

USP Press

News and Information about the United States Pharmacopeia

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USP U.S. PHARMACOPEIA
 The Standard of QualitySM

Spring Governance Meeting Brings USP Members, Volunteers, and Staff Together

ON MARCH 29–30, 2006, USP held its annual Spring Governance Meeting, bringing together USP's staff and primary governing, scientific decision-making, and advisory bodies. Individuals from the Board of Trustees, Council of the Convention, Council of Experts, and USP staff convened in Jackson Hole, Wyoming, to discuss where USP is today and opportunities and challenges for the future.


The interactions among individuals in these various groups provided an opportunity for USP's members, volunteers, and staff to learn more about the critical issues that their peer groups are facing and to better understand how the work across all of these bodies is managed and integrated. Throughout the meeting, the participants discussed matters of science, clinical drug information, governance, grand challenges for the organization, and more.

In addition, the Spring Governance Meeting resulted in several significant changes to the processes USP uses to develop public monographs and reference



Individuals from the Board of Trustees, Council of the Convention, Council of Experts, and USP staff gather at the 2006 Spring Governance Meeting.

standards that help ensure the consistency and quality of drugs worldwide. The changes are designed to allow more timely development of public standards while strengthening the credibility of USP's standards-setting activities and responding to the needs of stakeholders.

For more information about the rule changes, please see "USP Revising Rules for 2005–2010 Cycle" and visit www.usp.org/USPNF/notices. 

USP Revises Rules for 2005–2010 Cycle

IN APRIL 2005, USP'S COUNCIL OF EXPERTS PROVISIONALLY ADOPTED RULES AND procedures for the 2005–2010 cycle. The changes were designed to allow more timely development of public standards while strengthening the credibility of USP's standards-setting activities and responding to the needs of stakeholders. After nearly a year of considering comments from members and stakeholders, the Council has published the revised rules, which are expected to take effect on September 1, 2006:

- Reinforce the ability of an Expert Committee to finalize and approve revisions to USP-NF without the need to republish the proposed revisions in *Pharmacopeial Forum* (PF);

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Upcoming USP Meetings

USP Annual Scientific Meeting

Tuesday–Friday

September 26–29, 2006

Marriott Denver City Center

Denver, Colorado

The USP Annual Scientific Meeting 2006 is your opportunity to interact with USP's scientific staff and Council of Experts. Learn what changes are being implemented and how they will impact you and your organization. Engage in discussions that will help establish standards-setting priorities for USP and help shape the quality requirements for therapeutic products.

This year's Annual Scientific Meeting will feature:

- TRACK I Biologics and Biotechnology
- TRACK II Excipients
- TRACK III Dietary Supplements
- TRACK IV Impurities in Drug Substances and Products
- TRACK V Making USP Work for You
- TRACK VI Reference Standards
- TRACK VII Chromatography
- Special Topic: International Quality and Performance

Back for 2006!

Expanded Exhibitor Program

Exhibitor booths will be sold on a first-come, first-served basis! Spaces are limited and going fast.

Contact Information

Call USP at (301) 881-8134 or email conferences@usp.org for full details and to reserve your space.

Spouse/Guest Program

Given the success of the 2005 Program, we've planned an expanded array of sight-seeing and social opportunities in Denver. Visit us online at <https://secure.usp.org/eventsEducation/asMeeting/regGuest.html> to read more.

European Stakeholder Forum

Tuesday–Wednesday

December 12–13, 2006 (Tentative)

Hilton Hotel

Basel, Switzerland

Message from the CEO



The Future Belongs to Those Who Plan for It

USP HAS JUST COMPLETED

a highly successful FY 06 and created, based on decisions from the USP Board of Trustees, a budget for FY

07. Staff members have also begun work with the Board to begin planning and budgeting for FY 08. This “cycle of life” is key to USP's success, and the close involvement and oversight from the Board of Trustees is the foundation of our achievements. Because USP is a volunteer-based organization with myriad new activities, it is worth emphasizing now and in future columns the remarkable commitment of the USP Board—11 officers and trustees who give greatly to USP in the midst of busy lives. They convene for days of intensive meetings four times a year, sometimes in the midst of other busy USP meetings, including the Annual Scientific and the Spring Governance meetings. In addition to this commitment, there are numerous telephone calls, committee meetings, and reams of background material—all of which must be absorbed, considered, discussed, and evolved in the best way possible. Although it is impossible for USP to ever fully recognize the contributions of the USP Board of Trustees, and those of prior Boards stretching back more than 100 years, it is surely worth emphasizing them occasionally and expressing sincere appreciation from staff, volunteers, and the community at large. Surely this is voluntarism at its finest!

USP's Board—with staff and volunteers—focuses on public health activities that I sometimes term “core” and “noncore.” Both are critical to the organization, but the former is much larger and claims more attention. The core activities refer to the continuous revision of the *United States Pharmacopeia* and *National Formulary (USP-NF)* and the development of official USP Reference Standards. And associated with these important public health documents are allied activities that include related publications and line extensions (e.g., *Pharmacopeial Forum*, the *USP Pharmacists' Pharmacopeia* and the *USP-NF Spanish Edition*), USP's verification programs (a combination of review and audit, resembling regulatory functions for articles where regulatory oversight may be constrained), and pharmacopeial education.

