

# USP-CHINA

Quarterly Update



in this issue

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

## USP-China Builds Relationships, Expands Activities



John Hu, Ph.D.

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

quarter following our highly successful site inauguration in September, and we have been building on much of the foundation laid during that inauguration over the past few months.

Following up on initial meetings held during inauguration week, USP's John Fowler, chief global services officer; Bill Zeruld, vice president of global development and strategic integration; and I met with officials from the State Food and Drug Administration (SFDA) and the Chinese Pharmacopoeia Commission (ChP) in November in Beijing to discuss further collaboration on monograph acquisition, USP publication translation, joint scientific meetings and scientist exchange programs, and verification programs. More detail on these activities will follow in the coming months, and USP looks forward to hosting the head of the ChP at its USA headquarters in Rockville, Md., in March, to solidify many of these plans. Mr. Fowler, Mr. Zeruld, and I also met with representatives from the National Institute for the Control of Pharmaceuticals and Biological Products (NICPBP) recently to discuss opportunities for expanding our

existing collaborative efforts. Additionally, Mr. Fowler presented NICPBP with an official invitation to become a member of the USP Convention. We are very pleased with the strong relationships that are being forged with these organizations, and look forward to continuing our work with them to advance the quality of medicines in China and the region.

In other news, six months into USP-China's operation in October, the site successfully completed the first external assessment audit to the ISO 9001:2000 international standard, and was recommended for certification. ISO 9001:2000 gives requirements for an organization's quality management system and addresses what an organization should do to fulfill customers' requirements and expectations, and applicable regulatory requirements. The auditors looked at all of the processes and business areas operated at USP-China. There were zero non-conformances raised during the audit, and I am proud and thankful for USP headquarters' management for their support and assistance as well as the entire team on site who demonstrated USP-China's commitment to quality. In 2008, the site will seek ISO 17025 certification to further demonstrate our laboratory operation is fully in compliance with ISO international quality standards. I will report more on this in the coming months.

Progress and expansion of USP-China's laboratory activities is also a major area of

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U.S. PHARMACOPEIA  
The Standard of Quality<sup>SM</sup>



Roger Williams, M.D.

From the **CEO**

## The Year Ahead: Globalization and the Pharmaceutical and Food Industries

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 China, India, 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

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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*.”

## upcoming courses/ meetings

Visit [www.usp.org](http://www.usp.org)  
for updates!



### TRADITIONAL CHINESE MEDICINE WORKSHOP

Tuesday, March 4, 2008

USP Headquarters

Rockville, Maryland, USA

### NAVIGATING GENERAL CHAPTER <467> RESIDUAL SOLVENTS

March 17/19/21/24-25, 2008

Beijing/Chengdu/Guangzhou/Shanghai

China

### API CHINA

May 12-14, 2008

Dalian, China

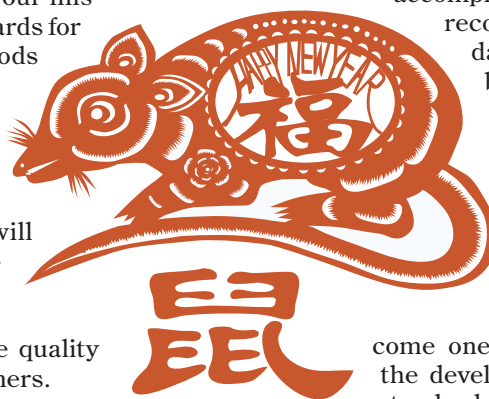
Meet USP Customer Relationship Managers at Booth B210!

### ANNUAL CHP-USP JOINT SCIENCE SYMPOSIUM

May 28-30, 2008 (Subject to change)

