

USP-CHINA

Quarterly Update



USP-ChP to Hold Joint Annual Scientific Meeting in November

From November 6 to 7, USP and the Chinese Pharmacopoeia Commission (ChP) will host the fourth joint USP-ChP Annual Scientific Meeting in Tianjin, China. The meeting will concentrate on scientific topics of shared interest to the United States and China, including Traditional Chinese Medicine (TCM) and dietary and herbal supplements. Sessions will focus on regulation of such products, quality control methods, and testing for metals and other impurities.

Expert representatives from academic institutions, government and regulatory agencies, and scientific organizations from around the world will present the different perspectives and approaches from their countries on these topics. Opening the meeting will be Mr. Shao Minli, commissioner of the State Food and Drug Administration (SFDA). Dr. Roger Williams, USP executive vice president and CEO, and Mr. Wu Zhen, secretary-general of the ChP and deputy commissioner of the SFDA, will follow with an update of cooperative activities between USP and ChP. The organizations signed a Memorandum of Understanding in March, agreeing to collaborate in the areas of standards setting, working relationships, translation of compendia, and third-party certification programs for pharmaceutical ingredients.

More specifically, sessions will look at:

Traditional Chinese Medicine — Officials from ChP and SFDA will discuss regulation of and standards-setting activities for TCM, as well as strategies to protect and promote TCM in China. Officials from



Mr. Wu Zhen of the SFDA and ChP speaks at a USP meeting in March. Mr. Wu will be one of the presenters at the USP-ChP ASM.

the U.S. drug regulatory agency—the Food and Drug Administration (FDA)—will discuss FDA's perspectives on regulating these traditional medicines as dietary supplements and as drugs. Other topics will include quality control of TCM and metal detection in TCM—from both Chinese and U.S. experts.

Worldwide Perspectives — The World Health Organization's (WHO) Dr. Sabine Kopp will discuss drug quality control requirements and WHO's Prequalification Program for manufacturers. Dr. Susanne Keitel, director of the European Directorate for the Quality of Medicines (EDQM), will discuss European perspectives on drug quality control. Updates on the British Pharmacopoeia and French Pharmacopoeia will also be provided.

For more information on this invitation-only conference, contact USP-China's Diana Zhang at dz@usp.org or (021) 5137-0600, ext. 8899.

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U.S. PHARMACOPEIA
The Standard of QualitySM



From the **CEO**

USP to 2010 and Beyond: Elevating Global Public Health through Quality Standards

by *John Mauger, Ph.D.*
Chair, USP Board of Trustees

John Mauger, Ph.D.

Regular readers of this newsletter know that this space is normally occupied by Dr. Roger Williams, USP's executive vice president and CEO. Dr. Williams invited me to speak to you directly through this issue's CEO Column as we head to the USP Convention meeting in April 2010—not so far away now. He also intends to ask Dr. René Bravo, president of the USP Convention, to speak to you via this column in a future issue. Dr. Williams signaled these opportunities to readers of his column in the April Edition of this newsletter, when he noted the remarkable governance structure of USP in which the activities of the Convention, Board, Council of Experts, and USP staff are allied in a common public health purpose and mission.



I look forward to continuing the important work of this cycle during the next 18 months as we help to ensure the quality of medicines and foods for people throughout the world—to 2010 and beyond.

John Mauger, Ph.D.



I'd like to first address the Board of Trustees' new strategic plan for USP. The plan has broad implications for the organization's future—both immediate (through the end of the 2005-2010 cycle) and longer-term (into the 2010-2015 cycle). It posits four main types of activities for USP: 1) core compendial, with a focus on expanding and enhancing documentary and reference standards for medicines and food ingredients; 2) allied compendial, focusing on building and strengthening programs related to standards setting such as education programs, verification programs, technical assistance in developing countries, and anti-counterfeiting programs; 3) non-compendial, which more directly involve practitioners and patients and include USP activities related to the use (rather than the creation) of standards such as medication error reporting programs; and 4) global initiatives, which speak to USP's commitment to operate both nationally and internationally to maximize the public health benefit resulting from its work.

