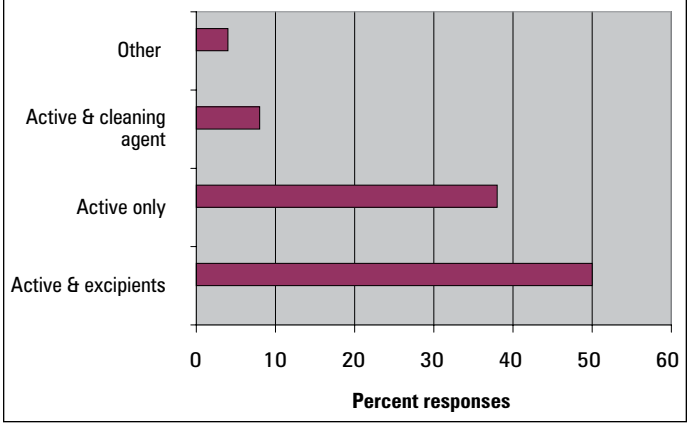



*"Other" responses included diagnostics, suppository, and sterile powder.

### Recovery Studies/Swab Sampling Recovery

For recovery studies for the active for *finished drug product* manufacture, 50% of the respondents spiked the active along with excipients, 38% spiked only the active, 8% spiked the active with the cleaning agent, 0% spiked the active with both excipients and cleaning agent, and 4% had an "Other" response, which was spiking the entire product or formulation. Results are presented in Figure 2.

**Figure 2: What spiked for active in finished drug manufacture**




**[Editor's Note:** For full results, go to http://www.pda.org/MainMenuCategory/ScienceandTechnology/ScienceTechnologyNews.aspx.]

For recovery studies for the active for *bulk drug* manufacture, 50% of the respondents spiked only the active, 40% spiked the active with processing aids or stabilizers that might be present, 10% spiked the active with the cleaning agent, and 0% spiked the active with both processing aids/stabilizers and cleaning agent.

In dealing with *intermediates* for bulk drug manufacture, 46% applied the recovery study of the active to all intermediates, 38% performed a separate recovery study for intermediates, 15% performed a recovery study on a representative intermediate and applied that study to all intermediates, and 0% had an "Other" response.

For swab recovery studies, the minimum acceptable percentage recovery established was as follows:

Table 1

| Minimum Acceptable | <40% | 40% | 50% | 60% | 70% | 75% | 80% | >80% |
|---|---|---|---|---|---|---|---|---|
| Percent Responses | 4% | 4% | 25% | 7% | 36% | 0% | 14% | 11% |

If the minimum acceptable percentage was not achieved, 57% of the respondents would perform an investigation to find the cause of the low recovery, 71% would modify the swabbing procedure until an acceptable recovery was achieved, 39% would use another sampling technique (such as rinse sampling) with acceptable recovery, 50% would write a justification for utilizing the low recovery percentage, and 7% had "Other" answers.

Figure 3 addresses how the minimum acceptable recovery percentage. A small percentage of respondents use this information to qualify the swabbing procedure. 22% use the percentage recovery to correct either the limit or analytical result when percentage recovery was below a certain target value.

**Figure 3: How acceptable swab recovery used**

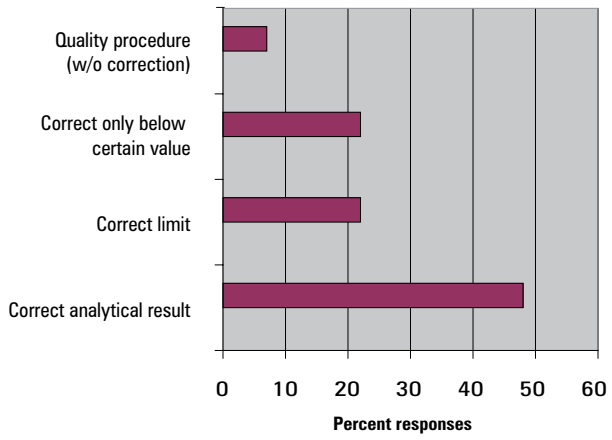


Figure 4 addresses which MOCs are tested. Testing every surface type was by far the most common practice, with 59% reporting that they do this.

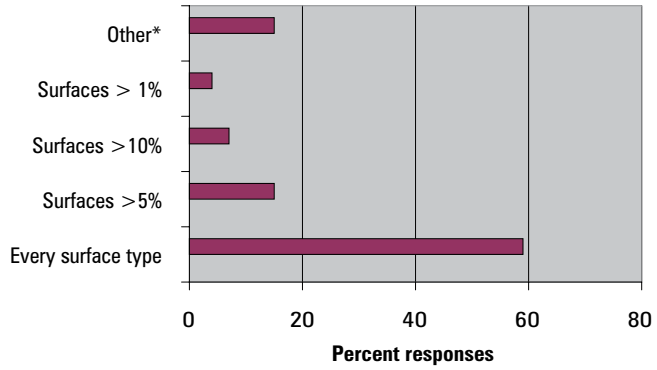
For situation where a MOC was excluded from a recovery study (based on a product contact area determination or similar criterion), for the *recovery percentage for that excluded MOC:*

- 13% use the minimum acceptable recovery percentage
- 25% use the lowest recovery percentage of any other material tested
- 25% use the lowest recovery percentage of any other similar material (metal, plastic) tested
- 38% do not sample those surfaces where a recovery study was not performed

Figure 5 addresses the number of spiked residue levels evaluated.

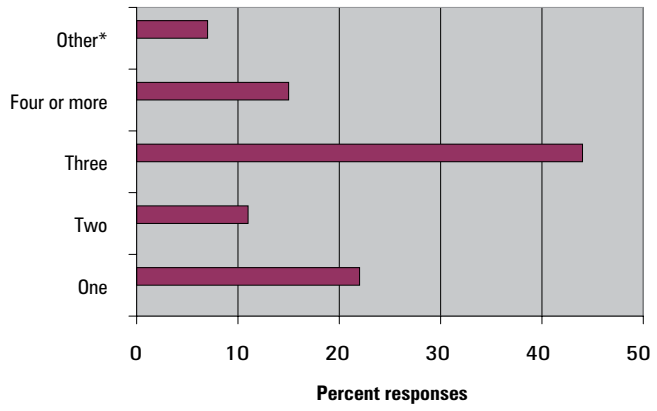
Regarding the *number of different people* who were required to perform the recovery study (Figure 6) shows that one or two persons were required by most respondents.

**Figure 4: For which MOC were swab sampling recoveries performed**



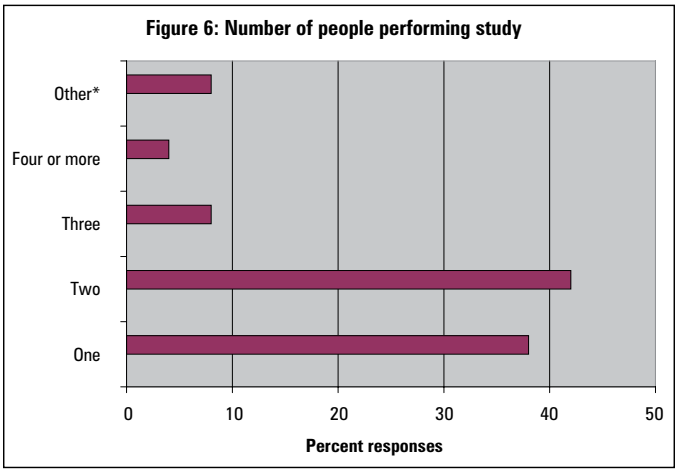

*"Other" scenarios included grouping based on historical data and discontinuing testing of every surface based on data.

**Figure 5: Number of spiked levels evaluated**




*Both "Other" answers indicated "three or more" levels.

**Figure 6: Number of people performing study**



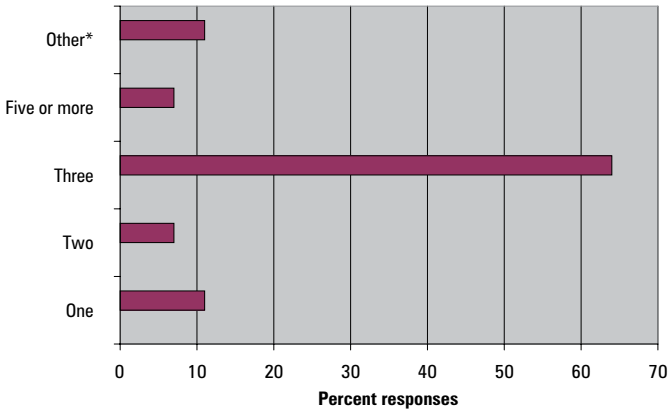

*All "Other" responses indicated that the number of people depended on the specifics of the situation.

Figure 7 addresses the *number of replicates* at a given level that must be performed by a given person. Three replicates per person was the most common strategy. No respondent required 4 or more per person.

In terms of selecting the "official" recovery percentage for a *given spiked level*, 30% of the respondents selected the lowest percent of any one swab result, 26% selected the lowest average percentage of any one person, and 44% selected the average percentage of all replicates.

In terms of selecting the "official" recovery percentage when *two or more spiked levels* were performed, 43% of the respondents selected as the "official" recovery percentage for the residue the lowest recovery percentage of the different spiked levels, 39% selected the lowest average percentage of different spiked levels, 13% used a "staged" recovery percentage that depended on the measured residue result, and 4% had an "Other" response, which was to utilize the recovery percentage at the acceptance level.

**Figure 7: Number of replicates per person**




*All "Other" responses indicated the number of replicates per person depends on the spiked level.

For those who performed swab sampling with an *extension pole*, 41% of the respondents also performed swab recovery studies using the extension pole, and 59% did *not* perform swab recoveries using the extension pole.

## Rinse Sampling Recovery

**[Editor's Note:** For full results, go to http://www.pda.org/MainMenuCategory/ScienceandTechnology/ScienceTechnologyNews.aspx.]

In terms of the method used for recovery:

- 70% performed sampling recovery by spiking a coupon and then simulating the rinse by allowing water/solvent to flow across the coupon into a clean collection vessel
- 13% spiked the bottom of beakers of the appropriate material of construction and added a fixed volume of water/solvent and agitated it to simulate rinsing
- 9% spiked a test coupon, placed the spiked coupon in the bottom of a clean beaker, added a fixed volume of water/solvent and agitated it to simulate rinsing
- 9% spiked or the inside of a reflux condenser or a coupon inside a reflux condenser and then simulated solvent refluxing

Table 2 – Acceptable percentage recovery established for either an active or cleaning agent

| Minimum Acceptable | <40% | 40% | 50% | 60% | 70% | 75% | >80% |
|---|---|---|---|---|---|---|---|
| Percent Responses | 4% | 0% | 22% | 4% | 39% | 4% | 26% |

If the minimum acceptable percentage was *not* achieved:

55% of the respondents would perform an investigation to find the cause of the low recovery

50% would modify the rinsing procedure until an acceptable recovery was achieved

45% would use another sampling technique (such as swab sampling) with acceptable recovery

36% would write a justification for utilizing the low recovery percentage.

Figure 8 addresses how respondents use the minimum acceptable recovery percentage.

**Figure 8: How acceptable rinse recovery used**

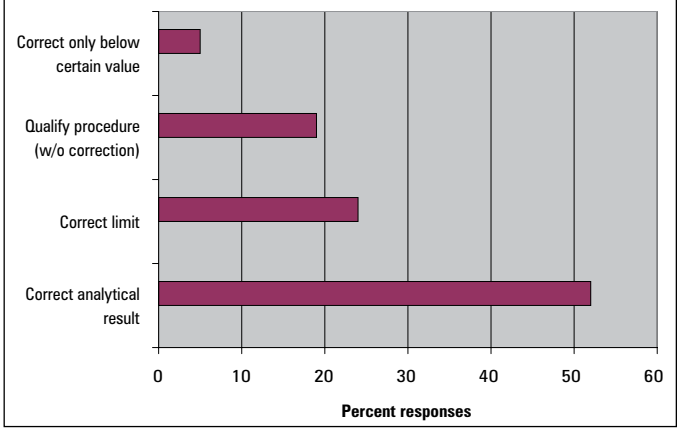
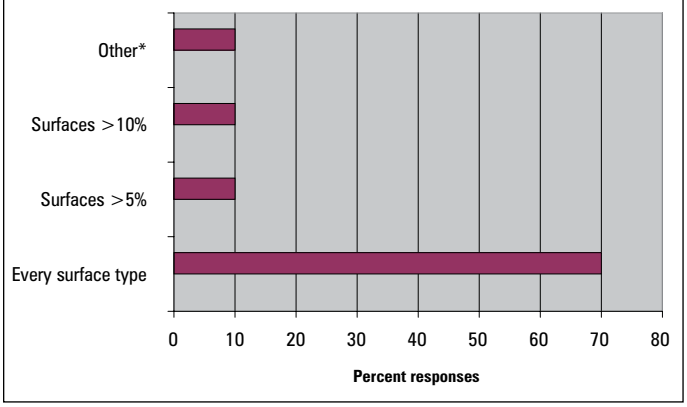


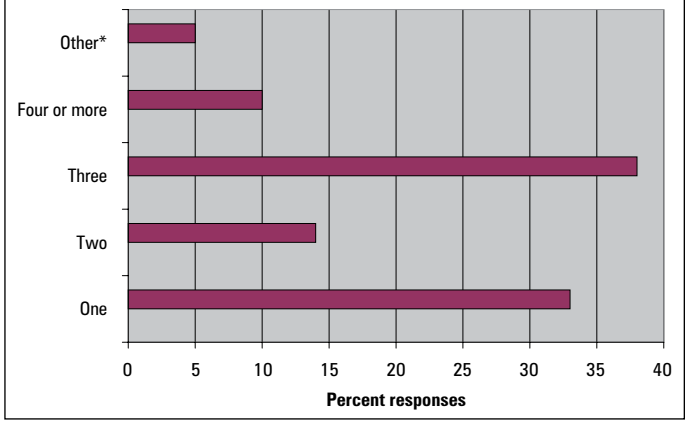
Figure 9 demonstrates how respondents perform recovery studies on surfaces of different MOC. Figure 10 captures the number of spiked residue levels evaluated by respondents. Results presented in Figure 11 demonstrate the number of different people who were required to perform the recovery study. Figure 12 covers the number of replicates at a given level that must be performed by a given person.

