

USP-INDIA

Quarterly Update



in this issue

Message from the **Vice President, International-India**

Site Expansion, Annual Scientific Meeting on the Horizon for USP-India



Kumud Sampath

I am pleased to share with you the latest edition of the *USP-India Quarterly Update*. In this column, I will provide a summary of recent activities and developments of the USP-India facility. USP-India has had an exciting quarter,

and we are looking forward to an even busier next few months as we continue to build relationships, expand educational offerings, and grow the capabilities of our site.

One of the most exciting pieces of news I have the pleasure of sharing is that the USP Board of Trustees recently approved an expansion of USP-India. The expanded site will consist initially of a 40,000 square foot office and laboratory building to be constructed in the same area as the current site in ICICI Knowledge Park. The new site is expected to be operational in the first half of 2009. This expansion will allow us to increase our capacity to perform additional lab testing work, expand outreach efforts in our region, and continue to build USP's presence and activities in India and surrounding countries.

In other news, USP-India recently collaborated with USP's headquarters staff to offer the first online education class in India. From the United States, Dr. Valentin Feyns, a scientific expert who worked at USP for almost 30 years in monograph and reference standards development and evaluation, led a group of 18 students from Dr. Reddy's Laboratories through the live opening Webinar for USP's online version

of the General Chapter *Residual Solvents* <797> class. USP-India also recently hosted its first on-ground course offering, "Validation of Compendial Procedures," which sold out in two days. With the success of this on-ground training, recruiting efforts began for a team of India-based faculty, which included a visit to the Bombay College of Pharmacy.

As I briefly mentioned in my last column, the USP-India Annual Scientific Meeting (ASM) will be held February 6 to 7, in conjunction with BIOAsia, in the new Hyderabad Convention Center. The theme of the meeting is "Quality of Manufactured Medicines: APIs, Dosage Forms, Biologics and Biotechnology, and Special Topics." Preceding the ASM will be meetings of the USP-India Advisory Group, the India Stakeholder Forum, and four Advisory Panels to the Council of Experts. For more information visit www.usp.org.

In addition to the USP-India activities mentioned above, Roger Williams, M.D., USP executive vice president and CEO, recently spoke to a large group of Indian pharmacists at the 59th Indian Pharmaceutical Congress in Varanasi. In his address, "Pharmaceutical Science: Education and Research Moving Forward," Dr. Williams introduced attendees to USP, explaining how the organization is governed, its strategic direction including its international strategy, its

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From the CEO

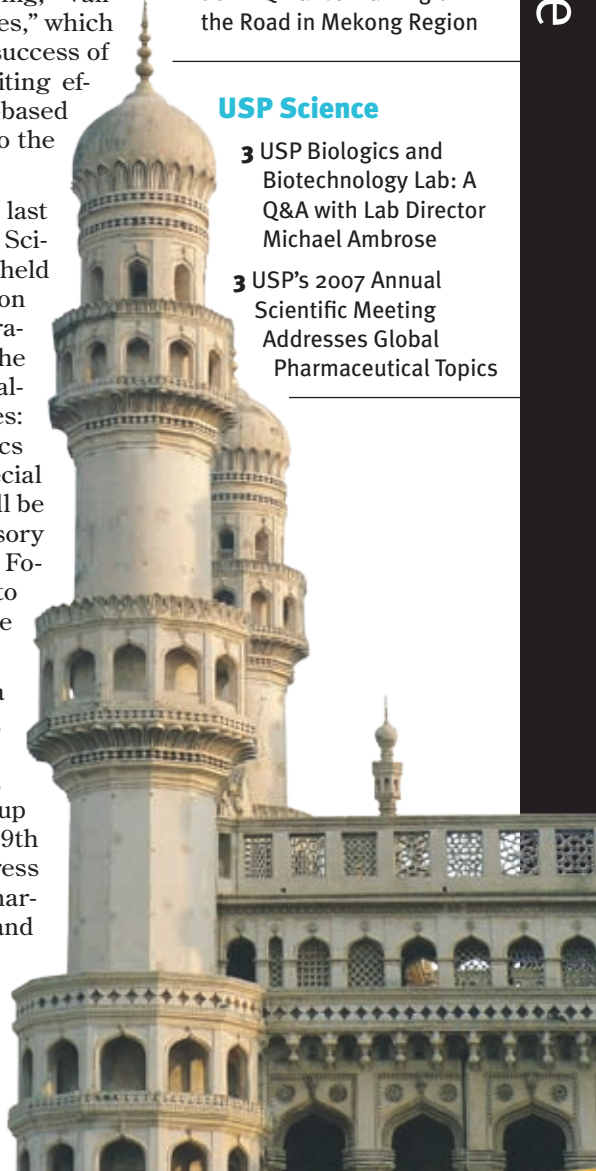
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From the **CEO**