USP is actively working to bring these core activities to pharmaceutical manufacturers, compounding professionals, and regulatory bodies throughout the world. Despite some challenges to the concept of public standards, I am proud to be associated with this remarkable effort, which has many aspects and ramifications nationally and internationally. The concept of public standards for the public trust is as important today as it was in 1820. And there is a strong metrologic science base to USP's documentary and physical standards. USP's approaches allow testing laboratories—first parties (e.g., manufacturers), second parties (e.g., purchasers), and third parties (e.g., government)—to be assured that they get the same results without regard to space and time. Through application of sound science, test results for an article should be the same, with due regard for sources of variance, both within and between laboratories. USP works hard to make this happen and is part of a compendial network in which USP is proud to participate. In fact, USP is the only compendia in the world to do this for therapeutic products, as far as I can tell. Manufacturers and regulatory agencies tend to work toward private agreements that, regardless of how sophisticated the analytical methods and how careful the validation is, do not directly address the issue of cross-laboratory comparisons.

In terms of USP's compendia, the work plan for the Council of Experts will be published shortly and has been given to the Board of Trustees. Of course this work plan is always evolving based on strong input from volunteers from around the world by their involvement in the revision process. When the citation for the work plan is available, I will be sure to share it with readers of this column and to discuss it in more depth because it represents the extraordinary work of USP's other major group of volunteers, those who give so generously of their time on the Council of Experts.

Beyond core activities, USP is working to evolve its noncore activities. These opportunities relate to what I term quality of care (good pharmaceutical care) efforts that speak directly to practitioners and patients. My view is that these USP activities need to be nurtured and grown, in accordance

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USP Science

USP, FDA Office of Regulatory Affairs to Begin Collaborative Testing

THIS SPRING, USP ENTERED INTO A Cooperative Research and Development Agreement (CRADA) with FDA's Office of Regulatory Affairs (ORA) laboratories.

This CRADA will facilitate collaboration with ORA laboratories in the evaluation of candidate physical reference standards and will allow USP to strengthen its partnership with FDA.

FDA has historically participated in USP's collaborative reference standards-setting process and is referenced in USP General

Chapter *Reference Standards* <11>. The Center for Drug Evaluation and Research (CDER), Office of Pharmaceutical Science laboratories has performed this function for many years. However, due to internal changes in priorities, the CDER laboratories were unable to continue the agreement.

USP approached and ultimately selected the ORA laboratories based on their expertise in drug analysis and willingness to participate in USP's collaborative testing program. Data from the ORA laboratories will

be examined along with data from USP's Reference Standards Laboratory and other collaborating laboratories. A summary of these data will be presented to USP's volunteer Reference Standards Expert Committee, which will ultimately approve or reject the candidate based on its suitability for applications described in *USP-NF*.

USP looks forward to continuing to strengthen its partnership with FDA to ensure that USP's Reference Standards remain the gold standard for the industry. 📌

USP Conducts Pilot Program to Produce Certified Reference Materials

USP HAS INITIATED A PILOT STUDY to evaluate five candidate bulk materials to be officially certified USP Reference Standards. The certification process is consistent with ISO guidelines.

If they meet the criteria, these Reference Standards will be designated as Certified Reference Materials (CRM), a designation of quality recognized worldwide.

One of the main features of a CRM is the Certificate of Analysis that accompanies it. This document provides information about how the evaluation was done and a statistical analysis of the data used to assign content (purity). The study of these materials demonstrates USP's dedication to continuous improvement of its processes and the scientific basis of its activities.

Upon completion of the pilot program, USP will assess the process and, if appropriate, will expand the approach. Details of this pilot program and progress to date will be presented and discussed at the USP Annual Scientific Meeting in Denver, Colorado, September 2006. Although it is novel for USP, the approach is widely applied in other contexts. For example, the reference materials in the National Institute of Standards and Technology (NIST) catalogue generally conform to the ISO criteria for a CRM. 📌

USP Convenes Pharmaceutical Research Consortia

ON APRIL 21, USP HOSTED A MEETING with several organizations to provide a neutral forum where research centers could meet, discuss improvements in pharmaceutical quality, and share ideas for future collaboration.

Stan Finkelstein, Ph.D., from the Program on the Pharmaceutical Industry at the Massachusetts Institute of Technology, chaired the meeting. Representatives from government institutions and leading schools of pharmacy and engineering delivered presentations that provided background and insight about research activities at their respective institutes. Attendees included representatives from industry, academia, and federal government organizations, as well as the chairman of the USP Board of Trustees, John Mauger, Ph.D., and

members of several USP expert committees.

According to Roger L. Williams, M.D., executive vice president and CEO of USP, "The meeting was excellent, giving all attendees, including USP, an opportunity

to learn about various research perspectives from other organizations and to explore potential relationships."

The attendees and presenters represented the following organizations:

- Center for Biomedical Innovation
- Center for Pharmaceutical Processing Research
- Center for Process Analytical Chemistry
- Consortium for the Advancement of Manufacturing of Pharmaceuticals
- Department of Commerce
- European Federation for Pharmaceutical Sciences
- FDA
- National Institute for Pharmaceutical Technology and Education (Purdue-based consortium)
- National Institute of Standards and Technology
- National Science Foundation
- Harvard University
- Massachusetts Institute of Technology
- Program on the Pharmaceutical Industry (Massachusetts Institute of Technology)
- Purdue University
- University of Washington 📌

USP Science

USP Proposes Changes to General Chapter on Compounding Sterile Preparations

ON MAY 1, USP INITIATED A PUBLIC review process for General Chapter *Pharmaceutical Compounding—Sterile Preparations <797>*, inviting the public to comment on the proposed changes to practice standards USP sets to help ensure that compounded sterile preparations are of the highest quality.

The proposed revisions include the addition of a glossary; new sections on radiopharmaceuticals, hazardous drugs, and single-dose versus multi-dose containers; and modifications to the section on environmental monitoring.