**Figure 9: For which MOC were rinse sampling recoveries performed**



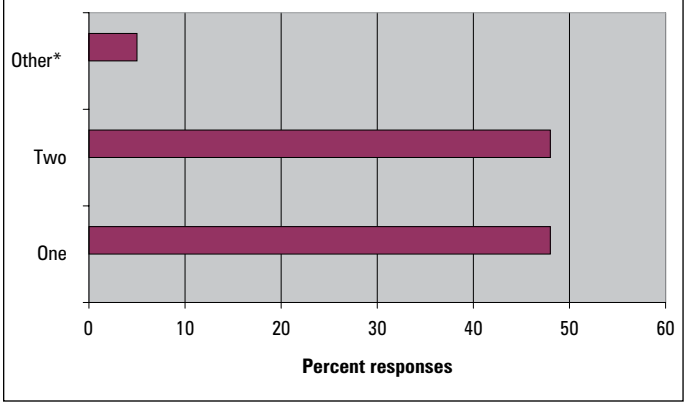

*"Other" answers, which included grouping based on historical data and MOC not factored into rinse recovery studies.

**Figure 10: Number of spiked levels evaluated**



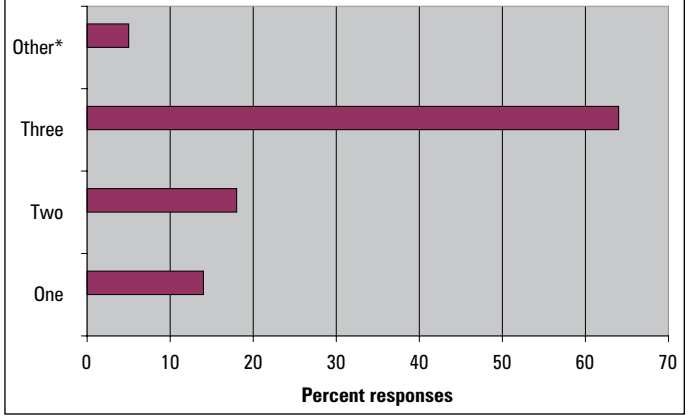

*All "Other" answer indicated "three or more" levels.

**Figure 11: Number of people performing rinse study**




*All "Other" responses indicated that the number of people depended on the specifics of the situation.

**Figure 12: Number of replicates per person**




*"Other" answers indicated different numbers of replicates depending on the spiked level.

In terms of selecting the "official" recovery percentage when *two or more spiked levels* were performed:

- 47% of the respondents selected as the "official" recovery percentage for the residue the lowest recovery percentage of the different spiked levels
- 37% selected the lowest average percentage of different spiked levels
- 11% used a "staged" recovery percentage that depended on the measured residue result 5% had an "Other" response, which was to utilize the recovery percentage at the acceptance level

In addressing surfaces of different materials of construction, 41% performed a recovery study on the exact materials used in manufacturing equipment and 59% use a representative material for a related group of materials (the example given was 316 and 304 stainless steels).

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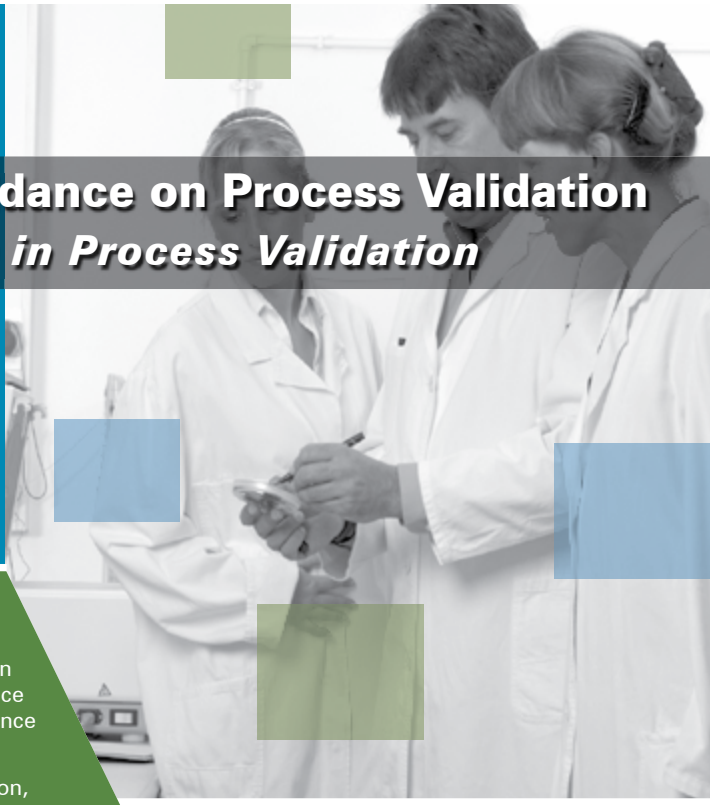

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## Microbiological Sampling Recovery

The next set of data addresses microbiological sampling recovery.

35% of the respondents performed *quantitative recovery of bioburden from surfaces*, and 65% did not. Table 3 addresses the minimum acceptable percentage recovery established by those performing quantitative recoveries from surfaces.

Table 3 – Minimum acceptable percentage recovery

| Minimum Acceptable | 10% | 20% | 30% | 50% | 70% | >70% |
|---|---|---|---|---|---|---|
| Percent Responses | 13% | 13% | 0% | 50% | 13% | 13% |

Of those performing quantitative recoveries from surfaces, 63% used facility isolates for testing, 25% used pharmacopeial "restricted" organisms for testing, and 50% used specifically identified "objectionable" organisms.

## Considerations in Evaluating Responses

While this survey is not scientific in its selection of respondents, it does provide some basic information on current industry practices for sampling recovery studies in cleaning validation for pharmaceutical manufacturing. However, it should not be used to determine "best practice" or even acceptable practices. Note that these questions were asked in the context of sampling recovery practices *for cleaning validation*, and answers might not apply to those same sampling methods used for other purposes. Caution should be applied in using these data, since responses for different types of manufacturing situations (biotech vs. small molecule, or API manufacture vs. finished drug manufacture) may be different.

[**Editor's Note:** Due to the comprehensive nature of the survey, not all of the results could be presented in the print version of the *PDA Letter*. The complete results can be reviewed at http://www.pda.org/MainMenuCategory/ScienceandTechnology/ScienceTechnologyNews.aspx.]

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*New Era for PDA Journal Begins, continued from cover*

been licensed to Fluorometrix, which he co-founded. Moreover, Dr. Rao serves as a consultant to several companies, and in 2007, he was elected as a Fellow of the American Association for the Advancement of Science.

When it comes to publishing, Dr. Rao brings a wealth of experience, having served as the Chair of the Biotechnology Division of the American Chemical Society and on the Editorial Board of several prominent journals. He is currently an Associate Editor of *Biotechnology & Bioengineering.* During his career, Dr. Rao has published over 130 papers in professional journals. He has co-authored papers with **Kurt Brorson,** CDER, and **Michael Hanson,** a 2006 recipient of PDA's Predoctoral Fellowship Grant. Dr. Rao's most recent publications are:

"Disposable Bioprocessing: The Future Has Arrived. Invited Perspective Article," with Antonio Moreira and Kurt Brorson, in *Biotechnology & Bioengineering* in 2009 (vol. 102, pp. 348-356).

"A Novel Method for Monitoring Monoclonal Antibody Production During Cell Culture," with H. Szmacinski, D. Smith, M.A. Hanson, Y. Kostov, and J.R. Lakowicz, in *Biotechnology Bioengineering* in 2008 (vol. 100, pp. 448-457).

"Comparisons of optical pH and Dissolved Oxygen sensors with traditional electrochemical probes during mammalian cell culture," with Michael A. Hanson, Xudong Ge, Yordan Kostov, Kurt A. Brorson, and Antonio R. Moreira, in *Biotechnology Bioengineering* in 2007 (vol. 97, pp. 833-41).

"SPCE-Based Sensors: Ultrafast Oxygen Sensing Using Surface-Plasmon Coupled Emission from Ruthenium Probes," with Derek Smith and Yordan Kostov, in *Sensors and Actuators,* in 2007 (vol. 127, pp. 432-440).

It is Dr. Rao's vision that PDA's Journal will present more research coming out of the bioprocessing/biotechnology community. Indeed, this vision aligns with PDA's efforts to do more to help professionals in these fields, exemplified with the creation of the Biotechnology Advisory Board in 2006.

In outlining his vision of the Journal, Dr. Rao wrote, "My goal will be to expand the coverage of the Journal to broader areas that are more reflective of the business that PDA represents and of its membership."

### New Online Journal to Launch in Summer

Dr. Rao becomes the Journal's seventh editor since 1947, and this year could be one of the most memorable. Later this summer, a new website launches for the Journal that will bring it fully into the 21st century. Partnering with Stanford University's HighWire Press, PDA has created a custom website full of features that will bring greater value to the membership and enhance the usability of the PDA Journal.

PDA was able to select from dozens of features and options to create a site that fits the needs of our members, authors, the editor and subscribers. One is the ability to display content as

## Brief History of the PDA Journal

| Journal Format | | Editor |
|---|---|---|
| *The Bulletin of the Parenteral Drug Association* | 1947 | **Arthur D. Herrick** One of PDA Founders |
| | 1957 | **David Ashkenaz** PDA Director, Past-President |
| | 1964 | **Robert E. King,** PhD, Phila. College of Pharmacy and Science |
| *The Journal of the Parenteral Drug Association* | 1977 | |
| | 1978 | **Joseph R. Robinson,** PhD, University of Wisconsin |
| *Journal of Parenteral Science and Technology* | 1981 | |
| | 1987 | **Joseph B. Schwartz,** PhD, Phila. College of Pharmacy and Science |
| *Journal of Pharmaceutical Science and Technology* | 1994 | |
| | 2000 | **Lee E. Kirsch,** PhD, University of Iowa |
| | 2008 | **Rich Levy,** PhD PDA (Acting Editor) |
| *www.journal.pda.org launches Summer 2009* | 2009 | **Govind Rao,** PhD July 2009 |

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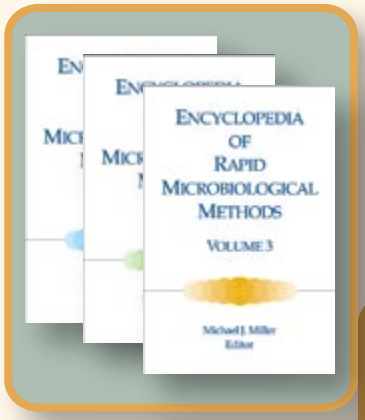
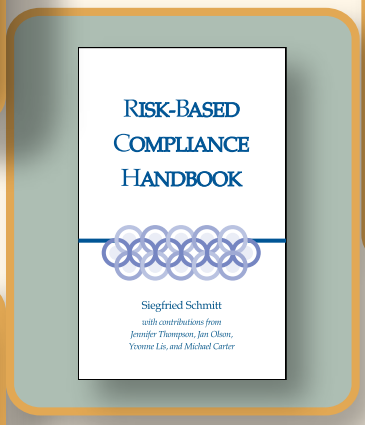
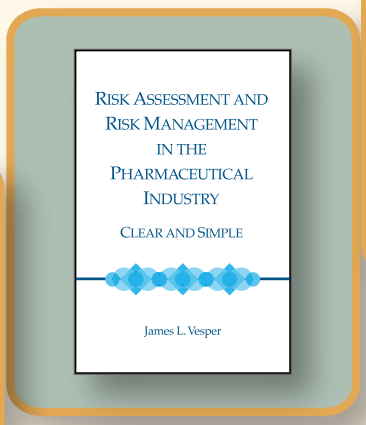


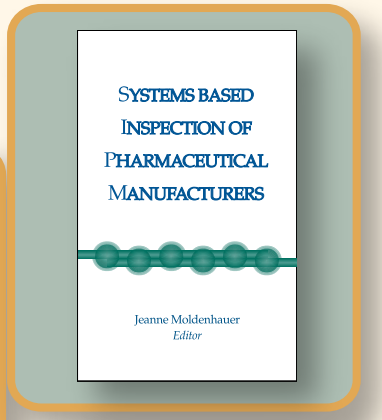

**Encyclopedia of Rapid Microbiological Methods Volume I, II & III**
*Edited by Michael J. Miller*
(Item No. 17252)



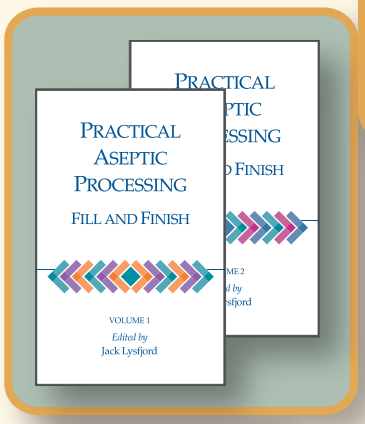

**Risk-Based Compliance Handbook**
*By Siegfried Schmitt*
(Item No. 17281)




**Risk Assessment and Risk Management in the Pharmaceutical Industry: Clear and Simple**
*By James L. Vesper*
(Item No. 17219)




**Systems Based Inspection for Pharmaceutical Manufacturers**
*Edited by Jeanne Moldenhauer*
(Item No. 17243)

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full text HTML pages or as PDFs, giving users a lot of flexibility. The site will provide personalization and alerting options to fit the needs of each member.

