



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

USP-India Looks Forward to ASM, Hosts USP Headquarters Staff in Hyderabad



K.V. Surendra Nath, Ph.D.

I am pleased to share with you the latest edition of the *USP-India Quarterly Update*. In this column, I will share recent developments as well as upcoming events and activities for the USP-India facility.

I'd like to begin with the USP-Indian Pharmacopoeia Commission (IPC) 8th Joint Annual Scientific Meeting (ASM)—a meeting that we are currently in the thick of planning. The meeting will be held February 11–12, 2009, in Hyderabad, and will include a number of different tracks (Drug Substances; Reference Standards; Drug Product Manufacturing and Control; Biologics and Biotechnology, plus special tracks on Metal Impurities and New Compendial Approaches). I will be providing more details on the specific sessions and speakers as they become available, but I wanted to make readers aware of the meeting—which we are very pleased to be partnering with the IPC on once again. It is always a truly remarkable and collaborative event focused on the latest advances and most pressing issues in pharmaceutical science and standards setting. I invite you to check USP's Web site in the coming months for the latest updates on this event.

On the subject of meetings, I recently had the pleasure of hosting two of USP's U.S.-based experts, Dr. Todd Cecil,

vice president of compendial sciences, and Dr. Shawn Dressman, vice president of standards acquisition, for two different meetings held here in India. Dr. Cecil was in Hyderabad in September for the Pharmaceuticals Export Promotion Council's (Pharmexcil) 4th Annual General Body

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Drs. Surendra Nath and Dressman at the USP-India laboratory in September.



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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.

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 next USP Convention meeting (held every five years) 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.

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). The new strategic plan—which was formally unveiled at the North American Annual Scientific Meeting in September—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; 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 setting 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,

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Meeting, where he delivered a lecture on “Quality by Design.” Dr. Cecil explained that Quality by Design (QbD) is a U.S. Food and Drug Administration (FDA) approach that says quality should be built into a product, and end testing alone cannot be relied on to ensure product quality. For pharmaceuticals, this means designing and developing formulation and manufacturing processes to ensure predefined quality by understanding how formulation and manufacturing process variables influence the quality of a drug product. This QbD approach is intended to reduce recalls of products as well as FDA oversight, which are costly, time consuming, and problematic in a variety of other ways. QbD will affect all manufacturers of drug products sold in the United States in the future as details on its global implementation are worked out—with both opportunities and challenges for the industry. I will be sharing more on this important topic in future newsletters and in my outreach to companies and regulators in India.



Following the Pharmecil meeting, Dr. Cecil joined Dr. Dressman, USP-India staff, and representatives from India's pharmaceutical industry and the IPC for a meeting of USP's Indian Monographs and Reference Standards Advisory Panel—a subset of USP's International Health and Reference Standards Expert Committees. The goals of the meeting were to review the status of monograph sponsorship and reference material provisions by Indian pharmaceutical companies; to promote participation in USP general chapter development; and to identify topics of interest and im-

portance for the USP-IPC ASM.

During the meeting, Dr. Dressman provided the group with background on USP's new department for Standards Acquisition (more about this department and its goals in the Q&A with Dr. Dressman on page 3 of this newsletter), and noted that USP sees India as a crucial partner in its effort to acquire missing monographs. He also offered more detail on USP's Pending and Non-U.S. monograph approaches—both relatively new initiatives and both attempts by USP to remove barriers to the creation of standards in the interest of public health. The Pending approach allows manufacturers to submit information supporting a monograph before the U.S. FDA grants full approval to the manufacturer, reducing the amount of time that a manufacturer's product is available in the United States without a corresponding USP standard. The Non-U.S. approach offers a vehicle for standards for medicines approved outside the United States for the treatment of infectious, neglected diseases. USP will be working closely with members of the Indian Monographs and Reference Standards Advisory Panel to acquire monograph and reference material donations for Non-U.S. standards in the coming months and years—and will meet with the panel again in February to discuss progress. On the topic of General Chapters, Dr. Cecil provided an update

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USP Expands Standards Acquisition Efforts

A Q&A with Vice President Shawn Dressman

inside
USP

In July 2008, USP's Shawn Dressman, Ph.D., was named vice president of standards acquisition, which is 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.

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 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. 📍

USP Holds First Global Site Managers Meeting

This past July, USP held its first Global Site Managers Meeting, a week-long event that brought together the management staff at USP's headquarters with the leaders of USP's four international sites: Peter Bippus (Europe), John Hu, Ph.D. (China), K.V. Surendra Nath, Ph.D. (India), and Flavio Vormittag, Ph.D. (Brazil). As USP looks to grow its international sites and opens its newest site in Brazil, the meeting served to integrate all USP sites and their activities to ensure that the organization's standard of quality is carried throughout the world.

"USP has expanded globally in a short period of time—just a few years—with the four new international sites being established since 2005," noted John Fowler, USP's chief global services officer. "As we develop throughout the world, it is important for us to understand the unique challenges of each site and the needs of each host country and its citizens; share lessons learned and best practices as our sites open and progress; and make certain that USP's superior standards are upheld in the areas of documentary and reference standards, pharmacopeial education programs, verification programs, drug quality assistance programs, and other initiatives. This meeting was an excellent forum for accomplishing these goals as we work towards our ulti-

mate mission of improving the health of people throughout the world through public standards that help ensure the quality, safety, and benefit of medicines and foods."

One of the key points emphasized during 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 (MOU) and similar partnership vehicles. Roger Williams, M.D., USP's executive vice president and CEO, noted that this is an essential part of the process of establishing and maintaining international sites—to both learn from the host country and exchange expertise. USP has already signed MOUs with a number of groups, including the Indian Pharmacopoeia Commission, Chinese Pharmacopoeial Commission, National Institute for the Control of Pharmaceutical and Biological Products in China, and Febrapharma in Brazil.

While at USP, the four site leaders also participated in a Global Awareness Panel designed to raise awareness of potential cultural and language barriers in each region—and how USP employees can work through them effectively. Similar meetings are being planned for the future. Look to future issues of this newsletter for more information. 📍

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 Council of Experts (USP’s scientific decision-making body) did, working rapidly both nationally and internationally. This is a good example of the value of the partnership between FDA and USP created by the 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 support applied regulatory and compendial research are increasingly hard to come by.

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I look forward to continuing the important work of this cycle during the next 15 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.

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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 15 months as we help to ensure the quality of medicines and foods for people throughout the world—to 2010 and beyond. 🏠

on improvements to various chapters, including those on residual solvents, metal impurities, and chromatography, and encouraged attendees to stay involved in this activity.

Obviously, there was much more covered at these meetings than I can discuss here in this brief column. I welcome you to contact me with questions or comments on the USP-IPC ASM or the standards activities described in this column at kvs@usp.org. As mentioned earlier, I will be providing the latest updates on all of these important topics in subsequent issues of this newsletter.

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USP-IPC 8th
ASM2009
ANNUAL SCIENTIFIC MEETING

PUBLIC DISCOURSE - QUALITY STANDARDS

FEBRUARY 11-12
Hyderabad, India
Hotel Taj Krishna

www.usp.org/meetings/asMeeting