Throughout May and June, USP hosted five Webinars with faculty speakers from the USP Sterile Compounding Expert Committee, highlighting the significant proposed changes to Chapter <797> and offering insight into the rationale for these changes. These Webinars also provided participants with an overview of the USP revision process and a forum for questions and answers.

After the comment period ends on August 15, the Sterile Compounding Expert Committee and USP staff will review all comments, and the Expert

Committee will make final decisions regarding modifications to Chapter <797>. Once the revisions become official, USP plans to publish a summary of comments received, along with the Expert Committee's responses.

All of the proposed changes are posted on the USP Web site at <http://www.usp.org/USPNF/pf/generalChapter797.html>. From May 1 to August 15, health care professionals and interested parties can submit comments to USP on the Web site, via e-mail to 797comments@usp.org, or via regular mail to USP headquarters. 📧

Patient Safety

USP Hosts Compounding Stakeholder Forum

USP RECONVENED ITS COMPOUNDING Stakeholder Forum on June 16 in Bethesda, Maryland. The forum began in 2002. The June meeting—chaired by Kasey Thompson, Pharm.D., director of practice standards and quality division and director of patient safety for the American Society of Health-System Pharmacists—brought together more than 50 health care professionals from various professional and trade associations, representatives of the FDA, USP staff members, and nearly all members of USP's Expert Committee on Compounding Pharmacy (Loyd Allen, Ph.D., chair) and Expert Committee on Sterile Compounding (David Newton, Ph.D., chair).

The goal of the meeting was to provide a forum in which stakeholders could meet and discuss pharmacy compounding standards-setting activities. The proposed revisions to *USP-NF General Chapter Pharmaceutical Compounding—Sterile Preparations <797>* was one of the key topics of discussion. The proposed changes were published in the May–June 2006 *Pharmaceutical Forum (PF)*. USP

also presented its plans for a comprehensive outreach program to educate compounding professionals so that they learn about and are able to submit comments on the proposed changes prior to the chapter's becoming official. Other topics included:

- A preview of the Work Plans for the USP Compounding Pharmacy and Sterile Compounding Expert Committees.
- An advisory to look for the new General Chapter *Quality Assurance <1163>*, which will be proposed in the September–October 2006 *PF*.
- A discussion of the use of USP Compounding Standards by conformity assessment/accreditation bodies (the Pharmacy Compounding Accreditation Board is an example of one such body).
- A discussion of compounding ingredient standards.
- A discussion of practitioner and patient interaction as it relates to compounding standards.

A major component of the Stakeholder Forum included two panel discussions. The first covered compounding issues regarding legal issues, conformity assessment, and accreditation, and the second focused on the people involved in compounding, the environment, and the processes related to compounding.

Final discussions included hot topics in compounding, which fell into the following categories:

- Implementation, Education, and Training
- Special Populations
- Facilities and Environment/Economic Analysis
- Conformity Assessment.

There was considerable discussion about these topics and USP agreed to consider forming one or more Project Teams to address the topics. A call will be issued to compounding stakeholder organizations for recommendations of individuals to serve on the Project Teams as they are formed. 📧

Drug Quality Initiatives



Expert Panel Advocates Use of Zinc Supplementation for Acute Diarrhea

A PANEL OF EXPERTS RECENTLY CONVENED AT THE 33rd International Conference on Global Health to discuss the use of zinc in the management of childhood diarrhea.

Acute diarrhea remains a leading cause of death among children in developing countries, despite the use of oral rehydration salt (ORS) solution. Zinc supplementation has proven effective in the prevention and treatment of diarrhea in children, especially those younger than five years of age.

Zinc supplementation is effective for infectious diarrhea,

but health professionals are not certain of its mechanism of action. Experts in the field believe that zinc most likely boosts the body's immune response because it affects a broader range of ailments than just diarrhea. Fortification of food with zinc is one of the best approaches for treatment, according to participants. Experts agreed that the amount, frequency, and fortification of other minerals must be determined before any supplementation programs could be implemented.

Speakers at the conference included Robert E. Black, M.D., M.P.H., chairman of the Johns Hopkins Bloomberg School of Public Health; Patricia Paredes Jodrey, M.S., M.D., Dr.Ph., senior advisor for Global Health Technology from the U.S. Agency for International Development (USAID); and Abdelkrim Y. Smine, Ph.D., manager of Drug Quality Control and Laboratory Training for the USP Drug Quality and Information (USP DQI) program. 📌

Speakers from the International Conference on Global Health (L-R): Abdelkrim Y. Smine, Ph.D., manager of Drug Quality Control and Laboratory Training for the USP Drug Quality and Information (DQI) program; Patricia Paredes Jodrey, M.S., M.D., Dr.Ph., senior advisor for Global Health Technology from the U.S. Agency for International Development (USAID); Robert E. Black, M.D., M.P.H., chairman of the Johns Hopkins Bloomberg School of Public Health; and Joyce Carpenter, M.D., associate director of the USP DQI program.

USP Developing Antimalarial Medicine Monographs for Zambia

ON MAY 4–9, USP PARTICIPATED IN the annual stakeholders meeting of Medicines for Malaria Venture (MMV), a public–private partnership committed to discovery, development, and delivery of new drugs for malaria.

Held in Livingstone, Zambia, the meeting featured a special session focused on how MMV should move into drug delivery to increase access to antimalarial medicines. Nancy Blum, USP vice president of international affairs, attended the meeting along with invited representatives of nongovernmental organizations, WHO, and national malaria programs.