The Year Ahead: Globalization and the Pharmaceutical and Food Industries

Roger Williams, M.D.

As we embark on a new year, taking stock of progress we have made and challenges we will likely meet over the next 12 months, we recognize that 2008 will be a year of change. Much of this change will be due to the globalization of the pharmaceutical and food industries. While globalization can, and has, added to uncertainty on the part of both industry and consumers about the safety and quality of pharmaceutical and food products, USP is committed to working with our international partners to do our part to address these concerns. Through expansion of our programs and collaborations with other nations, we will continue to further our mission of advancing public health through good quality medicines and foods. Our increasingly global presence, with laboratory and office facilities in India, China, and soon Brazil, greatly adds to our ability to do this successfully.

USP's core activity has always been—and continues to be—standards setting for pharmaceutical, over-the-counter, and health care products via the *USP-NF*. This alone is a major contribution to the public health, helping assure the quality, purity, and strength of medicines. As previously reported, USP is now expanding our standards-setting activities into the food ingredients arena, a major activity for 2008. In early spring, we will officially launch the Sixth Edition of the *Food Chemicals Codex (FCC)*, a compendium of more than 1,500 food ingredient monographs that we obtained from the Institute of Medicine. We see this as a natural extension of our mission, given our continuing work on setting standards for dietary supplements, which are regulated as foods in the United States. USP has re-vamped *FCC*, adding new monographs and streamlining all monographs for more consistency and user-friendliness. This work is designed to assist all manufacturers by establishing food grade requirements for food ingredients. For USP, 2008 will be a year of educating food ingredient manufacturers about the importance of the compendium. The quality of food products all over the world is at risk, and we need to continually monitor the quality and purity of these products on behalf of consumers.

Dietary supplements and supplement ingredients, also considered foods under U.S. law, are also of concern. Given lessened regulatory control of foods, consumers may want special assurance that dietary supplements

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“USP's core activity has always been—and continues to be—standards setting for pharmaceutical, over-the-counter, and health care products via the *USP-NF*.”

drug quality initiatives

USP DQI Takes Training on the Road in Mekong Region

USP's Drug Quality and Information (USP DQI) Program recently conducted workshops on quality assurance and quality control of medicines in Cambodia and Laos. Supported by the USAID/Regional Development Mission-Asia and USAID/Cambodia Mission, USP's Souly Phanouvong, Ph.D., Pharm.D., and Edwin Toledo provided training to provincial health authorities, provincial hospitals, procurement units, and warehouses in two provinces of Laos on “Good Practices for Medicines Procurement, Distribution, Storage, and Dispensing.” Workshop instructors came from Thailand's Mahidol University Faculty of Pharmacy, a participating center of Asian Network of Excellence in Quality Assurance of Medicines (ANEQAM), an organization established through USP DQI activities.

USP DQI chemist Sanford Bradby joined Dr. Phanouvong and Toledo in Cambodia to facilitate a training course on “Establishing Quality Monitoring for Anti-infective Drugs Using Basic Tests, Sampling Procedures, and Drug Quality Data Management.” ITN Channel 4 News-China correspondents filmed the training of chemists from 10 provincial surveillance sites in Cambodia, including three new sites along the Vietnam and Laos borders. Reporters also interviewed USP DQI trainers about the problem of substandard/counterfeit medicines and the USP DQI program in Southeast Asia.

USP DQI staff later attended the Association of South-East Asian Nations–United States Patent and Trade Organization (ASEAN-USPTO) “Workshop on Counterfeit Products” in Bangkok and met with Thai officials about USP DQI-supported activities in Thailand.