What we believe will offer the most value to our members is the advanced search and discovery tools available on the new website. It offers advanced research tools such as taxonomic browsing, content collections, sequence and structure database links, citation mapping and more. The new Journal Editor has the option of adding multimedia data to the website.

A unique feature of the HighWire Press site is its "Toll Free Reference Linking," in which a reader who subscribes (either individually or through an institution) to one journal can click through to a referenced article in another participating HighWire journal and read the full text of that article, whether or not that reader has subscription rights to that second journal.

Another tool PDA feels members will enjoy is the one that allows readers to click on an image or figure in an article and create a fully-cited PowerPoint slide. Speakers at PDA meetings are sure to appreciate this function.

Keeping track of new content is easier than ever with the HighWire site. RSS feeds and email alerts are available, as are a host of "Web 2.0" networking technologies. These will keep the most interested readers well-informed and well-engaged with the PDA Journal.

Of all PDA's choices for establishing a new online presence for the PDA Journal, HighWire Press offered a number of advantages that we liked. Near the top was the fact that the company is a not-for-profit, like PDA itself. In addition, PDA remains the publisher of its Journal—HighWire Press acts as a website development and hosting company, that's it. So when readers log on to the new site later this month, they will find an easily recognizable PDA environment.


The Journal has evolved from a bulletin in 1947 to an interactive website in 2009

Quality & Regulatory Snapshot

# Health Authority *Special Report*

## MHRA's Risk-Based Inspections Seminar

**Dr.-Ing. Stephan Rönninger, F. Hoffmann-La Roche Ltd and Siegfried Schmitt, PhD, Parexel Consulting, with contributions from Ian Birch, F. Hoffmann-La Roche**

Around 260, mostly UK delegates attended this public seminar on May 22 in London. The Medicines and Healthcare products Regulatory Agency (MHRA) gave a first-hand insight into its current approach to risk-base inspections. The seminar covered the inspection practices for Good Laboratory Practice (GLP), Good Clinical Practice (GCP), Good Distribution Practice (GDP), Good Manufacturing Practice (GMP) and Good Pharmacovigilance Practice (GPvP). In the field of risk-based inspections, the MHRA provides thought leadership among other European agencies. The high turnout reflected the interest in and the importance of the event.

This seminar was to explain the approach and solicit feedback from the affected industry. The participants were encouraged to enter into a dialogue about the program's details with regulators during the breakout sessions. This provided a rare opportunity to speak to all of the inspectorate's section heads. Previously, the MHRA provided information on this program at a conference in Manchester, and liaised with selected stakeholders during the consultation period prior to launch.

### The MHRA Approach

Using a risk-based approach in the execution of the inspectorate's duties is not new for the MHRA, as risk-based principles have been around for a long time. In the UK a code of practice was put in place for government regulators.[1]

- Regulators should use risk assessments to optimize use of resources
- Regulators should provide authoritative assessable advice easily and cheaply
- No inspection should take place without a reason
- Businesses should not have to give unnecessary information or the same information twice
- Businesses that persistently break regulations should be identified quickly and face proportionate and meaningful sanctions
- Regulators should be accountable for the efficacy and effectiveness of their activities

The MHRA presented their model for risk-based inspections (RBI), which incorporates elements of intelligence information, such as a company's compliance status and inspection history, business reports and license variations, among others. A key element is the organizational behavior towards compliance, e.g., through a robust change management culture and self assessments. The Agency expects demonstrable commitment from senior management to regulatory and GMP compliance, expressed through leadership and the provision of appropriate resources, for example. Robust and comprehensive processes, based on quality risk management, are equally expected and taken into consideration when assessing the overall risk.

The expected outcome of the RBI approach is to:

- Identify high risk sites and organizations
- Define the frequency of inspections (where not defined in legislation)
- Define the length and scope of inspections
- Encourage behavioral changes towards self regulation, appropriate Quality Management Systems and Quality Risk Management processes

These outcomes are in line with and supported by the European Federation of Pharmaceutical Industries and Associations (EFPIA) as stated in their position paper on "GMP - Inspections of Global Pharmaceutical Supply Chains."[2]

### GxP-Specific Impact

As the different GxP regulations and the associated inspections came into force at different times in the past, and are also based on individual and specific legislation, MHRA found it necessary to develop individual algorithms for each of the GxPs, leading to GxP area-specific risk values. Consequently, a risk value assigned to a company for GCP cannot be directly correlated to the value for GMP. As MHRA put it, different GxPs are applying different procedures on the same platform for comparable outcomes.

It was shown during the pilot phase that different inspectors arrived at the same conclusions for the final ranking. Concerns were raised that MHRA could be forced to disclose the risk ranking and/or the contents of the self assessment questionnaires under the Freedom of Information (FoI) act. The MHRA does not intend to make this information publicly available, thus protecting commercial confidentiality. Companies will not be given the precise risk score,

only a relative ranking of high, medium or low risk.

As a result of the focus on self assessments, MHRA now asks all organizations before an inspection to complete a questionnaire. The Agency indicated that the information sought through the questionnaire is not readily available to MHRA through other sources. This was somewhat disputed by a number of attendees, as for example, details asked for on the GMP questionnaire are also provided in site master files.[3]

Delegates had the opportunity to participate in a breakout session for their particular GxP area of interest i.e., GMP, GDP, GCP, GPvP and GLP. This was a chance for delegates to examine further the implications of the changing procedures and discuss strategies for managing the new risk-based inspection process.

## The GMP Break Out Session

This was the most popular of the four streams, which therefore had to be split into three parallel sessions. It is essential to bear in mind that, as a rule, all manufacturing sites are considered GMP-compliant, unless actions are taken against their license. In MHRA's experience, 90% of cases where critical compliance problems were identified the management's (cultural) leadership was lacking.

The focus in the GMP area is about the frequency and scope/content of the inspection. GMP certificates are issued as result of an (successful) inspection. These are valid for three years. Consequently, from a legal standpoint, a re-inspection must be performed after this period. A question was raised with regards to the recognition of inspections by other regulatory authorities (e.g., European Union agencies and countries with which mutual recognition agreements are in place). The documented basis for which could be the Certificate of Pharmaceutical Product in accordance with the World Health Organization (WHO) GMP certification scheme is available at the WHO website.[4]

The key elements of the new RBI approach are compliance self assessments (reports) to be provided by the inspected site, risk rankings, inspections frequency and interim updates between inspections. These compliance reports detail changes since the last inspection, such as changes to products, key staff members and company ownership. Only significant changes need considering, and an explanation of this term can be found on the MHRA website. These reports should be signed by the site manager or CEO.

During discussions, it was commented that the site master file document in Pharmaceutical Inspection Co-operation Scheme (PIC/S) format[3] may serve as a basis provided the changes are suitably highlighted, e.g., marked in yellow.

In the future, MHRA inspection reports will have an annex for the risk ranking results, detailing the associated GMP inspection frequency every 6, 12, 24 or 30 months. In addition for the 30 months, there is a 50% reduction in duration possible in the best case scenario. **Note:** *The legal renewal cycle for GMP-certificate is 36 months (= 3 years). The 6 month difference is time needed to conduct and conclude an inspection.* There will be no retrospective assessment of already completed inspections. Prospectively, recalls, company intelligence, compliance history and product types are considered risk factors.

Special attention was paid to the MHRA's inspection philosophy for Active Pharmaceutical Ingredients (APIs), manufacturers of which are inspected if:

- The manufactured API is a biological product. In the interpretation of MHRA there is no distinction to be made between regulatory requirements for biopharmaceutical APIs and drug products.
- An API manufacturer asks for a GMP certificate.
- An API manufacturer is identified during a drug product inspection as warranting an inspection.

A survey among the participants in this break-out session showed that about 70-90% found the model acceptable with regards to, amongst other elements, administrative impact, adequate visibility and inspection frequencies.

## The GDP Break Out Session

The inspections in the GDP area are closely linked with criminal investigation teams in the government. Often GDP is assessed in conjunction with other GxP activities. Specific risk factors include enforcement and poor compliance history. There are a high number of applications from distributors each year. The inspection frequency takes into account the circumstances of these types of business (often short-lived enterprises). For new applications an inspection is performed before the license is issued and these will normally be re-inspected within 9-15 months. Otherwise the inspection frequency is currently every three years.

## The GLP Break Out Session

In this area there is a long inspection history with a wide range of activities. Key

questions are when, what and how long to inspect. Risk factors include, for example, if an organization conducts pivotal toxicology studies, the (poor) compliance history, volume and type of studies conducted, degree of outsourcing and contracting activities, and compliance of other GxP operations at the site. There are about 4,000 pre-clinical studies conducted per year in the UK. Therefore, the risk-based approach is focused on the nature and number and impact of the deficiencies found. The likely effectiveness of corrective and preventive actions is given particular consideration.

## The GCP Break Out Session

The inspection program in this GxP section has started five years ago. A high number of about 1,000 clinical trial sponsors in UK represent a challenge for the regulators. The risk factors include, for example, the number of phase I studies conducted, (poor) compliance history, number of reported adverse events, subject population, trial activities and compliance risk.[5] The completion of the self-assessment questionnaire is particularly difficult for CROs and healthcare trusts as some of the information requested is not normally captured or easily traceable. Depending on the type of study conducted, a site may automatically be assigned high risk status, which would not necessarily be affected by the information submitted on the questionnaire.

## The GPvP Break Out Session

This area could also be named "Good Drug Safety Practice." Risk factors considered include, for example, new chemical entities, black triangle products, (poor) compliance history, and on-time reporting of adverse events.

There is only a five year inspection history, and currently there is much ambiguity about the number of sites to inspect. The risks in this area are linked to incorrect, untimely or incomplete information; types of products; available resources; supporting IT systems; compliance; complexity of the operation; and the suitability of the quality management systems. Feedback on the self-assessment questionnaire was positive, and it was stated that this assessment could also be useful for the companies' internal audit process.

## Impact On Industry

Specific to the GMP area, other inspectorates in the European Union, PIC/S, and the United States FDA are currently developing risk-based models in a similar manner. MHRA views its approach as a leading example. However, they do not know if others might follow and take the same approach. The participants made it very clear that there should not be an isolated UK model only and that internationally recognized standards should be used as much as possible (e.g., the PIC/S site master file form or the WHO Certificate of Pharmaceutical Product form including GMP certification).

Although filling in the self-assessment questionnaire is not mandatory, MHRA encourages its completion by assigning an automatic high-risk rating to any organization that does not comply. Those few who had attempted to fill in the respective questionnaires concluded that it will easily take 250 or more man-hours to complete this one-page document. This raises the question if this is in line with the adage not to put any extra regulatory burden upon those being inspected.

There has been little evidence that there will be any significant change in the inspection scope or pattern, other than a possible shortening of the duration of the inspection for low risk sites. GMP-specific, the law only allows for a maximum period of three years between inspections thereby limiting the agencies discretion.

## Next Steps

As the program has only now started and is being applied prospectively, it is only fair to expect minor changes to the MHRA's procedures for RBI, including the self-assessment questionnaires and the risk-ranking scales. A comprehensive review of the risk assessment procedures is planned for early 2010, and further changes to the process are anticipated. In order to manage the RBI program, appropriate IT systems are needed that will replace the current use of spreadsheets. MHRA has applied for funding and hopes to have a system in place by 2010. There was general consent that a repeat of this stakeholder meeting in early 2010 would be beneficial.

## Conclusion

There was general agreement that the seminar proved a great success, as it gave attendees an opportunity to hear in detail about the risk-base inspections program from both the MHRA and participants in the pilot schemes and an opportunity to ask MHRA inspectors and section heads direct questions was given. The event certainly proved the MHRA's intention to inform stakeholders and solicit their feedback as a key activity for better regulations.