At this meeting, Blum pledged that USP will contribute to MMV objectives in the area of quality assurance and pharmacovigilance. Both of these important public health tools are almost nonexistent in Zambia, where 33,000 people die of malaria each year. USP will work with

A health center in Zambia, where the annual stakeholders meeting of Medicines for Malaria Venture was held.



industry representatives present at the meeting to develop monographs and reference standards for antimalarial drugs.

These independently developed standards are an important tool that USP's Drug Quality Initiative (DQI) has used in

a number of other countries to improve quality assurance for antimalarial medicine. Once the standards are developed, USP will make them available through a free-access Web site. 📌

Drug Quality Initiatives

USP Presents Successful DQI Programs at Russia's Man and Drugs Conference

ON APRIL 3-7, IN MOSCOW, USP PARTICIPATED IN THE 13th National Man and Drugs Congress, the largest meeting on pharmaceuticals in Russia.



Souly Phanouvong, PharmD., Ph.D., manager, Drug Quality Assurance and Regulatory Policy, USP DQI speaking to attendees at the Man and Drugs Conference.

Souly Phanouvong, PharmD., Ph.D., USP manager of drug quality assurance and policy development, gave a presentation on successful USP Drug Quality Initiative (DQI) programs working to improve the quality of medicines and diminish the spread of antimicrobial resistance (AMR).

Dr. Phanouvong reported on the monitoring of drug quality in the Greater Mekong Subregion. After initially focusing on antimalarials, several countries have recently extended the program to include other infectious diseases, such as HIV/AIDS, tuberculosis, sexually transmitted diseases, and bacterial infections. In addition, he discussed the recently established Asian Network of Excellence in Quality Assurance of Medicines, which is working to improve drug quality and reduce the incidence of substandard and counterfeit drugs with more standardized testing and the development of regional networks of quality laboratories.



Kirill Burimski, program manager/technical advisor, USP DQI; and Elena Ushkalova, Russia program coordinator in Moscow during the Man and Drug Conference.

The conference also featured a special roundtable session about the first Internet-based distance learning program developed by Smolensk Medical Academy and USP DQI. In an effort to improve the program, representatives from each of the 10 secondary distance learning centers in Russia discussed challenges and successes from their individual centers. 📍

Working Against Infectious Diseases in Latin America

USP RECENTLY PARTICIPATED IN TWO international meetings focused on drug quality control in Latin America.

Abdelkrim Smine, M.D., manager of drug quality control and laboratory training, represented USP at a steering committee meeting of the South American Infectious Disease Initiative (SAIDI) held

in Peru. The meeting focused on recent progress and future efforts to contain the advance of antimicrobial resistance in Bolivia, Paraguay, and Peru.

Dr. Smine also represented USP at the Amazon Malaria Initiative (AMI) Technical Meeting in Ecuador. USP's Drug Quality Initiative (DQI) supports AMI's efforts

to fight malaria in eight Amazonian countries. These efforts include helping each participating country develop a process to monitor drug quality by sampling and testing antimalarial drugs.

The U.S. Agency for International Development (USAID) supports both initiatives. 📍

Catherine Wachira Joins USP as Director of the Drug Quality and Information Program

USP HAS HIRED CATHERINE WACHIRA, a talented professional with 14 years of experience in the health care field, as director of the drug quality and information (DQI) program.

Most recently, Ms. Wachira was director of clinical research for Callisto Pharmaceuticals, where she managed clinical operations for studies in multiple myelo-

ma, advanced cancers, and leukemia. Her career also includes experiences with the United National Development Program, Bristol-Myers Squibb, the Catholic Medical Mission Board, and Family Health International.

Ms. Wachira holds a bachelor's of science degree in biochemistry from the University of Nairobi in Nairobi, Kenya,

and a master's of business administration in strategic management from the University of Nairobi/The George Washington University. She is currently completing her thesis in global health from the Yale University School of Public Health.

As director of DQI, Ms. Wachira will direct the planning and implementation of USP's cooperative agreement with USAID to provide technical assistance in drug quality assurance and drug information development for developing countries. 📍

International

USP to Establish New Site in China

THE USP BOARD OF TRUSTEES HAS approved the establishment of a new site in China, a project that will continue USP's efforts to help to ensure good pharmaceutical care for all.

Construction has begun on an approximately 10,000 square foot site in Zhang Jiang High Tech Park in Shanghai. The structure will have both office and laboratory space, providing USP staff with

the facilities they need to conduct laboratory testing and service customers in China. The construction is expected to be complete by September 2006.

USP is planning to hire a staff of about 16 people for the China site. Dr. John Hu, vice president, international-China, is managing the site and has



already hired his first local employee. Diana Zhang, who recently earned an M.B.A. from the joint program between Massachusetts Institute of Technology and Fudan University in Shanghai, will be serving as USP-China's customer relationship manager.

USP plans to open the China site in February 2007. 🇨🇳

USP Hosts Seminar on Anti-Counterfeiting

ON APRIL 10, 2006, USP HOSTED A professional development seminar titled "Anti-Counterfeiting: Domestic and International Measures." A panel of four experts discussed the problem of counterfeit drugs, including an industry overview of the counterfeiting problem, the FDA counterfeit drug task force action plan, counterfeit drugs as an international trade problem and how counterfeit goods affect the public's health and safety.

The panel included Thomas T. Kubic, executive director of the Pharmaceutical Security Institute; Ilisa B.G. Bernstein, director of pharmacy affairs for FDA; Jeffrey Gren, director of the U.S. Department of Commerce Office of Health and Consumer Goods, U.S. Department of Commerce; and Michele Forzley, director of philanthropic investments and corpo-

rate social responsibility for MAP International. Roger L. Williams, M.D., executive vice president and CEO of USP, moderated the discussion.

