



## USP-IPC Hold Seventh Annual Scientific Meeting in India

The seventh joint Annual Scientific Meeting of the Indian Pharmacopoeia Commission (IPC) and USP was held at the Hyderabad International Convention Centre from February 6 to 7, 2008. The theme of the meeting was "Quality of Manufactured Medicines: APIs, Dosage Forms, Biologics and Biotechnology, and Special Topics." Representatives from the Indian government, the Government of the State of Andhra Pradesh, the Indian Pharmacopoeia Commission, the National Institute of Pharmaceutical Education and Research (NIPER) Hyderabad, pharmaceutical and food manufacturers, and various stakeholder organizations attended the meeting. In all, nearly 350 participants from more than 70 companies and organizations were present. Additionally, 14 exhibitors and 17 poster presenters were featured at the event.

The group of esteemed speakers at this year's meeting included honored guest J. Hari Narayan, Chief Secretary to the Government of Andhra Pradesh; A. Krishna Dev, Assistant Drug Controller General

India; Dr. Raman M. Singh, Director of Research and Development, Indian Pharmacopoeia Commission; Dr. Prakash Diwan, Project Director, NIPER, Hyderabad; Dr. Ellen Cosgrove, USP Board of Trustees Member; Dr. Darrell Abernethy, USP Chief Science Officer; and Dr. William Koch, USP Chief Reference Materials Officer, among others.

Opening remarks were made by Narayan, Singh, Diwan, Cosgrove and Abernethy. In his remarks, Narayan said that the Government of Andhra Pradesh (AP) is initiating three new major health care reforms: a new direct-dial emergency care number, "108," which will enable AP citizens to access lifesaving emergency responders; a new mobile health care unit to provide medical care; and affordable health insurance for AP's needy residents. In their remarks, Drs. Cosgrove and Abernethy offered overviews of USP's Board of Trustees and USP, respectively. Additionally, Kumud Sampath, Vice President, International-India, gave attendees a summary of USP-India as well as a report on the IPC-USP Memo-

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USP-India's Kumud Sampath presents a memento to J. Hari Narayan, Chief Secretary to the Government of AP.



Dr. Raman M. Singh of the IPC presents the latest Indian Pharmacopoeia to USP's William Koch, Darrell Abernethy, and Angela Long.



From left to right: Sampath; Dr. Prakash Diwan, NIPER, Hyderabad; Dr. Ellen Cosgrove, USP Board of Trustees; Abernethy; J. Hari Narayan, Government of AP; A. Krishna Dev, Assistant DCGI; Dr. Raman M. Singh, IPC.



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Kumud Sampath

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

## India Annual Scientific Meeting Concludes, Outreach on Verification Activities Progresses

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 developments at the USP-India facility, as well as information about USP headquarters' initiatives related to USP-India. Since my last column, USP-India has seen some exciting activity, including the India Annual Scientific Meeting and much progress on outreach in the region on USP's verification programs, which is one of USP-India's key areas.

I am happy to report that the seventh USP-India Pharmacopoeia Commission (IPC) Annual Scientific Meeting was a great success. As noted on the front page of this newsletter, more than 350 people participated, and we were honored with the involvement of a number of highly regarded Indian guests, including J. Hari Narayan, Chief Secretary to the Government of Andhra Pradesh. The India Annual Scientific Meeting is extremely important to USP, as evidenced by the attendance of high-level USP participants including Board of Trustees Member Dr. Ellen Cosgrove. The meeting is the organization's way of providing a forum for interactive discussion by a cross section of experts. It also allows the pharmaceutical industry to provide direct feedback to USP, which is very valuable to us. USP



Sampath and Cosgrove at the ASM

is grateful for the support of the Indian pharmaceutical industry and trade organizations in making this meeting possible. We also appreciate our continued collaboration of the IPC on this meeting as well as other shared activities. As indicated, you can find more details and most of the presentations from the meeting at [www.usp.org/meetings/asMeetingIndia](http://www.usp.org/meetings/asMeetingIndia).

Prior to the Annual Scientific Meeting, the USP India Advisory Group, USP India Stakeholder Forum, and three USP Advisory Panels (Monographs and Reference Materials; Dietary Supplements — Botanicals; and Biologics and Biotechnology — Proteins and Polysaccharides) met. The advisory group meeting included discussion of USP-IPC joint working group activities, while the stakeholder forum focused on hot topics in the Indian manufacturing community and updates on USP's Council of Experts 2010-2015 workplan and nominations for Council membership. Each of the advisory panels focused on items of immediate interest in their respective areas, as well as next steps.

On a different note, I recently had two wonderful opportunities to speak at major industry events in India. In February, I represented USP-India at the 4th Nutraceuticals Summit in Mumbai. The meeting focused on key trends

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Roger Williams, M.D.