It will be very welcome if MHRA continues sharing information on its activities and their outcomes with other agencies in the EU and abroad. Channels, such as PIC/S, should be pursued towards harmonization of the inspection schemes. Such consolidation will require establishing suitable IT platforms where inspection relevant information and data can be shared, amongst agencies and across borders. Such a multi-national approach may also require extensions to or additional mutual recognition agreements, treaties on sharing protected data and acceptance of other agencies' compliance assessments.

The goal of all this must be better health care for the benefit of all parties involved—the patients, the agencies and the industry.

## References

1. Philip Hampton Principles, *Reducing Administrative Burdens: Effective Inspection and Enforcement,* March 2005, http://www.hm-treasury.gov.uk/d/bud05hamptonv1.pdf

2. EFPIA Position Paper, *GMP-Insepctions of Global Pharmaceutical Supply Chains,* http://tinyurl.com/kmjhgm

3. PIC/S , *Explanatory Notes for Industry on the Preparation of a Site Master File,* http://tinyurl.com/mwnje6

4. WHO, *Certification Scheme on the Quality of Pharmaceutical Prodcuts Moving in International Commerce,* http://tinyurl.com/mtugb8

5. MHRA, *Good Clinical Practice: Risk Based Inspections,* http://tinyurl.com/n9kxlb

# Regulatory Briefs

**Regulatory briefs are compiled by PDA member volunteers and staff directly from official government/compendial releases. Links to additional information and documentation are available at http://www.pda.org/regulatorynews.**

## North America

### Agency Guidance on Pharmaceutical Development Available

The U.S. FDA has announced the availability of an updated industry Guidance entitled, *Q8(R1) Pharmaceutical Development*.

This guidance was prepared under the auspices of ICH and includes the parent Q8 Guidance and a new Annex which provides further clarification of key concepts outlined in Q8 and describes the principles of quality by design.

## Europe

### MHRA Concept Paper Released on Project to Consolidate and Review Medicines Legislation

A concept paper on a Medicines and Healthcare products Regulatory Agency (MHRA) project to consolidate and review medicines legislation has been released.

The purpose of the concept paper is to seek the input of stakeholders on the review and consolidation of medicines legislation. The document also identifies a number of areas where possible reforms can be made.

The vast number of amendments and expansions of medicines legislation over the last 40 years has resulted in a very complex and fragmented set of legal provisions. The MHRA has recently commenced a project with one of the goals being to seek opportunities to make improvements and to simplify provisions where possible. With input from stakeholders over the next 2 to 3 years, the MHRA intends to develop a medicines legislative framework which is comprehensive, comprehensible and fit for current purpose.

### EMEA Guidance Clarifies Evaluation of GCP Compliance

An EMEA guidance seeking to clarify the evaluation of the Good Clinical Practices (GCP) compliance of marketing authorization applications for mutual recognition and decentralized procedures has been published.

The guidance entitled, "Guidance for Coordination of GCP Inspections and Cooperation Between GCP Inspectors, the Reference and Concerned Member States And CMD(h)1, in the Context of the Evaluation of the GCP Compliance of Marketing Authorization Applications for Mutual Recognition and Decentralized Procedures," details how GCP inspections are to be carried out by the competent authorities of Member States in the context of the mutual recognition procedure and decentralized procedure practice.

# PDA CONSULTANT + CONTRACT MANUFACTURING DIRECTORY ABSTRACTS

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Key words = microbial air sampler, cleanrooms control, homogenizer, sample preparation, engineering

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For more information contact:
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Kai received his PhD in 1972 from UMass in Food and Biological Process Engineering and has worked under the late Dr C R Stumbo and Dr M Tung. Kai has also worked under Dr I J Pflug's guidance.

Kai's experience includes (12) years at General Foods and Baxter and industrial consulting for over the past (20) years.

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To develop a new sterile or liquid product, you need to identify and complete a challenging set of tasks. Sterile and Liquids Consulting, LLC (SLC) has the expertise and over 30 years of experience to help you; and to help make your new sterile or liquid product a reality.

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PDA Parenteral Drug Association

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emea

# 2009 PDA/EMEA Joint Conference

# Ensuring Patient Safety through Supply Chain Control and GMP


**The 3rd PDA/EMEA Conference covers legislation, guidance and initiatives from the European Commission and EMEA. Three parallel tracks will address: (1) Supply chain quality, (2) Implementation of ICH Q8-9-10, and (3) Manufacturing and GMP. Key topics include:**

- The QP: role in outsourcing; responsibilities in light of ICH guidance
- Inspection of importers, pedigree, and management of supply chain
- Risk based inspections - planning and practice by inspectorates
- QbD and Inspections
- Translating design space into CMC section of dossier
- Investigational Medicinal products and GMP Annex 13
- Advanced Medicinal therapies and GMP Annex 2
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And much, much more.....

Based on your requests, we will be allowing extra time for discussions of key issues and to focus on 'real life' and practical experiences. As in previous years, more than 50 inspectors and 400 total delegates will join us for this unique European opportunity. This is the only GMP and Inspections event in Europe with direct support from the EMEA to reach affected stakeholders. As an attendee last year commented, "....more than a conference, more than training, a one-of-a-kind opportunity that can't be missed."

**Scientific Planning Committee**

**Conference co-Chairs:** Katrin Nodop, EMEA Inspections Sector; Regine Leo, Inspectorate, Germany; Veronique Davoust, Pfizer

**Authorities/Inspectorates:** David Cockburn, EMEA Inspections Sector; Vjaceslavs Krauklis, Lativa; Karl-Heinz Menges, Germany; Annie Rietveld, The Netherlands; Ian Thrussell, UK

**Industry:** Thomas Barthel, Boehringer Ingelheim; Martyn Becker, MB Associates; Anita Derks, F. Hoffmann La-Roche; Liam Murphy, Amgen Ireland; Tesh Patel, Astellas Pharma Europe

## 13-14 October 2009
## Berlin, Germany

**Conference, Exhibition: 13-14 October**
**Training Courses: 15-16 October**

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

**Register by 11 Sept 2009 and SAVE!**

# A Breakfast For New Members, A How To Luncheon For Volunteers

## Monday, September 14

**New Member Breakfast–*Space is limited***
**7:30–8:30 A.M.**

Welcome new PDA members! If you joined PDA on or after September 1, 2008, you are invited to kick-start your PDA membership by attending the New Member Breakfast hosted on site at the *2009 PDA/FDA Joint Regulatory Meeting*. This is a wonderful opportunity to learn more about PDA and to meet other new members, board members and staff.

Please RSVP by August 31st, 2009. For more information and to RSVP, please contact Hassana Howe at +1 (301) 656-5900 ext. 119 or howe@pda.org.

**NOTE:** You must be a full conference attendee to attend this event. RSVP is required.

## Tuesday, September 15

**How to Volunteer Luncheon–*Space is Limited***
**1:00–2:00 p.m.**

Take part in a complimentary networking lunch and learn how PDA volunteer opportunities can support your career while contributing to the PDA community and industry. Areas that will be covered include PDA Task Forces, Committees, Advisory Boards, Interest Groups, chapter leadership and publishing opportunities. There are many different levels of involvement.

Please RSVP by August 31st, 2009. For more information and to RSVP, please contact Hassana Howe at +1 (301) 656-5900 ext. 119 or how@pda.org.

**NOTE:** You must be a full conference attendee to attend this event. RSVP is required.

PDA Tools For Success

# Should You Fire Your Training Department?

## 6 Criteria to Evaluate the Effectiveness of Your Learning Department

By Sam Palazzolo

Nothing contributes more to your organization's profits or losses than your employees. Having the right employee in the right position at the right time executing the right processes is a recipe for success. However, few managers are fortunate to have this recipe, consistently, in their organizations, so they rely upon the learning department to train employees for success. Unfortunately, the guidance these employees receive from the learning department often causes them to fail because the training doesn't provide tangible or measurable results.

The American Society of Training and Development's Certified Professional in Learning and Performance recommends taking a proactive stance when it comes to developing, delivering and following up on training. This proactive stance should be taken by learning departments, where organizational training needs are anticipated and identified, then delivered accordingly. If you question your learning department's training contribution to your profit picture, use the following six proactive criteria to evaluate their effectiveness.

1 **Strategic** - Training initiatives should be developed with the organization's strategies and objectives in mind. Too often, training departments prepare and present material that is a "current" or "hot" topic instead of what is imperative to achieving the organization's business goals. Your learning professionals should take an active role to assist leadership by showing the positive impact training will have on the organization as a whole. Training will continually improve the organization's ability to compete in its market and it's the most effective means of leveraging the organization's knowledge and talent. A shift in learning department employees from "trainers" to "consultants" or "trusted advisors" is needed.

2 **Professionalism** - The training professionals of the future will be able to perform with a high level of preparation and personalization. Customization is king when it comes to preparing training for the organizational audience. "Canned" training—presentations pulled off of the shelf or those not updated for the current organizational goals—will not suffice in the current "change in a minute" or "around every corner" business climate of the modern workplace. With this in mind, personalization and customization will set your learning department's training apart and deliver higher value to your organization.

3 **Implementation/Sustained Process** - Training is just presentation for the sake of presenting if the material is never implemented. Worse yet, if training is implemented with a "when times are good" mentality or without a schedule, it will never be sustained. When times become "not good," the natural tendency will be to revert back to the original process of how things were done in the past. The goal of training is to be able to execute in good times as well as tough times. Therefore, establish continuous training goals for the greater good of the organization, regardless of economic swings. Implementation works best when the top of the organization supports the learning department's continuous training, and support from the top substantially increases the likelihood that the process will be sustained. Training objectives should be measured periodically to ensure satisfactory progress or regress. If progress slows, identifying modifications in the original process will provide further areas of improvement.

4 **Responsibility** - The "R" word—responsibility is rarely considered in learning departments when it comes to training efforts. Instead, learning departments often cast blame on less-than-successful training initiatives in the other departments within the organization. Inevitably, the other departments similarly shed this blame by identifying one another as the reason success wasn't achieved. Regardless of who's to blame, if the organization's results were less-than anticipated, the training department must take responsibility for the initiatives they present. A key part of this responsibility is properly developing effective and accurate metrics and measurement tools to track and report the value to the organization. Once value has been presented, the responsibility is still upon the learning department's shoulders to execute accordingly.

5 **Learning** - Learning isn't a one-time event! Instead, consider it a process in need of continuous improvement. Instilling this learning process in every part of the organization is key to longevity and success. No two departments learn the same way, and no two leaders will request the same methods. The training team must work in sync with the leadership team to ensure the proper learning methodologies are identified

and delivered for maximum return.

**6** **Proactive** - Obviously it pays to be as proactive as possible, but even more, it's a competitive advantage! Learning departments must work hand-in-hand with organization leadership so they know exactly where their training destinations should be. Again, the more proactive learning departments can be when assessing and identifying what training will have the greatest economic value for the organization, the better. In order to do so, leaders within the learning department must take a proactive stance when it comes to the development and delivering of the training. Training does not end when the sessions conclude either. Learning departments should review the training goals, which were established at the outset, and measure whether or not they are being met. If they are, consider it "Mission Accomplished" and if they are not, learning departments should analyze where specifically the training fell short of accomplishing the desired goals. Then a new training message should be delivered and implemented. Thereafter, and periodically after installation, the learning department should continue to measure and compare for desired results.

Properly anticipating the best training methodologies and delivering them in sync with the organization's goals is paramount for success. This success can be measured by how well your training department performs the six steps identified above.


## About the Author:

Got Influence? You're either an "InfluencerR" or you're being "InfluenceD!" Take the Influential Leader Inventory at www.GotInfluence.com and see where you rank against other leaders who have the "Influential Edge!" **Sam Palazzolo**, CPLP, MBA is the author of *The Influential Leader: 10 Critical Skills You MUST Possess For Success.* As President and Chief Influence Officer at Pathos Leadership Group LLC, Sam conducts Influential Keynotes, Workshops, Webinars, and one-on-one Coaching. Discover more at www.PathosLeadershipGroup.com, e-mail sp@pathosleadershipgroup.com or call 817-605-1942.

# Recipients of the 2008 Honor Awards:

www.pda.org/2008honorawards

## Honorary Membership, Gordon Personeus Award, Frederick J. Carleton Award

The Honor awards have been bestowed to esteemed PDA members since the first award was given in 1958. It is our intention to highlight each of the 2008 Honor Award Winners, all of whom were announced at this year's PDA's Annual Meeting banquet. **[Editor's Note:** We have selected three of PDA's 2008 awardees to highlight in this issue. Be sure to look at this section in future issues for additional winners.]

**Honorary Membership:** This is PDA's most prestigious award, conferring lifetime membership benefits to the recipient. The award is given in recognition of very long service, of a very significant nature, to PDA. The award requires unanimous approval of the PDA Board of Directors, and honorary members are not eligible for other awards in the same year.