Many weapons are used to combat counterfeiting around the world, and although the arsenal is growing, so is the pervasiveness of fake drugs. As international trade increases, so do the instances of counterfeiting. The experts agreed that multilateral cooperation among nations and international health organizations, interventions at the higher echelon of governments, and education of health providers on the front lines are key to stemming the tide of counterfeits.

During the question and answer session of the seminar, USP employees shared their first-hand experience with the crisis of counterfeiting, working in more than 30 sites (provinces) in Latin

America, Asia, and Africa doing basic tests (visual/physical inspection, simple disintegration, and thin-layer chromatography) to screen the quality of drugs. USP's program staff, funded by a grant from USAID, work in other countries directly with health programs, drug regulatory authorities, procurement services, academia, and international organizations. Focusing on the quality control aspect of identifying counterfeits, USP has been instrumental in reducing the number of substandard and counterfeit drugs that reach the most vulnerable populations and has contributed significantly to raising awareness of counterfeit drugs to a global level.

To learn more about USP's efforts to fight the counterfeit drug problem, nationally and internationally, please visit www.uspdqi.org. 🇺🇸

Inside USP

Six Fellowships Awarded by USP for the 2006–2007 Term

FOR THE 2006–2007 ACADEMIC TERM, USP awarded six fellowships to graduate students enrolled in chemistry, pharmacy, and other health care and scientific programs. USP's fellowship program supports research in the areas of drug standards and their use. For their participation in the one-year term, each student is

awarded a \$20,000 award of which a portion is used to help support the fellow and the costs of the research he or she conducts. This year's fellows, listed below, began work at USP in July.

USP Fellowship Recipients:

- Shumet Hailu, University of Connecticut, School of Pharmacy *Area*

of Research—Chemical Stability of Amorphous Drugs in the Presence of Silicates

- Aaryn Cohen Olesen, University of North Carolina at Chapel Hill, School of Pharmacy *Area of Research*—Analysis of Medication Error Data for Incidents Limited to Patient Harm
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Inside USP

Members of New Information Expert Committees Elected

IN APRIL 2006, THE MEMBERS OF USP's Information Expert Committees (IECs) for the 2005–2010 cycle were elected.

The IECs support USP's work related to the Medicare Prescription Drug Benefit Model Guidelines by reviewing new drugs and indications for drugs within each

committee's therapeutic area of expertise. The IECs will provide recommendations to the Model Guidelines Expert Committee to support the ongoing maintenance of and revisions to the Model Guidelines. Each IEC is led by a chair, and these chairs collectively form the Model Guidelines Expert

Committee. In addition to the Model Guidelines work, the IECs will engage in other drug information activities, including developing articles for the *Annals of Internal Medicine*. Below is a list of the results of these elections, the 2005–2010 Information Expert Committees.

The 2005–2010 Information Expert Committees

Cardiology (Chair: Sarah A. Spinler, Pharm.D.)

Joseph R. Carver, M.D.
Mark J. Cziraky, Pharm.D.
Cynthia Kirman, Pharm.D.
Nancy M. Allen LaPointe, Pharm.D.
Barbara S. Wiggins, Pharm.D.
Alexander Shepherd, M.D., Ph.D. (2000–2005 Chair—returning)

Clinical Toxicology (Chair: Vacant)

Members to be elected

Dermatology (Chair: Dennis P. West, Ph.D.)

Robert J. Anderson, J.D.
Frederick A. Curro, D.M.D., Ph.D.
Steven R. Feldman, M.D., Ph.D.
Craig L. Leonardi, M.D.
Ali Molin, M.D.
Michael E. Bigby, M.D. (2000–2005 Chair—not returning)

Endocrinology (Chair: Karim A. Calis, Pharm.D.)

Glen D. Braunstein, M.D.
Frederick G. Hom, M.D.
Charles D. Ponte, Pharm.D.
Frank Pucino, Pharm.D.
Robert E. Ratner, M.D.
Lawrence Frohman, M.D. (2000–2005 Chair—returning)

Gastroenterology (Chair: Bruce R. Bacon, M.D.)

Roger A. Clemens, Ph.D.
Neal M. Davies, Ph.D.
Arthur I. Jacknowitz, Pharm.D.
Cynthia Kirman, Pharm.D.
John G. McHutchinson, M.D.
Karl E. Anderson, MD (2000–2005 Chair—returning)

Hematology (Chair: Patrick A. McKee, M.D.)

Joseph E. Addiego, M.D.
Judith C. Andersen, M.D.
Philip C. Comp, M.D., Ph.D.
Kevin L. Moore, M.D.
Gabriel A. Shapiro, M.D.

Immunology (Chair: John Grabenstein, Ph.D.)

Roy D. Altman, M.D.
Leonard Bielory, M.D.
Philip Marcus, M.D., M.P.H.
Dennis M. Williams, Pharm.D.
Cheston M. Berlin, M.D. (2000–2005 Chair—returning)

Infectious Diseases (Chair: Douglas W. MacPherson, M.D.)

William B. Baine, M.D.
Shukai Bala, Ph.D.
Paul O. Gubbins, Pharm.D.
Paul D. Holtom, M.D.
Marisel Segarra-Newnham, Pharm.D., M.P.H.

Nephrology/Urology (Chair: Vacant)

Members to be elected.

Neurology/Otorhinolaryngology/Ophthalmology (Chair: Mitchell F. Brin, M.D.)