China

**Vice President.** Continued from page 1.



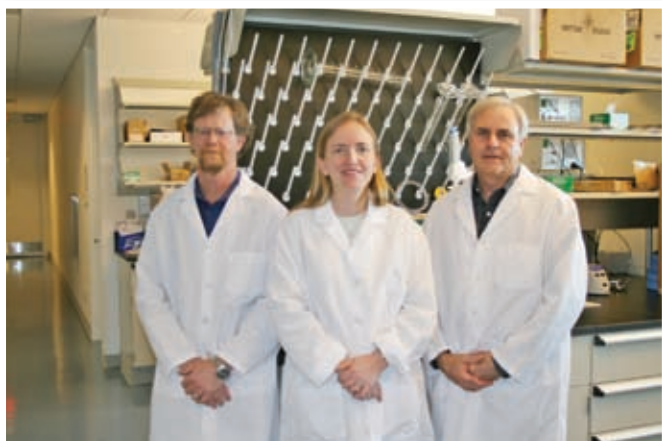
accomplishment for our site, with a record number of reference standard collaborative test projects being completed in November since the lab opened. As our scientists are becoming more and more familiar with USP's reference material development process and collaborative testing requirements, I am confident that the USP-China lab will gradually become one of the major contributors to the development of future USP quality standards.

Finally, February 7, 2008 marks the start of Chinese New Year, or the year of the Rat according to the Chinese astrological cycle. According to Chinese culture, the Rat is revered for its quick wits and its ability to accrue and hold on to items of value. Rat is also the first in the Chinese astrological cycle, and 2008 marks the first year of USP-China in full operation. I would like to take this opportunity to wish USP's friends and customers in the greater China area a happy and prosperous New Year and a year filled with joy and success.

I look forward to continued success and growth of USP-China and its activities. I would be very pleased to hear from you with comments or questions. Please feel free to contact me at [jh@usp.org](mailto:jh@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](mailto: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](http://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.

## Third USP-ChP International Workshop Focuses on Collaboration



Attendees at the workshop

USP sponsored the third “Chinese Pharmacopoeia Commission International Workshop” at USP’s headquarters in the United States in September. Approximately 26 people from China’s State Food and Drug Administration (SFDA), the Chinese Pharmacopoeia Commission (ChP), and the Institutes for Drug Control from several Chinese provinces attended the four-day workshop.

USP’s goals at this third workshop were to promote USP internationally and to interact with its partners to share ideas that can help identify the most up-to-date issues. This workshop was about the mutual desire to collaborate and exchange ideas.

“I came to USP nine years ago,” said Ms. Ji Shen, director of the Traditional Chinese Medicine (TCM) Division at the Institute for Food and Drug Control of Shanghai. “China is developing so rapidly that the big gap between USP and China back then is a lot smaller now. There is more communication and collaboration. We can share and learn from each other.”



Wang Ping

Dong Runsheng

Mr. Dong Runsheng, director of the TCM Division for SFDA, Mr. Wang Ping, deputy secretary of ChP, and Ms. Ji gave presentations about TCM to USP staff. This workshop allowed USP to have face-to-face interactions to learn more

about TCM and share the different perspectives of the U.S. Department of Commerce, media, and the general public.

“Before coming to this workshop I knew there were misunderstandings between China and the United States, and between China and Europe. Now I realize that the propaganda is huge about what is going on in China, so I think this was a timely visit,” said Mr. Wang. “If we do not clear up misunderstandings when they are small, they can be big roadblocks for future cooperation.”

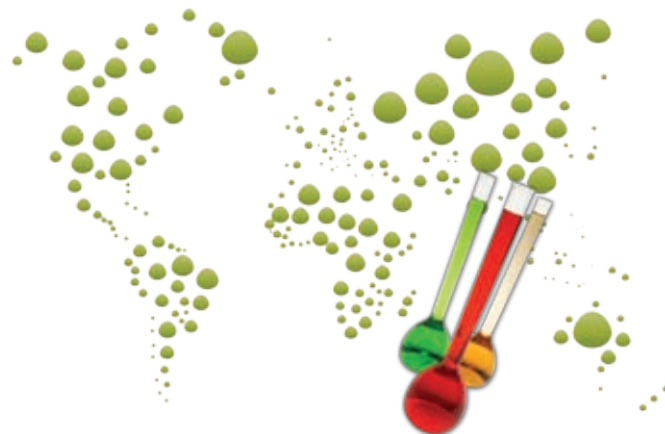
Mr. Wang’s final comment was that China and USP share a common goal—to promote the safety and quality of medicines—and sharing the same goal sets the foundation for collaboration. 📍

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may want special assurance that dietary supplements 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. 📍