The previous strategic plan was written during the 2005-2010 cycle and endorsed with minor modifications by the current Board of Trustees. Even though it is relatively recent in the context of USP's long and venerable history, USP has changed rapidly in the past few years—opening four international sites to operate globally rather than domestically, and adding new areas of standards set-

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From the **Vice President, International-China**

Global Activities Prevail for USP-China during Busy Quarter

by *John Hu, Ph.D.*
Vice President-International, China

John Hu, Ph.D.

I am pleased to share with you this latest edition of the *USP-China Quarterly Update*. As I write this column, I am concluding a busy period of travel that included a trip to the United States for the first USP Global Site Managers Meeting. I am now looking forward to some time back in China to host a group of domestic and international representatives for the upcoming USP-Chinese Pharmacopoeia Commission (ChP) Joint Pharmacopoeia Forum in Tianjin. I know this will prove to be a very valuable meeting and would like to begin this column by discussing it a bit.

As you may know, USP and ChP have jointly sponsored scientific meetings for the past three years to discuss issues of mutual interest related to the quality of medicines. This is one of a number of collaborative activities that USP and China engage in together. With the establishment of USP-China in 2007, this has evolved considerably and the fourth meeting in November will be a remarkable event focusing on scientific developments in the areas of Traditional Chinese Medicine and herbals and dietary supplements. As reported on the front page of this newsletter, the meeting will boast an impressive line-up of speakers. We are honored to have Mr. Shao Minli, commissioner of the State Food and Drug Administration (SFDA); Mr. Wu Zhen, deputy commissioner of the SFDA and secretary-general of the ChP; Mr. Zhou Fu Cheng, deputy secretary-general of ChP; Mr. Ji Shen, head of the TCM division for the Shanghai Institute for Food and Drug Control; and Mr. Wang Jun Zhi, deputy director general for the National Institute for the Control of Pharmaceutical and Biological Products, among other Chinese experts speaking at the meeting. Leading scientific authorities from the U.S. and around the world will also present. I want to encourage scientists, manufacturers, regulators, and others with whom we work in the region to attend this event. It is a wonderful opportunity to share our knowledge, expertise, and unique perspectives as we increasingly work together on standards setting.

On a related note, USP recently held its North American Annual Scientific Meeting (ASM) in Kansas City, which looked at the quality of manufactured medicines, food ingredients, and dietary supplements. Much of the focus was on impurities and adulterants—important topics given the globalization of the drug supply, and among those that will be discussed at the China meeting. You can find the presentations from the ASM on USP's Web site at www.usp.org. I will be providing you with updates via this newsletter as USP's work in these areas progresses.

As I mentioned, I recently attended USP's first Global Site Managers Meeting, an event that brought together the management at USP's headquarters with the leaders of USP's four international sites: Peter Bip-

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USP Expands Standards Acquisition Efforts

A Q&A with Vice President Shawn Dressman

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USP

In July 2008, USP's Shawn Dressman, Ph.D., was named vice president of standards acquisition, which is also a new department at USP. In this role, Dr. Dressman will lead the organization's efforts to acquire documentary standards that appear in USP compendia—including the *USP-NF*, *Food Chemicals Codex*, and *Pharmacists' Pharmacopeia*—and their allied reference materials. Dr. Dressman joined USP in 1999, and has held positions in both the documentary standards and reference materials areas. In the following Q&A, Dr. Dressman explains the goals of the new department, how USP will reach these goals, and why standards acquisition is so important to USP.

Q: What is your main goal right now?

A: The main goal right now is to build scalable processes internally to support an expected increase in monograph and reference materials development activities. With that, the plan is for some additional hiring in Standards Acquisition and I am working on finding the right people to join this important endeavor. We will bring on the new staff throughout the course of this year.

Q: What are your long-term goals?