Andrew Blitzer, Ph.D.
Neil M. Bressler, M.D.
Vinay Chaudhry, M.D.
Joel S. Mindel, M.D., Ph.D.
Melody Ryan, Pharm.D.
David A. Lee, M.D. (2000–2005 Chair Ophthalmology—returning)
Randal A. Otto, M.D. (2000–2005 Chair Otorhinolaryngology—returning)

Oncology (Chair: Barbara A. Burtness, M.D.)

Christine H. Chung, M.D.
Michael S. Edwards, Pharm.D., M.B.A.
Alok A. Khorana, M.D.
Nancy L. Lewis, M.D.
Sandra M. Swain, M.D.
Raymond B. Weiss, M.D. (2000–2005 Chair—not returning)

Psychiatry (Chair: Amy H. Schwartz, Pharm.D.)

Lawrence J. Cohen, Pharm.D.
M. Lynn Crismon, Pharm.D.
Marty Mattei, Pharm.D.
Paul M. Packman, M.D.
J. Russell Teagarden, M.A.
William Fann, M.D.

Pulmonary Disease and Allergy (Chair: Elliot Israel, M.D.)

Leonard Bielory, M.D.
Aaron Deykin, M.D.
David Lorber, M.D.
Karen J. Tietze, Pharm.D.
Dennis M. Williams, Pharm.D.
I. Leonard Bernstein, M.D. (2000–2005 Chair—returning)


Rheumatology (Chair: David H. Campen, M.D.)

Gregory J. Dennis, M.D.
Gail S. Kerr, M.D.
Lee S. Simon, M.D.
Fredrica Smith
Steve Zlotnick, Pharm.D.
Evelyn V. Hess, M.D. (2000–2005 Chair—returning)

Special Populations/Clinical Pharmacology (Chair: Joseph T. Hanlon, Pharm.D.)

Rudi Ansbacher, M.D.
Fredrick A. Curro, Ph.D., D.M.D.
Gerald DeYoung, Pharm.D.
Melvin B. Heyman, M.D.
Michael J. Koronkowski, Pharm.D.
Darrell Abernethy, M.D., Ph.D. (2000–2005 Chair Gerontology—returning)
William Troutman, Pharm.D. (2000–2005 Chair, Information Development and Dissemination—returning)
Wayne Snodgrass, M.D., Ph.D. (2000–2005 Chair, Pediatrics—returning)

Therapeutic Decision Making (Chair: Nancy J. Braden, M.D.)

Trinka S. Coster, M.D.
Brian L. Erstad, Pharm.D.
Sandra L. Kane-Gill, Pharm.D.
David B. Lorber, M.D.
Edward Westrick, M.D., Ph.D.
Elizabeth Chrischilles, Ph.D. (2000–2005 Chair—returning) 

Construction Update – New USP Buildings



CONSTRUCTION ON THE TWO NEW STATE-of-the-art USP buildings is underway. In November 2005, Phase 1, demolition and excavation of the Twinbrook 3 building, was completed. The Twinbrook 1 building was demolished in December 2005.

The second phase of the project, building the foundation, began in December and was nearly complete as of May 2006. Construction

on the main floors of both buildings has begun, and both are expected to be enclosed by fall 2006.

The construction project includes two new buildings: a 16,000 sq. ft. conference center, and a 141,000 sq. ft. lab and office building.

Completion of the new buildings is expected in summer 2007. 🏗️

USP Provides New Mechanism for Public Participation in Revisions to Medicare Model Guidelines

USP HAS DEVELOPED A NEW ONLINE FORM available to all interested parties who would like to suggest revisions to the Medicare Prescription Drug Model Guidelines, the list of drug categories and therapeutic classes that Medicare prescription drug plans may use as they develop their formularies.

The Medicare Prescription Drug, Improvement, and Modernization Act (MMA), which provided for the Medicare Part D prescription drug benefit, designated USP to create these Model Guidelines when President Bush signed the act into law in December 2003.

In addition to the development of the initial Model Guidelines, which occurred in 2004, the law instructs USP “to revise such classifications from time to time to reflect changes in

therapeutic uses of covered part D drugs and additions of new covered part D drugs.”

In February 2006 the USP Model Guidelines Expert Committee published the first revision—version 2.0 of the Model Guidelines.

Going forward USP drug information specialists will continually monitor for new FDA-approved drugs and new or revised FDA-approved indications, removal or discontinuation of drugs, and all new relevant safety and efficacy data for drugs covered under the Medicare Part D benefit. In addition, any interested party may use the new online form—available on USP’s website at www.usp.org—to propose revisions to the Model Guidelines as well as the Formulary Key Drug Types and Drug List Table. 🏗️

2006 USP Pharmacopeial Education Course Schedule

Effectively Using USP–NF Session I

August 23, 2006
USP Headquarters,
Rockville, Maryland

Effectively Using USP–NF Session II

August 24, 2006
USP Headquarters,
Rockville, Maryland

Effectively Using USP–NF Sessions I & II

September 26, 2006
Denver, Colorado
(USP Annual
Scientific Meeting)

Fundamentals of Microbiological Testing

September 26, 2006
Denver, Colorado
(USP Annual
Scientific Meeting)

Fundamentals of Dissolution—Lecture & Laboratory

October 3–4, 2006
North Brunswick, New Jersey

Inside USP

USP Invites New Organizations to Convention Membership

THE USP MEMBERSHIP COMMITTEE (MC) recently submitted its recommendation of organizations to be invited to Convention Membership for the 2005–2010 cycle. The USP Board of Trustees approved the list, and formal invitations have been sent to the organizations.

Convention Membership is considered by the MC throughout a five-year cycle.

In order for an organization to be invited to become a member, the Board of Trustees must approve the MC's recommendations. Fifty-one of the 52 invited organizations were also members during the 2000–2005 cycle. The American Association of Colleges of Veterinary Medicine is the newly invited member.