**Recipient:** **Julius Knapp**

**Reason Received Award:** Julius is well known for his scientific contributions which focus on the visual inspection of pharmaceutical products, and has been given the moniker, "Mr. Visual Inspections." Julius has published numerous papers in the PDA Journal, and was selected as an PDA Outstanding Scientist in 2006. Julius has been an active, dedicated member since 1972, and continues to participate in the Visual Inspections Interest Group and Workshops.

**Gordon Personeus Award:** Presented in memory of the late Gordon Personeus, past PDA President and long-time volunteer, this award is intended to honor a PDA member, other than a member of the PDA Board of Directors, for long-term acts or contributions that are of noteworthy or special importance to PDA.

**Recipient:** **Karen Ginsbury**

**Reason Received Award:** Karen has participated in many PDA meetings and programs as a committee members and as a speaker. She has been an influential and competent volunteer, providing her European perspective when working on PDA's comments that are sent to regulatory agencies. Karen has done great work with TRI, is a current member of the Regulatory Advisory & Quality Committee (RAQC), and is very active in PDA's European conferences and Interest Groups.

**Frederick J. Carleton Award:** Presented as a tribute to lifetime contributor, past President, past Executive Director and Honorary Member Frederick J. Carleton, this award is designated for a past or present member of the PDA Board of Director whose services on the Board are determined by his/her peers as worthy of such recognition.

**Recipient:** **Lisa Skeens**

**Reason Received Award:** Lisa has met the qualifications the award which stipulates that recipients must have served on the Board of Directors and the Executive Committee. While on the Board Lisa distinguished herself as a active contributor to Board discussions, and was also a member of the PDA Audit Committee, which provides oversight to the Board of Directors on PDA's financial performance and systems. Lisa has chaired both of PDA's signature meetings: the PDA/FDA Joint Regulatory Meeting, and Annual Meeting. Lisa was also a member of the RAQC.

# Volunteer Spotlights

www.pda.org/spotlight

## Tor Gråberg

Chief Pharmaceutical Inspector, Medical Products Agency, Sweden

**Education:** MSc, Pharmacy, University of Uppsala (Sweden)

**PDA Join Date:** January 1, 1991

**Areas of PDA Volunteerism:** Speaker at numerous PDA workshops, seminars and conferences.

**Interesting Fact about Yourself:** Before joining the Medical Products Agency, I worked as a production manager primarily with two different pharmaceutical companies in Sweden. I have a special interest in combining pharmaceutical knowledge and regulatory demands with practical implementation in the industry. A pragmatic and holistic view and the ability to communicate that view is my strength. Another very important topic for me is training and educating inspectors, as well as harmonizing efforts between regulatory bodies.

Starting in January 2010, I will be the chair of the Pharmaceutical Inspection Co-operation Scheme (PIC/S). In that capacity, I would like to continue to expand PIC/S as a true global organization. I also would like to strengthen the cooperation with PDA and ISPE, thus creating a bridge between the pharmaceutical industry and the regulatory arena.

**Why did you join PDA and start to volunteer?** During my first time I was working with sterile/aseptic manufacturing and therefore it was natural to seek information from PDA due to its good reputation. Since then I have had the pleasure to give many presentations at different seminars.

**Of your PDA volunteer experiences, which stand out the most?** It was a good experience to be part of the first PDA/EMEA conference in October 2006 in London. Another very good meeting was the first PDA-ISPE-PIC/S workshop dealing with EU GMP Annex 1, in Geneva in November 2008. During this workshop, there were many possibilities for interactions between industry representatives and regulators, and there was a mutual interest in open-minded discussions.

**How has volunteering through PDA benefited you professionally?** It is always pleasant to work with a professional organization with a broad base of skills. During seminars you will always pick up something new and of value for yourself.

**Which member benefit do you most look forward to?** I really appreciate the issuing of the technical reports. These are of a very high quality and reflect the current need-to-know knowledge and best practices.

**What would you say to somebody considering PDA membership?** Join today, you will not be disappointed.

## Valerie Welter

Director, Corporate Compliance Services, Baxter Healthcare

**Education:** BS, Microbiology, University of Missouri

**PDA Join Date:** 1994

**Areas of PDA Volunteerism:** Midwest Chapter (member); PDA Meetings Presenter; PDA/FDA Supply Chain Program Planning Committee (member). I am currently working on a PDA book chapter associated with Pharmaceutical Cleaning Validation.

**Interesting Fact about Yourself:** I love Bass fishing and Seattle rock bands.

**Why did you join PDA and start to volunteer?** I joined PDA when I first became involved in the manufacturing operation of a pharmaceutical firm, primarily to learn and be exposed to as many technologies and current philosophies as possible. I have stayed with PDA, and volunteer with PDA, to stay connected to people and to be a small part of creating direction for the industry. PDA is the best way for me as an individual to be part of a larger entity creating expectation and influencing cGMP. It is an enabling organization that allows for the flow of ideas and practices into policy and procedure.

**How has volunteering through PDA benefited you professionally?** Volunteering and being associated with the PDA has opened many avenues for me professionally. The ability to directly interact with the people setting expectations for our industry has allowed me to confidently facilitate direction within my own firm. Being exposed to the forefront of what's happening not only domestically, but internationally through the PDA and its many interest groups allows me to focus on and be prepared for what's coming and stay ahead of the regulatory curve. The benchmarking and interaction with colleagues that face the same challenges has benefited me throughout every stage of my career.

**Which member benefit do you most look forward to?** The *PDA Letter*. It keeps me up-to-date on current and coming events…and most importantly, I get to stay in touch with what my mentor, Martin VanTrieste, is up to as a PDA Director.

**Which PDA event/training course is your favorite?** My favorite PDA event is the annual Joint Regulatory meeting with the FDA in Washington, D.C. The meeting, breakout sessions, vendor interactions and the networking opportunities are top notch. I always come away with something that I can bring back to my firm and feeling reconnected with people that I have previously worked with.

# Please Welcome the Following Industry

**Ryuji Abe,** Taikisha
**Joshua Adams,** Merck
**Hirokazu Aizawa,** Spectris
**Robin Alonso,** Genentech
**Shirley Aseron,** Ciba Vision Sterile Manufacturing
**Melissa Bentley,** Lyophilization
**Tamar Bernstein,** Aminolab Pharma
**Stephen Black,** JE Dunn Construction
**John Bogle,** Genentech
**Kevin Bond,** Covidien
**Regine Bosson Wider,** PMI
**Jennifer Bruce,** Jazz Pharmaceuticals
**Nathan Case,** Boehringer Ingelheim
**Gerdil Catherine,** Sanofi Pasteur
**Yi Chengdong,** SHFDA
**Ernest Chow,** Baxter Healthcare
**Jean-Stephane Dupervil**, Sandoz
**April Einstein,** J&J
**Tamer Elbayoumi,** Midwestern University
**David Farrer,** Pharma Alliance International
**Brian Ferrazzani,** PDA New England Chapter
**Larry Fortney**, Summit Regulatory Services
**Jim Gombold,** Charles River
**Chandrika Govardhan,** Sanofi Pasteur
**Karen Green,** Pall Corporation
**Mingxu Guan,** Pfizer
**Ghada Haddad,** Genentech
**Dave Henderson,** Ben Venue Laboratories
**Aurora Henry,** Amgen
**Ingela Herrmann,** NextPharma Technologies
**Anh Hoang,** PDA New England Chapter
**David Hopkins,** Genzyme
**Laurence Huxham,** Novartis
**Drew John**, Gerresheimer
**Akshay Kamdar,** Eli Lilly
**Todd Kenney,** Genzyme
**Patrick Kenny,** MicroTest Laboratories
**John Kowalski,** Sterigenics International
**Hirofumi Kuroda,** Eisai
**Anna Kypridis,** Sigma Pharmaceuticals
**Diane Lagman,** Imclone Systems
**Robert Lamm,** RBL Consultants
**Padraig Landers,** Wyeth Biopharma
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**Marcy Matlosz,** Mallinckrodt Baker
**Tom Mayer,** Minnesota Thermal Science
**Shawn McCormick,** Merck
**Glenn Melrose,** Alexion Pharmaceuticals
**Julian Mensah Segbawu,** Baxter Healthcare
**Xu Minfeng,** Shanghai Food and Drug Packaging Material Control Center
**Noe Miyashita,** Hitachi Plant Technologies
**Myrna Monck,** GlaxoSmithKline
**Nelida Mondelo,** Gador
**Margaret Moran,** Csl Behring
**William Morehead,** Stiefel Labs
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**John Moys,** Sartorius Stedim Biotech
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**Kevin Murphy,** Commissioning Agents
**Ellinor Naumll,** Q-Med
**Shohei Nabeshima,** Kaken Pharmaceutical
**Shailesh Nagarsenkar,** Sanofi Aventis
**Kazuhisa Nagatsuka,** Toray Industories
**Anitha Nair,** New England Student Chapter
**Yasutaka Nakajima,** Chiyoda Corporation
**Stephen Nath,** New England Student Chapter
**Matthew Nelson,** Amgen
**Karen Nelson,** J&J
**William Nickson,** Commissioning Agents
**Chi Heng Nieh Koo**, Kelu Trading
**Janet Nixon,** Siegfried
**Mindy O`Leary,** GSK Biologicals
**Sylivia Ochola,** New England Student Chapter
**Masamitsu Okawara,** Nippon Dionex
**Kazuhiro Okochi,** Takeda harmaceutical
**Osvaldo Olivieri,** Amgen Manufacturing
**Satoshi Ono,** GE Healthcare Bio-Sciences
**Kunio Ono,** Ajinomoto
**Filippo Orlandi,** GlaxoSmithKline
**Er Ou Yang,** King To Nin Jiom Medicine
**H. Arien Pafford,** Millennium Pharmaceuticals
**Peter Pan,** Everest Pharm. Industrial
**Sachin Pannuri,** Enzon Pharmaceuticals
**Hui-An Pao,** Taiwan Liposome
**Nancy Papciak**, J&J / GPSG
**Daniel Pappas**, Medimmune
**Manish Parekh,** Epitopix
**Franco Pasquale,** Genentech
**Kamalkumar Patel,** New England Student Chapter
**Jui Lan Peng,** GenuineChemical Pharmaceutical
**David Perng,** Wyeth
**Camille Pesce,** CTP Consulting
**Jeffery Pettet,** Millipore
**Christopher Phillion,** Wyeth Biotech
**John Pietruszka,** Novartis
**MaryAnn Pollee,** Global Clinical Connections
**Jacky Pong,** Hui Chun Tang Pharma. Works
**Jeffrey Ren,** Taikisha
**Joni Renner,** Daxor

# Leaders to the PDA Community

**Mary Lou Rice,** Microtest Laboratories
**Alessandra Rispoli,** Sanofi Aventis
**Jerome Roa,** Baxter
**Juan Rodriguez,** Bausch and Lomb
**Marc Rogers,** Millipore
**Todd Rubin**
**Paul Salama,** Chiasma
**Joan Sangalang** Exislixis
**Carsten Sauer,** MG Sterile Products
**Sue Schroder,** Symyx
**Kathrin Seeburger,** F. Hoffmann - La Roche
**Michael Segool,** New England Student Chapter
**Chung Guang Shen,** Sun Ten Pharmaceutical
**Pi Ying Shen,** Pei Li Pharmaceutical
**Brian Shen,** Taikisha
**Gwo-Chang Sheu,** Centers for Disease Control
**Jyh-Jaan Shian,** Purzer Pharmaceutical
**Yasushi Shibayama,** Taiyo Pharmaceutical Industry
**Rui-Hui Shieh,** Taikisha
**Po Shen Shien,** Standard Chem. & Pharm.
**David Shih,** Utek International Corporation
**Huei-Chuan Shih,** Bureau of Controlled Drugs
**Atsushi Shiotsuki,** Nippon Kayaku
**Carolina Silva,** Abl Antibioticos Do Brasil
**Kathryn Slater,** Pall
**Carl Slutter,** Sanofi Pasteur
**Michael Smith,** Merck
**Shinobu Soejima,** Hisamitsu Pharmaceutical
**Ryan Starr,** Merck
**Kasimir Straubert,** Bayer Schering Pharma
**Hui Ling Su,** Hua Shin Chemical Pharmaceutical Works
**Yu Man Su,** Chung Mei Pharmaceutical
**Li Ling Su,** Chung Mei Pharmaceutical
**Kuei Chen Su,** Taiwan Tanabe Seiyaku
**Vincent Su,** Sunway Scientific Corporation
**Tung-Mao Su, Chi Sheng** Chemical Corporation
**Park Sub,** SK Chemicals
**Pei-Chien Sun,** Synmosa Biopharma Cooperation
**Jack Sung,** Purzer Pharmaceutical
**Vijay Kumar Sutariya,** Northeastern Ohio University
**Mathew Sweda,** Acceleron Pharma
**Yoshihiro Tada,** Ono Pharmaceutical
**Park Tae Hwan,** Donga Pharm.
**Tara Tagmyer,** Merck
**Hsueh-Yung Tai,** Department of Health
**Wei Cheng Tai**
**Yasunori Takada,** Hisamitsu Pharmaceutical
**Minoru Takahashi,** Hitachi Plant Technologies
**Hiroyuki Takahashi,** ASKA Pharmaceutical
**Saburo Takahashi,** ASKA Pharmaceutical
**Ping Wu Tang,** Shishin Technology
**Aya Tazaki,** Hitachi Plant Technologies
**Hideki Terui,** Eli Lilly
**Tracy Thompson,** CPEX Pharmaceuticals
**Suxia Tian,** GE Healthcare
**Ron Tomer,** Unipharm
**Joyce Tong,** Panco Health Care
**Fa Shing Tong,** Everlight Chemical Industrial Corporation
**Siriporn Toongsuwan,** Sepracor
**Denis Tsai,** ISNetworld
**Kuo Chang Tsai,** China Chemical & Pharmaceutical
**Vincent Tsai,** Synpac-Kingdom Pharmaceutical
**Pei His Tsai,** Taiwan Biotech
**Chi-Chang Tsai,** Syn-Tech Chem. & Pharm.
**Kelly Tsai,** Sanofi-Aventis
**Max Tsao,** Adimmune
**Wai Ming Tse,** King To Nin Jiom Medicine Maf.
**Chiu-Yen Tseng,** San Nang Chemical
**Chiang-Chang Tseng,** Mingtai Chemical
**I-Ching Tseng,** Union Chemical & Pharmaceutical
**I-Ming Tseng,** Union Chemical & Pharmaceutical
**I-Lung Tseng,** Union Chemical & Pharmaceutical
**Mina Tsukiyama,** LSG Corporation
**Mei-Fang Tung,** Kaimight Chemical & Pharmaceutical
**Melissa Turner,** Vistakon
**Christopher Tyree,** Bausch Advanced Technology
**Meir-Chyun Tzou,** Bureau of Food and Drug Analysis
**Satoshi Ueda,** Eli Lilly
**Shigeo Utsunomiya,** Kyowa Hakko Kogyo
**Niels van Namen,** DSV
**Ney Vann,** New England Student Chapter
**Paul Vernon,** Designed Materials