A: Public standards facilitate the flow of quality articles of commerce, and USP aims to have a public standard available for every article of commerce in the pharmaceuticals and food ingredients marketplace. Our current estimate is that, while we have about 5,000 such public standards, there are about 4,000 missing standards to develop. I hope to advance a mechanism at USP for prioritizing these 4,000 projects in terms of public health impact, and to increase the volume of new monographs and reference materials submitted to USP

by our stakeholders. At our current rate of acquisition, it would take over 20 years for USP to establish standards for what is currently missing. My goal is to significantly shorten that timeframe.

We want to reach out to as many interested and qualified parties as possible to partner with us in attaining this goal. Historically, we've had great support from U.S.-based manufacturers and we certainly want that to continue. Additionally, we recognize the rapid globalization of these industries, and aim to reach out to manufacturers, compendial bodies, and other regulatory agencies throughout the world. Our sites in Switzerland, China, India, and Brazil will provide a great platform for making this happen.

Q: What are you doing right now to advance these efforts?

A: We are building the processes within USP to address the expected expansion of the monograph development and reference materials. We are also establishing a donor recognition program to acknowledge the valued contributions we receive.

Q: What are you most excited about in this job?

A: From my past experience at USP in monograph development and reference standards development, I appreciate the commitment it takes to provide a monograph or reference material to USP. I am excited to work with people who share with me an understanding of the inherent value of public standards and I look forward to conveying this understanding to others who are less familiar. 🧪

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ting such as those for food ingredients via the *Food Chemicals Codex*. These changes warranted a new plan that better reflected USP's current work. What has not changed over the 188 years of USP's existence, however, is USP's core focus: setting public standards. The new strategic plan reaffirms this as USP's top priority.

I would like to discuss the importance of public standards. USP was created to provide standard recipes for the preparation of medicines by practitioners. These recipes were presented in the *United States Pharmacopeia (USP)*—first published in 1820, and now advancing into its 32nd presentation. Beyond *USP*, USP now publishes the *National Formulary (NF)* for excipients; a section in *USP* on dietary supplements; the *Food Chemicals Codex (FCC)* for food ingredients; and the *Pharmacists' Pharmacopeia* for compounded preparations and their ingredients. Creating and maintaining public documentary standards, as provided in these compendia, together with allied reference materials, is not easy. Let me be blunt—it can be arduous, challenging, and never-ending. I would like to use heparin as an example.

In late 2007 and early 2008, the U.S. Centers for Disease Control and Prevention (CDC) and the U.S. Food and Drug Administration (FDA) began receiving reports of adverse reactions, including deaths, of some patients who were administered heparin. Based on some brilliant detective work—and working with experts in the United States

and elsewhere—FDA quickly determined that over-sulfated chondroitin sulfate, used as a low-cost commercial diluent, was the culprit. In accordance with provisions of U.S. law—laid down by experts from both the U.S. government and USP experts a century ago—FDA requested that USP update its public monographs for heparin. This the USP's Council of Experts did, working rapidly both nationally and internationally. This is a good example of the value of the partnership between FDA and USP created by U.S. Congress early in the 20th century. By creating a sound public standard that affects all manufacturers equally, USP provides FDA an effective enforcement tool that works against commercial and other types of adulteration that can cause—and in the case of heparin, did cause—great harm to the public health.

But what does this episode say about public standards? USP's heparin standards were outdated and updating such standards is not easy. Also, USP's public standards reflect in one way or another the private regulatory standards that exist at FDA, and these standards are also difficult to maintain and update. The true lesson of heparin may thus be that standards do become out of date and thus weaken the safety nets that protect us all. Ingredients and products get more complex and sophisticated, as do analytical procedures and manufacturing requirements. Regulatory agencies and pharmacopeias are hard-pressed to keep up in their standards-setting activities, and resources to

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upcoming events

ADVANCED DISSOLUTION

October 27 to 28, 2008
Shanghai, China

WORKSHOP: CURRENT REGULATIONS ON DIETARY SUPPLEMENTS, BOTANICALS, AND FUNCTIONAL FOOD INGREDIENTS IN THE U.S. AND USP'S INITIATIVES

November 10 to 11, 2008
Guangzhou, China

EFFECTIVELY USING THE USP-NF/ VALIDATION OF COMPENDIAL PROCEDURES/NAVIGATING CHAPTER <467> Residual Solvents

October 29 to 30, 2008
Shanghai, China

CGMP: A QUALITY SYSTEMS APPROACH FOR APIS

December 9, 2008
Shanghai, China

For more information about these courses and to register, please visit the Chinese homepage of www.usp.org.