In addition to the invited organizations listed below, the Convention also consists

of a group of organizations named in USP's Constitution. These organizations are permanent members that enjoy enduring membership and are not subject to term limits. A list of Constitutionally named organizations was provided in the April 2005 issue of *USP Press*.

Below is the initial group of organizations invited to Convention Membership for the 2005–2010 cycle.

National and State Professional and Scientific Organizations

Academy of Managed Care Pharmacy
 American Academy of Family Physicians
 American Academy of Nurse Practitioners
 American Academy of Pediatrics
 American Academy of Physician Assistants
 American Academy of Veterinary Pharmacology and Therapeutics
 American Association of Colleges of Nursing
 American Association of Colleges of Osteopathic Medicine
 American Association of Colleges of Pharmacy
 American Association of Colleges of Veterinary Medicine
 American College of Clinical Pharmacy
 American College of Physicians
 American Geriatrics Society
 American Osteopathic Association
 American Type Culture Collection
 Association of American Medical Colleges
 International Academy of Compounding Pharmacists
 New Jersey Pharmaceutical Quality Control Association

Governmental Bodies

Agency for Healthcare Research and Quality
 Centers for Disease Control and Prevention
 FDA Center for Biologics Evaluation and Research
 FDA Center for Devices and Radiological Health
 FDA Center for Drug Evaluation and Research
 FDA Center for Food Safety and Applied Nutrition
 FDA Center for Veterinary Medicine
 National Institutes of Health
 U.S. Agency for International Development
 Health Canada


Health Science and Other Foreign Organizations and Pharmacopeias

Argentine Pharmacopeia
 Association of Faculties of Pharmacy of Canada
 Brazilian Pharmacopeia Commission
 Canadian Pharmacists Association
 Chinese Pharmacopeia Commission of the Ministry of Public Health
 European Directorate for the Quality of Medicines, Council of Europe
 European Federation of Pharmaceutical Scientists
 Fédération Internationale Pharmaceutique
 Indian Pharmacopeia Commission
 Pan American Health Organization
 Permanent Commission of the Mexican United States Pharmacopeia
 Royal College of Physicians and Surgeons of Canada

Consumer Organizations and Individuals Representing Public Interests

American Diabetes Association
 Center for Science in the Public Interest
 Consumers Union
 National Organization for Rare Disorders
 National Consumers League

Domestic, Foreign, and International Manufacturers, Trade, and Affiliated Associations

American Herbal Products Association
 Biotechnology Industry Organization
 Compressed Gas Association
 International Pharmaceutical Excipients Council of the Americas
 Joint Commission on Accreditation of Healthcare Organizations
 Nonprescription Drug Manufacturers Association of Canada
 Pharmaceutical Care Management Association 

USP Attends Harmonization Meeting in Japan

THE PHARMACOPEIAL DISCUSSION

Group (PDG), comprised of USP, the European Pharmacopeia (EP), and the Japanese Pharmacopeia (JP), met on June 5 to 8 in Yokohama, Japan, in association with the Expert Working Groups of the International Conference on Harmonization (ICH).

PDG has revised its working procedures to reflect the interaction with the ICH Q4B Expert Working Group (Q4B EWG). The Q4B EWG evaluates whether the harmonized standards developed through the PDG and published by the individual pharmacopeias may be recognized as interchangeable by regulatory authorities in each of the three ICH regions (North America, Europe, and Japan).

The revised procedures have resulted in changes to the interpretation of stage six and seven by adding a stage six-c (indication of harmonization). The former stage seven (inter-regional implementation) was redefined to be inter-regional acceptance. The date of stage seven is common to all three pharmacopeias and will be assigned after it has received formal notification from the Q4B EWG indicating that the harmonized chapter meets regulatory acceptance. This revised pro-

cedure will facilitate the work of the Q4B EWG and help users of the three pharmacopeias clearly understand when a harmonized chapter has reached regulatory acceptance.

ment packages of harmonized general chapters to Q4B EWG for their evaluation. The Q4B EWG has recognized both the chapter on extractable volume and the chapter on residue on ignition/sul-


Revised procedures will facilitate the work of the Q4B EWG and help users of the three pharmacopeias clearly understand when a harmonized chapter has reached regulatory acceptance.

The PDG signed off on the Hypromellose Phthalate monograph, for which USP led the coordinating effort. Uniformity of delivered dose of inhalers was added as a new topic for harmonization. The group also agreed to initiate the revision of the monographs for methyl paraben, ethyl paraben, propyl paraben, and butyl paraben and nominated EP as the coordinating pharmacopeia.

PDG met with several other groups during the week. On June 6, PDG met with industry associations from the three ICH regions for an update on PDG's current work program. This was followed by a joint meeting with Q4B EWG on June 7. PDG has submitted five docu-

phated ash as interchangeable. PDG is awaiting feedback from the Q4B EWG on the chapters for dissolution and particulate matter for injections. PDG is currently working to resolve issues with the chapter on sterility tests. PDG is also currently preparing packages for submission to Q4B EWG on disintegration, uniformity of dosage units, and microbiological quality.

On June 8, PDG meet with Tri-PEC (IPEC Americas, IPEC Europe, Japanese Pharmaceutical Excipients Council) to discuss PDG's work program on harmonization of excipient monographs.

PDG's next meeting will be held October 23 to 26 in Chicago, Ill. 

USP, the European Pharmacopeia, and the Japanese Pharmacopeia Harmonize Three General Chapters


USP, THE EUROPEAN PHARMACOPEIA (EP), and the Japanese Pharmacopeia (JP) recently harmonized the three General Chapters on microbial quality, continuing their efforts to provide consistency for the many manufacturers and health care professionals throughout the world who rely on the standards developed by these three pharmacopeias.