If your information appears inaccurate in this list, please visit www.pda.org to update your profile or email changes to info@pda.org.

**Editor's Note:** Due to the large number of new members and page constraints, the rest of the New Member List will be run in the September issue.

# Expand Your Network at the PDA/FDA Joint Regulatory Conference

**Washington, D.C. • September 14-18 • www.pda.org/pdafda2009**

The *2009 PDA/FDA Joint Regulatory Conference* offers numerous opportunities for attendees to network and gain valuable contacts in the pharmaceutical and biopharmaceutical industries.

There will be a lunch exhibit area on day one (September 14). That, and refreshment breaks throughout the conference schedule presents attendees with the chance to discuss the day's presentations and hot topics with presenters, peers and colleagues. The exhibit area will be filled with companies who are ready to discuss your current challenges and how their products and services can help you overcome these challenges. Let these products and services become valuable resources that you can take back to your organization immediately!

A networking reception will follow the sessions on day one from 6:00–7:30 p.m. and is included in your registration (get extra tickets for just $60). Attend this special reception for an extended opportunity to discuss concerns, solutions to challenges and to build useful contacts.

Participants of the *PDA Combination Products Workshop* that immediately follows the *2009 PDA/FDA Joint Regulatory Conference* will have the opportunity to attend a networking reception from 5:00–6:00 p.m. on September 16. Refreshment breaks during this post-conference workshop will also allow attendees to network with exhibitors, peers and colleagues.

Networking is a key benefit that attendees can gain from attending this conference and post-conference workshop. Networking can help you improve your business performance, products, knowledge and skills. Use the valuable contacts gained at these events to gather new leads and gain key sources of information and support.

Register today for the *2009 PDA/FDA Joint Regulatory Conference* and the post-conference workshop by visiting www.pda.org/pdafda2009. Start adding to your contact list the instant you arrive in Washington, D.C.!

### Exhibit Space Still Available!

For more information, contact **Nahid Kiani** at +1 (301) 656-5900 ext. 128 or email kiani@pda.org

## Calling all Sponsors and Exhibitors to the PDA/FDA Joint Regulatory Conference

**Washington, D.C. • September 14-18 • www.pda.org/pdafda2009**

Exhibit or become a sponsor at the *2009 PDA/FDA Joint Regulatory Conference* and make your company's products and services a valuable part of our attendees conference experience.

The *2009 PDA/FDA Joint Regulatory Conference* is a great opportunity for your company to gain on-site exposure in front of highly qualified, upper-level professionals in the pharmaceutical and biopharmaceutical industry. Thousands attend PDA events to stay abreast of new regulations, trends and technologies. Don't miss this opportunity to be part of the action.

This conference offers the unique opportunity for attendees to join FDA representatives and industry experts in face-to-face dialogues. For more details on the conference, visit www.pda.org/pdafda2009.

Attendees of this conference will benefit from exhibitions including:

- Accugenix, Inc.
- American Stelmi Corporation
- Associates of Cape Cod, Inc.
- Biocorp, Inc.
- BioReliance
- Commissioning Agents, Inc. (Passport Sponsor)
- DBA Pharma
- EmpiriStat, Inc.
- Food & Drug Administration – Center for Biologics
- General Physics Corporation
- Hyde Engineering and Consulting
- Maas & Peither AG GMP – Publishing (Passport Sponsor)
- PAREXEL Consulting
- Regulatory Compliance Associates, Inc (Passport Sponsor)
- SkillsPlus International, Inc.
- Sparta Systems, Inc. (Silver Sponsor)
- SOLABS
- VelQuest Corporation
- Veltek Associates, Inc.

# Combination Products Workshop to Follow PDA/FDA Conference

**Workshop Chair Michael Gross, PhD, RAC, Biologics Consulting Group**

On September 16 and 17, immediately following the conclusion of the *2009 PDA/FDA Joint Regulatory Conference*, PDA will hold its first meeting on combination products at the *PDA Workshop on Combination Products.* The workshop will examine current gaps in the regulatory framework for combination products and how companies that develop, manufacture and market combination products are managing difficult regulatory problems in the absence of defined regulations and guidance.

The workshop will be an opportunity for you to learn about the status of combination product regulations and where gaps exist in the regulatory framework and how companies manage these regulatory gaps. The workshop is intended for individuals at all levels who work in the regulatory affairs, quality assurance/control, manufacturing, engineering, clinical affairs and safety reporting and business functions in drug, biologic and medical device companies. The workshop will emphasize case studies and presentations from companies developing combination products that represent model approaches to problem solving.

The opening session of the workshop will include a presentation by a representative of the U.S. FDA's Office of Combination Products on the status new regulation and guidance development for combination products. The workshop will cover five key areas in combination product development, registration and post-marketing compliance and will address how to:

- Design clinical studies programs for the efficient development of a variety of combination product types
- Structure the content and format of applications for a variety of combination product types
- Report various types of manufacturing and design changes to a variety application structures for a variety of combination product types
- File safety reports for different types of combination products
- Structure quality systems for different types of combination products

The workshop will provide ample time for networking and informal discussions of combination products with industry colleagues and regulators.

I hope you will join us for this unique event. It will not be like any other meeting on combination products.



# Upcoming PDA Web Seminars Schedule, www.pda.org/webseminars

| | |
|---|---|
| 7/23/2009 | Single-use Membrane Chromatography: Novel Applications and Regulatory Guidelines |
| 7/30/2009 | Impact of Tubing Material on the Failure of Product-Specific Bubble Points of Sterilizing-Grade Filters |
| 8/13/2009 | Process Analytical Technology-Case Study |
| 8/20/2009 | Disinfectants and Sporicides to Address Mold and Bacterial Endospore Outbreaks |
| 8/27/2009 | Optimization of Part Washer Productivity |
| 9/3/2009 | Clinical Trials: Responsible Parties and Shared Responsibilities, Sponsor Versus CRO |
| 9/17/2009 | Application of Process Analytical Technologies (PAT) for Effective Cleaning Validation Risk Management |
| 9/24/2009 | Optimal Cold Chain Management through North American Distribution Networks |
| 9/29/2009 | Thermal Validation: Matching the Tool to the Task |
| 10/1/2009 | Efficiency Improvements in the Purification of Protein-Based therapeutics Using Highly Specific Designed Affinity Ligands |
| 10/8/2009 | Container Closure Systems and Products Lifecycle |
| 10/15/2009 | A Novel Approach to Cleaning Validation for Biopharmaceutical Processes |
| 11/5/2009 | Validation Master Plan for a New Aseptic Filling Technology |
| 11/12/2009 | Molecular Methods for the Modern Microbiology Laboratory: Whole Genome Sequencing Methods For Microbial Characterization |

# Supply Chain Management featured at the PDA/FDA Joint Regulatory Conference

**Washington, D.C. • September 14-16 • www.pda.org/pdafda2009**

**Conference planning committee members, John Finkbohner, PhD, MedImmune, and Peggy Rooks, Abbott Laboratories**

To successfully distribute our products to patients, we must strive to ensure that supply chain dynamics are well-controlled and capable of achieving distribution goals in a robust manner. Only through implementing proactive supplier management; exercising robust, quality-driven auditing systems; and, performing distribution and import operations under the good practices umbrella, can we hope to optimize the ability to get our products to patients in an efficient and timely manner. In addition, these supply chain management activities play a significant role in ensuring that our branding is not damaged by the loss of public confidence arising from the impact of counterfeit medicines. With supply chains becoming increasingly complex due to market globalization, the challenges can seem insurmountable. The *2009 PDA/FDA Joint Regulatory Conference* focuses on a variety of topics falling into three parallel tracks. One of the tracks for focuses on the complexities of supply chain management and tools that are being used to better manage these complexities.

Achieving continual improvement of the supply chain through proactive management of suppliers is the topic of one of these discussions. This session will seek to provide an update on the U.S. FDA's considerations around continuous improvement and share the experiences of organizations who have implemented such systems in their supply chains. Optimizing supply chain capability through continuous improvement requires management support, both philosophically and financially. The continuous learning that arises from distribution and import experience provides supply chain understanding so that appropriate risk models can be optimized; potential weaknesses can be identified and controlled; timely remediation can be made when deviations occur; and product quality can be efficiently maintained throughout the supply chain. In addition to having a chance to gain the FDA perspective on this issue, speakers with experience in supply chain management from both pharmaceutical and non-pharmaceutical industries will share their practical experience in how

to implement and maintain proactive supplier management systems.

Auditing processes have always played an important role in supply chain management; however, the reality of a globalization in the pharmaceutical industry is now having a profound impact on various points along the supply chain. Recent events have highlighted how critical it is becoming to establish standards for suppliers and to actively ensure that these standards are being met on an ongoing basis. Meeting stricter client and international quality management standards requires some vendors to invest in improving practices, policies, and/or management systems. Aligning those standards and validating standards of practice for compliance across multiple vendors and product lines has resulted in an extremely complex matrix of tracking systems. Supporting these activities with an acceptable technology platform and building the setting where data can be accessed and shared is critical to establishing an effective overall supply chain control strategy. The session addressing auditing aspects of the supply chain will also focus on real-life case studies and the resulting lessons learned. Insights gained from this discussion will contribute to the participant's ability to apply best practices in their own unique company setting. In addition, the FDA perspective on auditing practices will be provided to set the stage for the overall discussion.

With the increasing emphasis on Good Distribution Practices (GDP) and Good Importer Practices (GIP), as evidenced by the EU legislative updates that are driving GDP updates, it is likely that regulatory scrutiny of distribution practices will become more intense as we move into the future. As seen through recent events, distribution and importation activities can have significant impact on product safety and efficacy. The session that focuses on GDP and GIP will review the current FDA expectations in this area and discuss the Qualified Trusted Importer Program. In addition to gaining insights into current FDA thought on this topic, participants will be able to gain insights from industry experts who will share examples of improvements in distribution practices resulting from the implementation of Good Distribution Practice principles.

We anticipate an exciting opportunity to discuss supply chain dynamics from a variety of differing perspectives with an emphasis on regulatory expectations and real-life experiences from industry representatives who will be sharing the lessons learned. We hope you will be able to join us at the *2009 PDA/FDA Joint Regulatory Conference* and take advantage of this unique opportunity to interact on current supply chain issues and hot topics with industry experts and regulatory health authorities. For more information, visit www.pda.org/pdafda2009.

# Faces and Places: Asia/Pacific Meeting: Shanghai


Yi Chendong, SHFDA


Weibing Wang, Zhejiang Hisun Pharmaceuticals; Dave Schoneker, Colorcon; Anthony Storey, Pfizer; Neil Wilkinson, David Begg Associates


Audience members engaged the speakers with many questions


Dittmar Nerger, Bayer HealthCare


Steve Wolfgang, FDA


Daniel Gold, D. H. Gold Associates


Hao Cui, China SFDA


Hung-Chih Chang Eli Lilly & Co.