From the **CEO**

## Moving USP Forward: A Plan for the Future

First some numbers: my opportunity to speak to the USP community through this column will arise 18 times in the 2005-2010 cycle. I have already taken the opportunity nine times, speaking in a somewhat *ad hoc* way on a diverse group of subjects. My hope is to be a bit more deliberate with the remaining nine opportunities as we head towards the cycle's conclusion, focusing on a series of topics that are core to USP. In this column, I would like to talk about Convention and Board governance, which provide direction to the organization as it moves ahead. I used a word the other day — leapfrogging — which perhaps isn't all that accurate and certainly isn't elegant, but it speaks to an aspect of USP governance that has great meaning and impact. The Convention and the Board of Trustees alternate (leapfrog) governance responsibilities in a beautifully orchestrated series of interlocking events and actions that carry the organization into the future. The Convention membership meets every five years (previously it was ten), elects a Board of Trustees and Council of Experts, and concludes Resolutions that guide the organization

over the ensuing five years. The Board then takes office and is given stewardship of USP for the cycle, assuming responsibility for USP's strategic direction and providing fiduciary oversight for its activities, while remaining ultimately accountable to the Convention.

USP always has had remarkable volunteers serving as Convention delegates, Council of Experts members, and on its Board of Trustees — hard-working, busy professionals who give greatly of their time to lead the organization. This cycle surely is no exception, and a specific manifestation of the current Board of Trustees' commitment is its new strategic plan, now in draft and expected to be finalized shortly. The existing strategic plan was created by the previous Board in the 2000-2005 cycle, and was updated by the current Board just after the start of this cycle. In 2007, the Board agreed to create a new plan, reflective of USP's changing opportunities and obligations, to chart the organization's course through the rest of this

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# USP Releases New Edition of the *Food Chemicals Codex*

On February 29, USP released the Sixth Edition of the *Food Chemicals Codex (FCC)* — the first edition published under USP's direction since it acquired the compendium from the Institute of Medicine in 2006.

Under the guidance of USP's Food Ingredients Expert Committee, chaired by Andrew Ebert, Ph.D., USP staff updated and expanded the compendium, adding new monographs and general tests and redesigning all monographs for easier use. In all, the new edition contains more than 1,000 monographs for food ingredients, such as colorings, flavorings, nutrients, preservatives, and processing aids. The compendium is used by manufacturers of food, food chemicals, and food ingredients as well as regulatory agencies to assure the identity, quality, and purity of these ingredients.

"The *Food Chemicals Codex* is an important addition to USP's core body of work in setting standards. It supports our continuing pursuit and advancement of the public health — a mission we have worked towards for almost 200 years with pharmaceuticals, and now with foods," said Darrell Abernethy, M.D., Ph.D., USP's chief science officer.

In addition to a redesigned format and revised monographs and tests, one of the major changes that USP has made since acquiring the *FCC* is implementing a review process similar to the one it uses for the *USP-NF*. As was done with this edition, public comments for future editions will be received through the online *FCC Forum* ([www.usp.org/fcc/forum](http://www.usp.org/fcc/forum)). USP is also putting publication of the *FCC* on a regular schedule, with the release of a new edition every two years and a supplement between editions.


The *FCC* had been published by the Institute of Medicine since 1966. It is recognized in law in Australia, Canada, and New Zealand, and is used widely by food ingredient manufacturers and suppliers in the United States and around the world. More information about the *FCC* can be found at [www.usp.org/fcc](http://www.usp.org/fcc). 

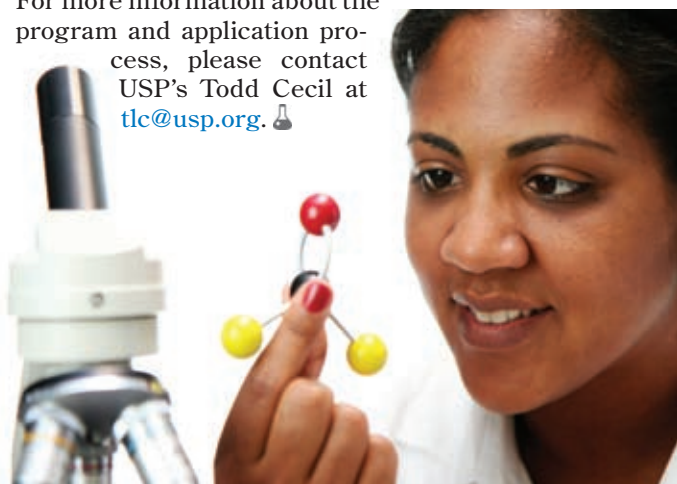
Members of the Food Ingredients Expert Committee and USP's Darrell Abernethy celebrate the release of the *FCC*.



## USP Seeks Applicants for Visiting Scientist Program


USP is accepting applications for its Visiting Scientist Program, an international program designed to advance the development of scientists committed to pharmaceutical work and foster international recognition of USP standards. Scientists from all over the world will come to USP's Rockville, Md., headquarters to learn more about pharmaceutical analysis relevant to the establishment and adoption of public standards for drugs and devices. USP will also train visiting scientists to better understand the process by which public, legally recognized standards are established in the United States and around the world. Participants will represent pharmaceutical or official control laboratory organizations from other nations, and will deliver a formal written report of their experience upon completion of the 8 to 16 week program. For more information about the program and application process, please contact

USP's Todd Cecil at [tlc@usp.org](mailto:tlc@usp.org). 