All three countries have received technical assistance from USP DQI since an assessment in 2003. While at varying stages of progress, all have greatly improved their quality control and assurance systems for medicines. 🧪

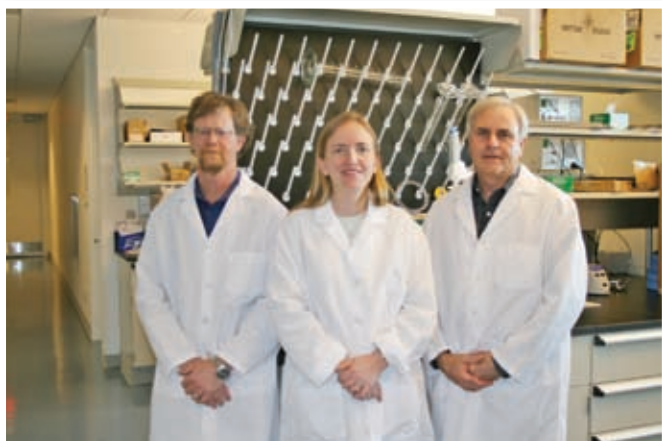
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standards for articles legally marketed inside and outside the United States, and its work with pharmacopeias around the world—including the joint working group of the Indian Pharmacopoeia Commission and USP. In late December, Dr. Williams and I participated in an executive outreach meeting at Ranbaxy Laboratories Ltd., a generic pharmaceutical manufacturer located in Gurgaon, in which we discussed opportunities for USP and Ranbaxy to work together on monograph and reference standards acquisition, monograph updates, and other possibilities for the future. Dr. Williams' participation in these meetings shows the dedication and commitment that USP senior management in the United States has made to fostering cooperation and knowledge exchange between USP and government officials and industry professionals in India.

As always, I would be pleased to hear from you on any comments or questions you have about USP-India and its work. Please feel free to email me at kxs@usp.org. 🧪

USP Biologics and Biotechnology Lab: A Q&A with Lab Director Michael Ambrose

Michael Ambrose, Ph.D., is director of USP's biologics and biotechnology laboratory and is responsible for the new laboratory and building its capabilities at USP. He provides the leadership and technical expertise for the development of the new biological reference standards. Dr. Ambrose offered some insights about the lab in the following Q&A:



Lab staff from left to right: Ambrose, Dr. Jeanne Fringer, and Dr. David Parmelee.

Q: Why was a biologics lab created?

A: The biologics lab was created at USP because of the increasing development of biological therapeutics and the biological methods used in development. USP needed these biological capabilities internally to support the development of the new documentary standards and physical reference materials for the biological methods. In the biologics area, USP is focusing on the ancillary and procedural standards that are required in the processing and manufacturing of biologics and therapeutics. As an example, we are currently working on a Protein A reference standard. Protein A is required for the manufacturing of monoclonal antibodies. During the process of purification of the monoclonal antibodies, some of the Protein A will be leached off through the monoclonal antibody. Manufacturers must quantify how much Protein A is in the monoclonal antibody sample. Protein A can be dangerous if too much is injected into the body.

Q: What do you hope to accomplish in the lab?

A: To develop the same high level of standards and procedures in the biological realm that USP has for small molecules. This is both in terms of the documentary standards created by USP and the physical reference standards. This is a broad undertaking but we are looking forward to the challenge.

Q: When will the lab be up and running?

A: We moved into the lab September 4, 2007, and will begin actual work in early 2008 after validating and certifying all equipment.

Q: What are some exciting new things that are happening in the lab today?

A: The really exciting news is that we have started an entirely new department, developing new methods and processes with the unique intricacies and features of biological products. The lab is divided into four general areas, but each area is not exclusive to itself. Many of the projects will require a concerted effort by the lab as a whole and other aspects of USP to reach a successful conclusion. The four areas are:

- 1) **Analytical biochemistry**—responsible for protein characterization, peptide mapping, amino acid analysis, and glycan analysis.
- 2) **Cell biology**—we will begin addressing reference standards for cell culture, bioassays, and tissue culture method development.
- 3) **Microbiology**—responsible for antibiotic resistance, sterility testing, and any of the microbiological tests that the Documentary Standards Division is working on now.
- 4) **Molecular biology genomics**—completely new to USP. This area looks at DNA and RNA standards, residual nucleic acid standards, and amplification standards.