(l-r) Eric Berg, Amgen; Season Xu, Sigma-Aldrich Life Science Technology; Julie Gu, Dow Chemical Investment


SHFDA working the registration desk (l-r) Joan Zhang; Ya-qin Gao; Xiaoping Zhang; David Wang

Hal Baseman, ValSource

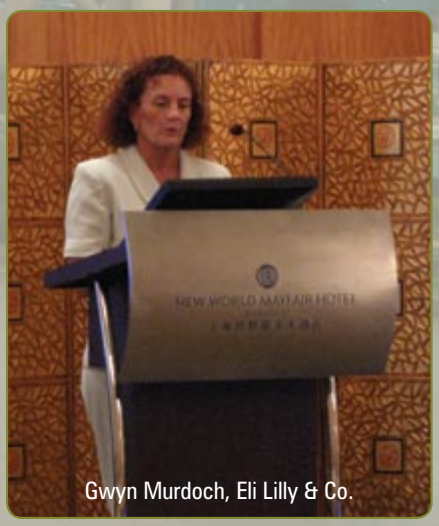
Chris Smalley, Wyeth

Yan Liang, Shanghai Municipal Food and Drug Administration


Nevin Cheng, IPEC China

Mihaela Simianu, Eli Lilly & Co.


(Clockwise l-r) Paul Heiden, Bayer HealthCare; Neil Wilkinson, David Begg Associates; Janeen Skutnik, Pfizer


Gwyn Murdoch, Eli Lilly & Co.

# Faces and Places: SHJDC Grand Opening & Strategy Meeting

Xu Lai, SIFDS

Yan Liang, SHFDA

Bob Myers and Tang Minhao symbolically unveil the SHJDC office

Post ceremony strategic meeting between PDA and SHFDA. Representing PDA on the left (front to back): Hal Baseman, Bob Dana, Rich Levy, Bob Myers, Wanda Neal, Nahid Kiani. Representing the SHFDA (clockwise from top center): Gao Huijun, Yang Yihan (not shown), Chow Cheng Qing, Xu Lai, Huang Li Qi, Tang Minhao, Yan Liang, Zhou Qun (not shown), Ni Li Qiang, Li Jie Min

# Faces and Places: PDA Tours SHJDC & Chinese Medicine Museum

PDA and SIFDS staff at the SHJDC


PDA representatives take a tour of the Traditional Chinese Medicine Museum in Shanghai


The new SHJDC office the day after the ceremony


Examining a display on acupuncture


PDA meets with SIFDS staff


Relief carving of Jing, Qi and Shen, which comprise the core beliefs of traditional Chinese medicine


PDA staff visits SIFDS

# Experience Manufacturing Excellence at the 2010 Annual Meeting

**Orlando, Fla. • March 15-22, 2010 • www.pda.org/annual2010**

**Committee Chair Harold Baseman, ValSource and Committee Vice Chair Christopher Smalley, PhD, Wyeth**

There seemed to be a common theme to many of the presentations and discussions at *2009 Annual Meeting*. From **Ian Morrison's** key note address to **Martin Van Trieste's** closing remarks, the message was that there is a need for more efficient manufacturing. GMP stands for Good Manufacturing Practices, because of the regulatory origin of the phrase we have come to understand this as a reference to the quality of our products. Product quality is obviously essential to manufacturing, but as Messrs. Morrison and Van Trieste and many of the other 2009 presenters would point out–Good Manufacturing Practices also should be concerned with efficiency and productivity. Better efficiency and productivity go hand-in-hand with improved quality and product yield. [**Editor's Note**: See the cover story in the June 2009 *PDA Letter* for more details on Morrison and VanTrieste's talks.]

Our industry has always been faced with challenges. Among these are maintaining product quality, dealing with global regulatory requirements and expectations, controlling contamination, product and supply chain security, implementing technological advancement and addressing the needs for processes to manufacture new products. Today, like many other industries, those who manufacture and distribute sterile drug and related products face the added challenge of optimal performance and improvement in an unprecedented economic environment. The members of PDA recognize that this challenge reflects a global need and the single most important theme to emphasize at our *2010 Annual meeting*.

The PDA *2010 Annual Meeting* in Orlando, Fla. will explore an area of immense importance to our industry–Manufacturing Excellence. Few would disagree that manufacturing of quality products is a keystone to the value of our industry. For years we have heard and recognized that production efficiency and productivity has not been emphasized to the same level as most industries. Today we recognize that properly planned and performed–process design, development, validation, sourcing, process control, contamination control, testing, handling, product and supply chain security, distribution, as well as manufacturing all have a direct impact on manufacturing excellence and the cost of production. The control of excess, defects, contamination, counterfeiting, and management of resources have a direct impact on the quality and cost of products.

*The 2010 Annual Meeting will be an opportunity to offer presentations, case studies, and initiate discussions on subjects related to manufacturing excellence, lean manufacturing, green design and operation, automation, new technologies and better process control.*

The *2010 Annual Meeting* will be an opportunity to offer presentations, case studies, and initiate discussions on subjects related to manufacturing excellence, lean manufacturing, green design and operation, automation, new technologies and better process control. These presentations, workshops and focused meetings will range from engineering/facility design, automation/database management, training on technologies that have impact on manufacturing excellence, improving quality, reducing cost, finding solutions to nagging problems and obtaining a competitive advantage. The Annual Meeting will have interactive sessions which will focus on core competencies of manufacturing methods and techniques, as well as tracks that provide innovative and advanced technology for those interested in advancing their knowledge. When thought about, almost all we do has some link to supporting the manufacturing process and creating an environment of quality and excellence. It is important to note that link and to explore ways to further enhance it, to improve yields, to improve efficiency and to do more with fewer resources.

Although a comprehensive overview of manufacturing excellence, there may be several topics that you will want further information in order to implement at your facility, or personally develop a higher level of expertise. To meet this need, there will be a suite of training courses offered by PDA's Training and Research Institute both before and after the Annual Meeting that will provide an in-depth examination of many of these topics.

If you are interested in the science related to advancements and practices in productive drug and medical product manufacturing and quality and you are able to attend one significant industry event this year, it should be the *2010 Annual Meeting* March 15-22 in Orlando, Fla. This is your opportunity to obtain knowledge, exchange ideas, and help colleagues understand and learn from collective experiences and views. Today, more than ever, this is important.

# A Decade of Excellence: TRI's Aseptic Processing Course

**James Wamsley, PDA**

This year, the PDA Training and Research Institute's most popular course hit a huge milestone: 10 years! That's right; the *Aseptic Processing Training Program* has been running at TRI since 1999. Throughout the many changes in staff, instructors, location and equipment, this TRI course not only remains the most popular, but it is also the most widely recognized training program of its type throughout the industry. In response to demand, the course is now offered five times a year reaching a total 100 students from operators to CEO's. The novelty of the *Aseptic Processing Training Program* has even reached industry, regulatory and academic personnel from all over the world.


The first Aseptic Processing brochure

The backbone of the *Aseptic Processing Training Program* are the instructors. When **Mike Korczynski** helped PDA open the Institute in 1997 as the first Director, he intended to create better training opportunities than what was available to the industry. In 1999, his idea came to fruition with the first offering of the *Aseptic Processing Training Program*. Although the conditions could have been better (he was reportedly perspiring quite heavily while performing an aseptic connection due to the lack of air conditioning), the course was a phenomenal breakthrough and has been ever since. I should also mention that there is no longer a cooling problem in the clean room!

After Mike retired, **John Lindsay,** President, Aseptic Solutions, and **David Matsuhiro,** President, Cleanroom Compliance, took over as the lead instructors of the course. John and Dave worked endlessly in keeping the course relevant to the evolving needs of the industry and to regulation changes. They performed marvelously, maintaining the popularity of this course with their dynamic instruction and engaging personalities. Dave took over as the lead instructor in 2007 when TRI moved to its current location in Bethesda, Md., and has continued working tirelessly to keep up with industry trends and students' needs. The rigors of this course can not be understated—Dave regularly works 12 and 14 hours a day, including performing all of the setup and cleanup that is required with so much hands-on activity. Without these instructors and the many others who have contributed their time, this course wouldn't be where it is today.

What also shouldn't be discounted in the success of this course is the uniqueness of the TRI facility and the drastic changes made to improve the learning environment for the students. It is still the only laboratory facility of its type dedicated solely to training. The first laboratory facility in Baltimore certainly had its challenges (besides the air conditioning, the clean room had soft walls, a sliding door, an alpha-beta isolator door for pass-through, unclassified rooms for material transfer and gowning), but students were always able to draw upon their instruction during the week to successfully perform a media fill. These "challenges" helped ensure a certain level of vigilance among students once in the clean room working around open containers and exposed product.

In 2007, PDA opened the doors to a brand new TRI facility, built from scratch! With substantial input from the instructors, TRI was able to design a fully operational aseptic filling suite with unidirectional personnel and materials flow, a proper gowning room, pass-throughs (that allow transfer of *all* our materials), and better HEPA coverage over equipment. While the new facility isn't entirely GMP, there has not been a single media fill failure to date. Congratulations are in order to all the students that have contributed to this success!

Essential to any successful training program is appropriate and informative instruction material. The course schedule has changed several times in the last ten years to reflect changing industry practices, as well as student requests and expectations. We've lengthened some sections, shortened others, added new sections, changed time slots, etc. One aspect of the schedule that has remained constant, however, is the number of hours required per day from students and instructors. It may seem like overkill to some at first, but we promise it's necessary! This rigor is necessary to stay competitive and relevant in training, and we would like to thank everyone for their contribution over the years in helping us improve.

So, because of the instructor, facility and schedule changes, the *Aseptic Processing Training Program* has remained wildly popular for the past 10 years. It remains the most comprehensive, in-depth and valuable aseptic processing training offered. TRI would like to express its sincere gratitude to the many instructors, donors of equipment and supplies, and past PDA staff that have made the past 10 years possible (and special). We are looking forward for the next 10 years—and beyond!

If you are interested in any upcoming Aseptic Processing Training courses, please visit www.pdatraining.org/aseptic. For information on the "Next Steps in Aseptic Processing" course, which will be held from December 7-11 in Bethesda, please visit www.pdatraining.org/advancedaseptic.

# Ten Training Courses Offered at the PDA/FDA Conference

**Stephanie Ko, PDA**

If you would like an opportunity to combine the benefits of attending a conference and training course in a single trip, consider going to the *2009 PDA/FDA Joint Regulatory Conference* scheduled in September in Washington, D.C. Ten training courses are available following the conference on September 17-18.

Out of those ten, four new courses will be offered. The first new course is "**Developing a Robust Supplier Management Process**." In this course, participants will be able to identify the primary steps and apply the use of risk management tools in the supplier management process, evaluate critical elements during on-site supplier audits, and develop an action plan to enhance the current supplier management process at their company.

Next, the "**Process Validation for Pharmaceuticals: Current and Future Trends**" course will enable students to discuss industry and non-U.S. regulators' concerns with the U.S. FDA draft guide, provide insights on how to grow beyond the 3-batch mindset approach to validation, identify key opportunities for improving effective process development, qualifications and verifications, and examine the roles of basic tools available such as risk analysis, quality by design, statistical analysis, and PAT.

*Out of those ten, four new courses will be offered.*

Another new course is the "**Role of the Quality Professional in the 21st Century.** Students will learn to construct a new and more proactive role in their organizations to meet the evolving challenges facing the pharmaceutical industry, such as recent regulatory emphasis on systems and risk management, and apply the new skills learned to fulfill their new role.

Finally, we are excited to offer "**Quality by Design for Biopharmaceuticals: Concepts and Implementation**." Participants will be able to discuss significant concepts such as Critical Quality Attributes and their application to QbD implementation, the challenges of QbD implementation, how QbD can be employed for commercialization of biotech products, the role of PAT and Risk Assessment, and describe how QbD can be implemented for commercialization of biotech products.

A few existing courses not offered last year have jumped back into the spotlight based on the developing needs of the industry. "**Qualification and Validation of API Manufacturing Operations**" will enable participants to qualify and validate an API plant, discuss associated regulatory and compliance issues, improve existing validation programs, and use the tools provided in the course to formulate validation programs. In another course, "**GMP for Clinical Trial Materials – Regulations and Applications**," students will be able to discuss how GMPs apply to the various phases of clinical research, identify which operations within clinical trial manufacture require full compliance with the cGMP regulations, determine what FDA guidance is available to address cGMP compliance, and what the FDA might expect at each phase of the manufacture of clinical trial materials. Finally, "**Preparing for Regulatory Inspections for the FDA and EMEA**," will help students expand their knowledge of GMPs beyond national borders to Europe. They will learn to discuss and apply EU GMP rules, identify the inspection techniques and methodologies used by the EMEA inspectorate, compare and contrast FDA and EMEA inspections and discuss strategies for hosting and managing FDA and EMEA inspections.

A course series just wouldn't be comprehensive without the oldies but goodies–the recurring courses based on topics that are always in demand in industry. "**Risk Management in Aseptic Processing,**" will discuss topics that will allow students to use risk management as a foundation to make informed, scientific decisions related to aseptic processing. Students will also be able to assess relative risk of aseptic process steps, identify process step hazards and impact of failure, evaluate and rank process steps and relative risk, and make informed decisions on ways to reduce risk. *In one of our most* popular courses, "**Global Regulations and Standards: Influences on Cold Chain Distribution, Packaging Testing, and Transport Systems**," students will understand the concepts and practices of cold chain development and packaging distribution systems. They will be able to describe the global practices and regulatory requirements for cold chain distribution compliance, explain guidance and regulatory compliance of the manufacturer, identify critical steps to the development of profiles for simulation testing, and describe the simulation environment. Finally, we offer **"Change Control: A Practical Workshop**," where participants will learn to construct and justify the need for a compliant, user-friendly and comprehensive change control program that includes the involvement of varied personnel within their company.