## Dr. Reddy's Certification of Four APIs

USP recently completed verification of two drug substances that Dr. Reddy's Laboratories, Ltd. submitted to USP's Pharmaceutical Ingredient Verification Program. The two verified ingredients are Clopidogrel Bisulfate and Olanzapine. Dr. Reddy's lab now has four verified drug substances that have passed the requirements of the program; the previous two drug substances are Ramipril and Finasteride.

In order to display the USP Verified Mark on a product, an ingredient must pass all USP verification requirements, including a Good Manufacturing Practices (GMP) audit, thorough documentation review, and testing for purity and potency. The USP Verified Mark can be used on each container of verified ingredients, as well as an accompanying Certificate of Analysis, demonstrating the quality and integrity of the product. USP Verified ingredients are also issued a USP Certificate of Standards Compliance — currently the highest quality and most comprehensive verification on the market. 



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in nutraceuticals and foods. I talked about USP's Dietary Supplement Verification Program to an audience including representatives from the dietary supplements, supplement ingredients, and extracts industries, as well as health care practitioners and policy makers. A number of manufacturers expressed interest in the program, and USP will be following up with these contacts.

I also participated in a one-day seminar organized by Satyam Infotech, one of the top three information technology companies in India. The company has a business unit focusing solely on pharmaceutical clients. In the session, "Smarter Ways in the Value Chain," I discussed USP in general and our Pharmaceutical Ingredient Verification Program. About 350 people attended the seminar, with most of them coming from the pharmaceutical industry. This was a good opportunity to educate the industry about USP and our verification activities.

Finally, Dr. Srinivivasan, USP's Vice President of Verification Programs, was recently in India, and he and I visited several companies in Delhi, Mumbai, and Hyderabad to discuss USP's verification programs and the benefits they could provide to companies. These efforts are all part of our goal of making manufacturers aware of such programs, as well as the vital function that they serve for companies. While we still have a lot of work to do, I feel that these meetings — along with various speaking engagements — have allowed us to make some headway in spreading the word.

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](mailto:kxs@usp.org). 📧

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cycle and into the next. This new strategic plan will set the stage for the Convention delegates to carry on the governance cycle through election of a new Board and Council of Experts and adoption of new Resolutions at the next Convention meeting, scheduled for April 2010 in Washington, D.C. It is a remarkable set of complementary and interwoven governance processes that allow continuing evolution in a rapidly changing health care environment.

It has been a privilege for me to participate in the extraordinary discussions of the current Board of Trustees on its draft new strategic plan, and I am honored to have had input into this plan both as chair of the Council of Experts and CEO of the organization. I might say that these two roles provide critical input in the governance of the organization, allowing USP's standards-setting body and its staff to speak to the Board and Convention on their respective interests and opportunities.

I would now like to use another inelegant term: buckets. The draft strategic plan speaks to three primary buckets of activities: compendial activities, allied compendial activities, and non-compendial activities. The compendial activities are the public documentary standards with reference materials for food and drugs that make up most of what USP does and are at the center of USP's public health mission. Allied compendial activities generally support and promote the use of public standards to improve product quality worldwide. And non-compendial activities usually refer to opportunities that relate to health care quality and information and more directly serve practitioners and patients. As USP moves into the final years of this cycle, we need to strengthen communications among the Convention, Board, Council, and staff so that these groups come together in 2010 united in purpose, devoted to public standards and allied reference materials, and supportive of new ways to serve the public nationally and internationally.

Okay, eight more to go, and I have the idea that I might share this 'pulpit' with other USP leaders as the cycle comes to a close. 📧

## upcoming courses/ events

### ESSENTIALS OF COMPENDIAL MICROBIOLOGY

May 5 to 6, 2008  
Hyderabad, India

### ESSENTIALS OF COMPENDIAL MICROBIOLOGY

May 8 to 9, 2008  
Mumbai, India

### USP CUSTOMER DAY

May 15, 2008  
Visakhapatnam, India

For more information and registration for USP-India events, please email [gm@usp.org](mailto:gm@usp.org)

### REGISTER TODAY

### USP ANNUAL SCIENTIFIC MEETING

Public Discourse — Quality Standards  
September 24 to 26, 2008  
Kansas City, Mo., USA  
More information and registration at  
[www.usp.org/goto/asm](http://www.usp.org/goto/asm), or email  
[conferences@usp.org](mailto:conferences@usp.org)

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randum of Understanding at the start of the meeting.

Also during the opening session, USP presented its concept for the expansion of its facility in India, which will consist in its first phase of a 40,000 square foot office and laboratory in ICICI Knowledge Park. This is expected to open in 2009.

Each of the four meeting tracks featured different sessions on a variety of relevant topics, presented by USP and other scientific experts. More information on specific sessions as well as speaker presentations are available on the USP Web site at [www.usp.org/meetings/asMeetingIndia](http://www.usp.org/meetings/asMeetingIndia).

The meeting closed with USP and the IPC identifying next steps for continued progress. 📧