The three USP General Chapters are General Chapter *Microbiological Examination of Nonsterile Products: Microbial Enumeration Tests* <61>, General Chapter *Microbiological Examination of Nonsterile*

Products: Tests for Specified Microorganisms <62>, and General Chapter *Microbiological Examination of Nonsterile Products: Acceptance Criteria for Pharmaceutical Preparations and Substances for Pharmaceutical Use* <111>. The objective of these harmonization efforts is to promote regulatory acceptance of interchangeability of the tests and acceptance criteria.

USP, EP, and JP comprise the Pharmacopeial Discussion Group (PDG), an organization that coordinates the harmonization of monographs and Gen-

eral Chapters in an effort to ensure consistency in pharmaceutical products around the world.

All three General Chapters have been published in the second *Supplement to USP 29-NF 24*. Although the second *Supplement to USP 29-NF 24* became official on August 1, 2006, the three harmonized chapters have a delayed implementation date of August 1, 2007. The second *Supplement to USP 29-NF 24* is available electronically and as hard copy. Both formats can be purchased through the USP Web site at www.usp.org. 

USP Staff News

APhA Honors Valentino and Grabenstein

IN MARCH, THE AMERICAN PHARMACISTS Association (APhA) recognized two members, of the USP community for their longstanding commitment to pharmacy.

Joseph G. Valentino, J.D., USP's former general counsel who retired in 2005 after 35 years of service, was honored with the Hugo H. Schaefer Award. This award recognizes APhA members who have made outstanding voluntary contributions to society, the profession of pharmacy, and APhA. Over a distinguished 50-year career, Valentino has helped to establish what is now the

APhA-Academy of Student Pharmacists National Patient Counseling Competition, co-founded the USP Drug Product Problem Reporting Program and the Laboratory and Medical Product Problem Reporting Program, and initiated the *USP Dispensing Information (USP DI)* program.

Colonel John D. Grabenstein, Ph.D., director of the Military Vaccine Agency within the U.S. Army Surgeon General's Office and a member of USP's Council of Experts, was presented with the Gloria Niemeyer Francke Leadership Mentor Award. This award recognizes an APhA

member who has promoted and encouraged pharmacists to attain leadership positions within pharmacy by being a role model and mentor. Two examples of Grabenstein's many mentorship activities are his development of the Pharmacy Leadership and Education Institute and involvement in creating the Leader Development Seminar for the Phi Delta Chi Fraternity.

USP is pleased and honored that these individuals, who have devoted so much of their time, talent, and intellect in support of USP, have been recognized by the broader pharmacy community. 📌

Six Fellowships Awarded, continued from page 7

- Leonard Nyadong, Georgia Tech, School of Chemistry and Biochemistry *Area of Research*—High-Throughput Detection of Counterfeit Drugs by Desorption/Ionization Mass Spectrometry under Atmospheric Pressure Conditions
- Atul Saluja, University of Connecticut, School of Pharmacy *Area of*

Research—Investigation of Factors Affecting Formulation and Storage Stability of High Protein Concentration Solutions

- Martin Telko, University of North Carolina at Chapel Hill, School of Pharmacy *Area of Research*—Characterization of Surface Energetics of Lactose Monohydrate Using IGC and

Complimentary Techniques

- Stephen Wang, University of Houston, School of Pharmacy *Area of Research*—Analysis of Red Clover Isoflavone Supplement Products

For more information about the fellowship program, contact Jennifer Payette at (301) 816-8198 or jrp@usp.org. 📌

USP Revises Rules, continued from page 1

- Allow the use of USP's Web site and other vehicles in addition to *PF* to post proposed revisions to *USP-NF*;
- Require USP to publish summaries of the public comments it receives regarding proposed revisions to *USP-NF* and the Expert Committee's responses to those comments;
- Increase to six months the time between publication of revisions to *USP-NF* and the date those revisions become official;

- Synchronize the official date of revisions to *USP-NF* with the release date of any new official USP reference standards called for in such revisions;
- Clarify the requirements and process for establishing standards in an expedited fashion through Interim Revision Announcements and Revision Bulletins;
- Streamline the development of monographs for articles pending approval at FDA;
- Allow the development of mono-

graphs for medicines legally marketed outside of the U.S. provided that the medicines are used to treat neglected diseases; and

- Enable FDA representatives to participate in USP's Expert Committee meetings as FDA liaisons, subject to confidentiality agreements.

Visit www.usp.org/USPNF/notices for more information about recent modifications to the USP standards-setting process, including corrections, postponements, retractions, policies, and announcements. 📌

Message from the CEO, continued from page 2 with the Board of Trustees' corporate objectives and overall strategic plan. The time now is right for strategic visioning in these areas, and I'm delighted that the Board has tasked staff and Council of Experts volunteers to begin this process. When I speak of *quality of care*, the nation and the world are of course struggling with this in many important ways. For our part, we devote considerable energies to our safe medica-

tion use and drug information programs. But I argue all of our efforts during the past several decades (and much longer, as USP historians know better than me!) are just the beginning. Practitioner and patient needs are so broad and deep now, it would be a missed opportunity indeed if USP stepped away from what we have done and can do instead to focus only on core activity work. As readers will see, I'm enthusiastic about taking on this challenge, and I

believe the USP Board is too. We don't know quite where USP will be in the next five to ten years as we consider our non-core opportunities, but a saying I rely on at times has special meaning now: The future belongs to those who plan for it.



Roger L. Williams, M.D.