2009 has been quite a year so far and TRI looks forward to offering even more great educational opportunities to you at the PDA/FDA Conference as well as at our training institute facility in Bethesda, Md., and other events throughout the rest of the year.

For detailed information about courses offered at the *2009 PDA/FDA Joint Regulatory Conference*, please go to www.pdatraining.org/pdafda. For more information regarding TRI's courses, please go to www.pdatraining.org.

## PDA/FDA Training Courses and Instructors

**"Developing a Robust Supplier Management Process"**
Lisa Hornback, Principal Consultant, Hornback Consulting

**"Process Validation for Pharmaceuticals: Current and Future Trends"**
Scott Bozzone, PhD, Sr. Manager of Global Quality Operations, Validation, Pfizer

**"Role of the Quality Professional in the 21st Century"**
Bob Kieffer, President, RGK Consulting

**"Quality by Design for Biopharmaceuticals: Concepts and Implementation"**
Anurag Rathore, PhD, Consultant, Biotech CMC Issues & Faculty, Department of Chemical Engineering, Indian Institute of Technology
Patrick Swann, PhD, Deputy Director, Division of Monoclonal Antibodies, Office of Biotechnology Products, Center for Drug Evaluation and Research, FDA

**"Qualification and Validation of API Manufacturing Operations"**
Daniel H. Gold, President, D.H.Gold Associates

**"GMP for Clinical Trial Materials – Regulations and Applications"**
Bob Dana, Sr. VP, Regulatory Affairs & TRI, PDA
Vince Mathews, QA Consultant, Eli Lilly

**"Preparing for Regulatory Inspections for the FDA and EMEA"**
David Chesney, VP, Strategic Compliance Services, Strategic Compliance, Parexel Consulting

**"Risk Management in Aseptic Processing"**
Harold Baseman, COO and Principal, ValSource

**"Global Regulations and Standards: Influences on Cold Chain Distribution, Packaging Testing, and Transport Systems"**
Rafik Bishara, PhD, Chair, PDA's Pharmaceutical Cold Chain Interest Group
Tom Pringle, Acting Technical Director, Tegrant

**"Change Control: A Practical Workshop"**
Peter Smith, VP, Pharmaceutical Compliance, Parexel Consulting

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# European Events Schedule


### IG Meeting: Rapid Microbiology Methods
**Meeting/Exhibition:** 21 September


### QbD applied to Modern Aseptic Production and to APIs
**Conference/Exhibition:** 22–24 September


### 2009 Pharmaceutical Freeze Drying Technology
**Conference/Exhibition:** 29–30 September
**Training Course:** 1–2 October


### 2009 Pharmaceutical Cold Chain Management
**Conference/Exhibition:** 6–7 October
**Training Course:** 8–9 October


### 2009 PDA/EMEA Joint Conference
**Conference/Exhibition:** 13–14 October
**Training Courses:** 15–16 October


### Workshop: The Future of Glass as Parenteral Primary Packaging
**Workshop:** 26 October


### The Universe of Pre-filled Syringes and Injection Devices
**Conference/Exhibition:** 27–28 October
**Training Courses:** 29–30 October


### Sterilization Technologies for Pharmaceuticals
**Conference/Exhibition:** 17–18 November
**Training Courses:** 19–20 November

PDA
Parenteral Drug Association
*Connecting People, Science and Regulation®*

2009 PDA Workshop on

# Quality by Design

## Putting Principles into Practice

**22-23 September 2009**
**Frankfurt, Germany**

**Workshop and Exhibition: 22-23 September**

**See the complete program at:**
**www.pda.org/QbD**

**Register by 24 August 2009 and SAVE!**

**PDA is holding its third meeting on Quality by Design (QbD) featuring the following topics:**

**• latest news from the Yokohama ICH Meeting on Q8, Q9, Q10 and Q11 • EFPIA's Mock documents for QbD applied to developing biotech and injectable products • regulator's expectations and experiences with QbD • practical examples on implementing QbD in existing facilities, processes, products • case studies on applying QbD for lyophilisation • QbD applied to Downstream processing of biological products • QbD and Real-Time-Release • Meet regulators from AFSSAPS, PIC/S, MHRA and EMEA as well as industry champions from Abbott, Baxter, Novartis, Wyeth, and others.**

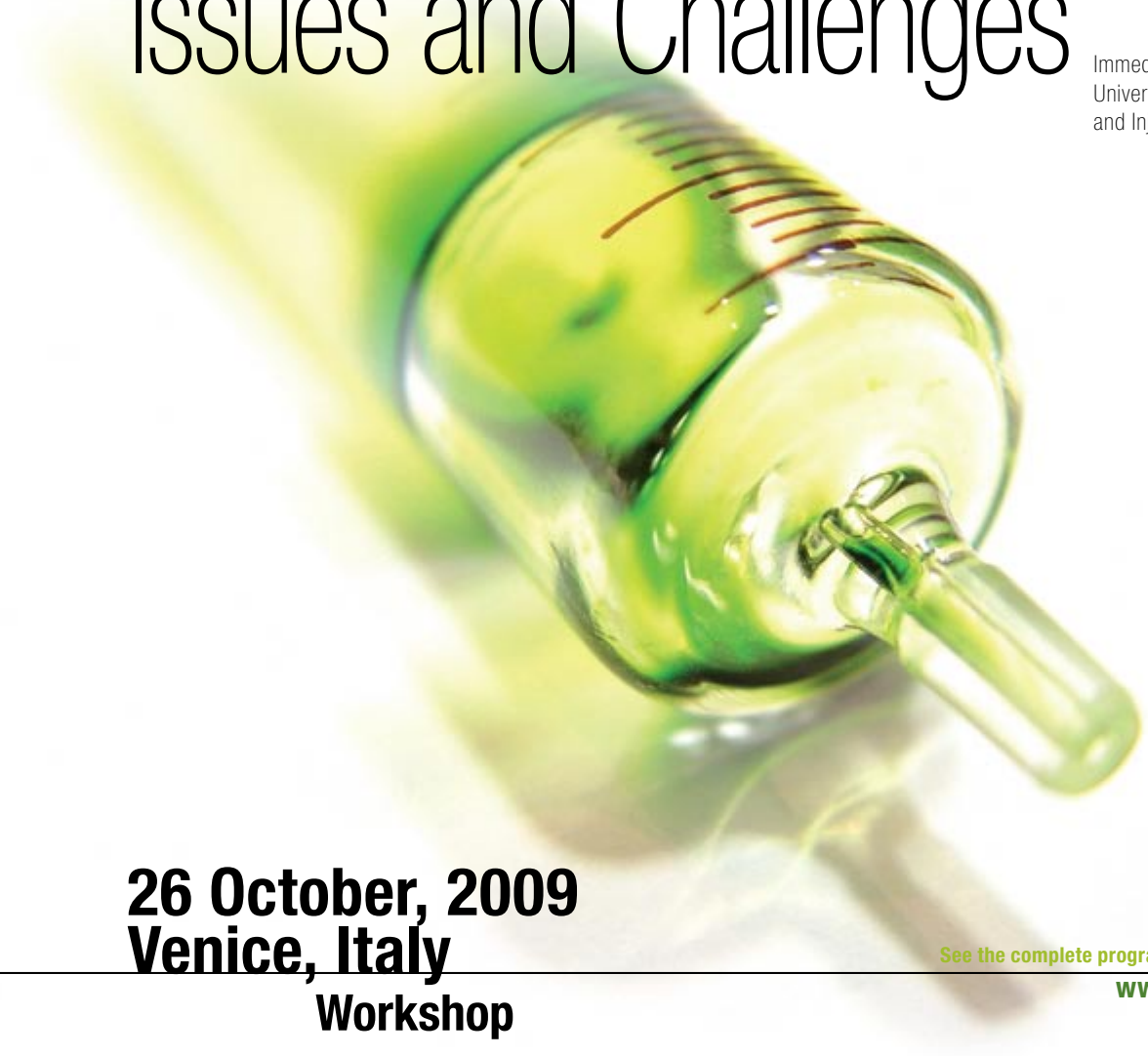
PDA Parenteral Drug Association

*Connecting People, Science and Regulation®*

Pre-conference Workshop with the International Commission on Glass

# The Future of Glass as Parenteral Primary Packaging: Issues and Challenges

Immediately Preceding The Universe of Pre-filled Syringes and Injection Devices



## 26 October, 2009
## Venice, Italy
### Workshop

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

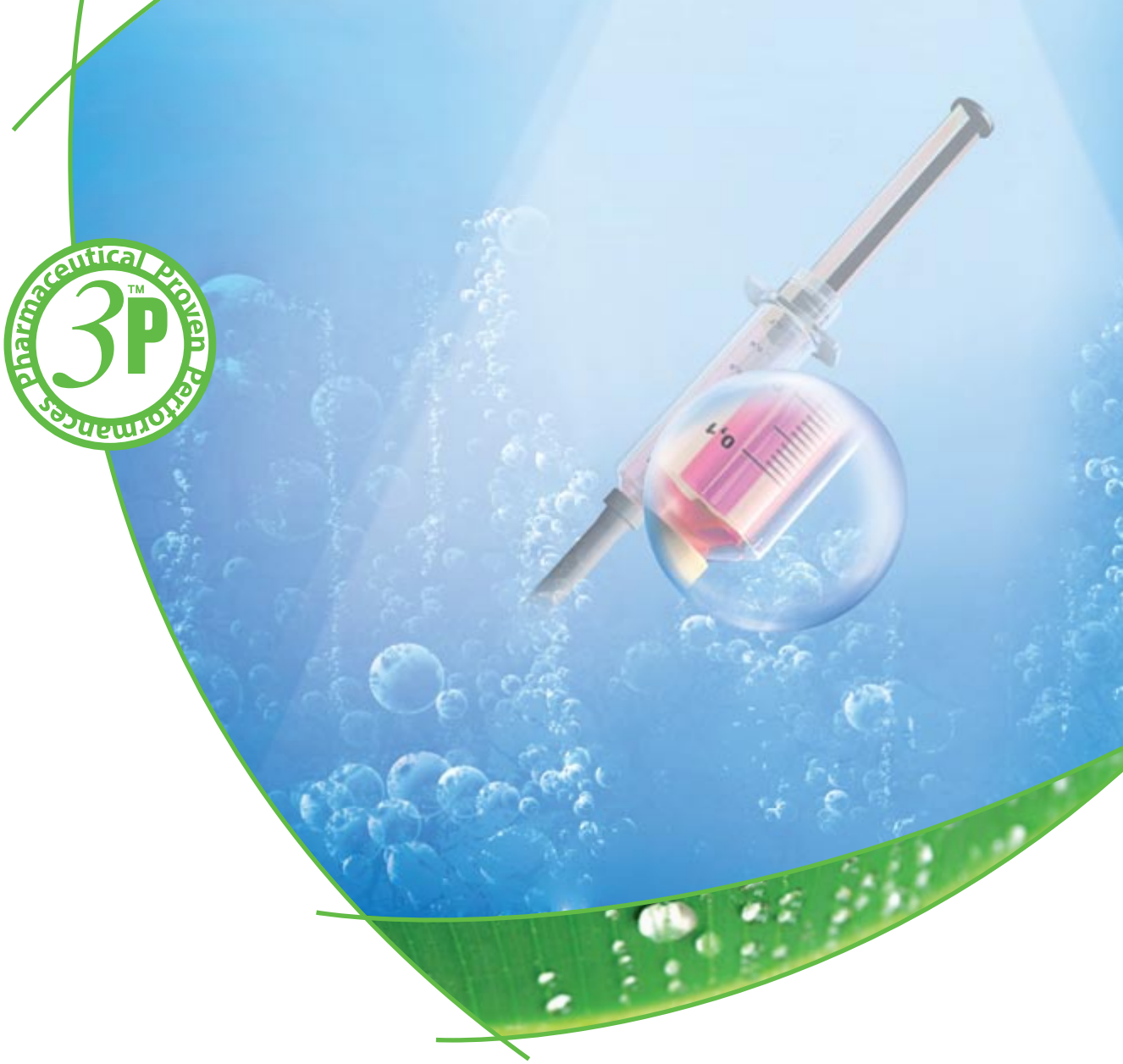
Register by 31 July 2009 and SAVE!

**This workshop is organised together with the International Commission on Glass. The goal of this interactive workshop is to get an update on the status of quality of glass syringes and also hear about the future challenges coming from new pharmaceutical products.**

**Session 1: Quality Control of Glass for Parenteral Products – Current quality standards – Manufacturing and quality controls**

**Session 2: Glass Pre-filled Syringes – Challenges Presented by New Pharmaceuticals**

**What quality should the glass syringes have: A wish list from the perspective of the pharmaceutical and biopharmaceutical industry. How can glass syringe manufacturer cope with the requirements.**

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