PRACTICAL APPLICATIONS OF USP <1010> AND RELATED STATISTICAL TESTS

November 4 to 5, 2008
Shanghai, China

ESSENTIALS OF MICROBIOLOGICAL TESTING

December 17 to 18, 2008
Hangzhou, China

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pus (Europe), K.V. Surendra Nath, Ph.D. (India), Flavio Vormittag, Ph.D. (Brazil), and me. As USP develops its international facilities, the meeting served to integrate site activities to ensure that the organization's standard of quality is conveyed consistently throughout the world. USP's leaders also reaffirmed their commitment to understanding the unique needs of each host country and its citizens as the sites evolve. As part of this effort, I was happy to join Peter, Surendra Nath, and Flavio as panelists in an International Culture Awareness Workshop sponsored by USP's Human Resources department in which we discussed the issue of cross-culture communications and shared our observations of what it is like to work at a USP international facility. A large turnout of USP's headquarters' staff attended to hear our thoughts and learn more about how to work best with citizens of our of respective countries.

One of the other key takeaways from the meeting was the importance of forming relationships with regulatory bodies and the pharmaceutical and food industries in the countries where USP works through Memoranda of Understanding (MOUs) and similar partnership vehicles—both to learn from the host country and to exchange expertise. Dr. Roger Williams, USP's executive vice president and CEO, emphasized this key point. USP has already signed MOUs in China with the ChP and the National Institute for the Control of Pharmaceutical and Biological Products.

Finally, I'd like to refer you to the Q&A on page 3 of this newsletter with the head of the new Standards Acquisition department at USP. While you can read about USP's purpose and goals for this department in the story, I want to note that this initiative has particular relevance in China, where USP hopes to collaborate more closely with manufacturers of Active Pharmaceutical Ingredients (APIs). As China is a leading world producer of APIs, there is great opportunity for manufacturers and USP to work together to improve the health of people around the world by creating public standards that help ensure the quality of medicines and foods.

As always, please feel free to contact me with any questions or comments at jh@usp.org.

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support applied regulatory and compendial research are increasingly hard to come by.

In this context, I remind readers that USP relies extensively on donations—donations of information and candidate material from sophisticated and skilled pharmaceutical manufacturers, and donations of extraordinary amounts of time from volunteers on the Council of Experts—both the Expert Committees and their Advisory Panels. And I sincerely thank all these donors for their time, energy, skills, and commitment to public standards.

Yet challenges always remain despite these considerable commitments and contributions. USP is missing hundreds of public monographs and many more need updating. Further, USP's new strategic plan emphasizes that USP is a science-based, standards-setting body, and good science takes time and resources. A case in point is USP's intent to advance many of its reference materials to the status of Certified Reference Materials. This will take a transformation in the way USP obtains, studies, and presents a collection of materials that now approaches 2,500 in number. And these thoughts are not new. As noted in the first USP of 1820, "The value of a pharmacopeia depends upon the fidelity with which it conforms to the best state of medical knowledge of the day."

I don't want to close this column by speaking only of our challenges. While setting standards isn't easy, it is always invigorating and stimulating. We must work together to take into account the exciting new science that is approaching us from many directions and to transform this science into meaningful and valid standards for drugs and foods that are useful to the global community. This is what USP has always been about, and what it will be about as it advances into the future. My compatriots on the Board of Trustees and I know that our moment in time at USP is coming to an end. In April 2010, Dr. Bravo will lead the USP Convention as it selects a new Board and conducts other key governance activities of the organization. I look forward to continuing the important work of this cycle during the next 18 months as we help to ensure the quality of medicines and foods for people throughout the world—to 2010 and beyond.