For more information, email Dr. Ambrose at mra@usp.org. Look for more news on the lab in future issues of this newsletter. 🧪

USP's 2007 Annual Scientific Meeting Addresses Global Pharmaceutical Topics

USP's fourth Annual Scientific Meeting (ASM), held September 25 to 27, in Tampa, Fla., drew more than 300 attendees representing 135 organizations and 16 countries, including a delegation of 20 individuals from the Chinese State Food and Drug Administration.

The 2007 themes, "Quality of Manufactured Medicines, Quality of Care, and International Health," aligned with three of the five new USP Convention Sections, and representatives of USP's Convention, Board of Trustees, and Council of Experts and Expert Committees joined meeting participants in attending two days of programming.

The meeting included five tracks: "Quality of Manufac-

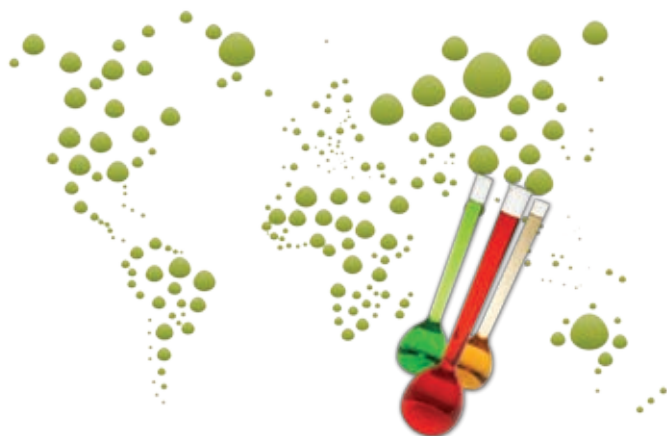
ured Medicines: Monographs and Reference Standards," "Quality of Manufactured Medicines: General Chapters and Performance Testing," "Quality of Manufactured Medicines: Biologics and Biotechnology," "Quality of Care," and "International Health."

Specific session topics in each track, track summary slides, and individual presentations from the meeting are available on the USP Web site at www.usp.org/meetings/asMeeting/track-Sessions.html. USP's 2008 Annual Scientific Meeting will be held September 23 to 25 in Kansas City, Mo., at the Westin Crown Center. 🧪

they buy are of high quality. In recent years, USP has created and expanded its verification programs for dietary supplement finished products and dietary supplement ingredients, which we will continue to grow in 2008. These “USP Verified” programs help assure that ingredients listed on the bottle are in the bottle; that contaminants are controlled; that the product will break down and release into the body; and that the product was made according to Good Manufacturing Practices (GMPs). We encourage consumers to look for a USP Verified mark on supplement bottles.

Recently, USP added verification programs for pharmaceutical ingredients—both drug substances (APIs) and excipients. These are primarily geared towards manufacturers and regulatory authorities, to provide added assurance that the ingredients used to manufacture drug products are of consistent high quality, and are made according to GMPs. Manufacturers can then pass this information along to their purchasers and consumers. Dr. Reddy’s, the largest pharmaceutical ingredient manufacturer in India, recently certified four ingredients through the program.

The coming year is certain to see increased emphasis on manufacturers who cheat the public through manufacture of counterfeit medicines. This is an especially dangerous practice because patients and practitioners may attribute absence of response to a poorly manufactured counterfeit to the course of a disease. Counterfeits in many countries of the world may be increasingly common. For this reason, USP creates and updates standards continuously, but this is only one piece of the puzzle. Many other factors are needed to assure that a market does not allow counterfeits. These include committed ethical manufacturers, a strong regulatory presence, and alert practitioners and patients. Resources need to be available to government officials to combat counterfeits, and USP is committed to assisting officials in the United States, and throughout the world, in any way possible.



Given all of these issues, I expect 2008 to be a busy year for USP. I look forward to working with all of you as we expand USP’s programs and products—doing our part to promote good quality pharmaceuticals and food ingredients for all people, all over the world. 🧪

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