



**Remarks of the Chief Executive Officer
Roger L. Williams, M.D.
As Delivered to the USP Convention**

**Washington, D.C.
Friday, April 23, 2010**

I speak to you now in my role as Chief Executive Officer of the United States Pharmacopoeial Convention, a role that I was given ten years and four months ago. I am privileged to have this role, in which I am fourth in my line. My distinguished predecessors were Lloyd Miller (1950-1970), William Heller (1970-1990) and Jerome Halperin (1990-2000).

At the beginning of the 2005-2010 revision cycle, the new USP Board of Trustees adopted the 13 resolutions concluded at the 2005 Convention into the prior Board's Strategic Plan. Then in 2008, the Board created its own strategic plan and finalized it in March 2008. That strategic plan now drives USP's work. It has five guiding principles:

1. Expand and Enhance USP's Core Compendial Activities
2. Build and Strengthen USP's Allied Compendial Programs
3. Engage in Other Public Health Programs That Fulfill Unmet Needs and Leverage USP's Unique Capabilities
4. Operate Both Nationally and Internationally to Maximize the Public Health Benefit of USP's Programs and Services throughout the World
5. Manage All USP Programs, Products, and Services Efficiently and Effectively

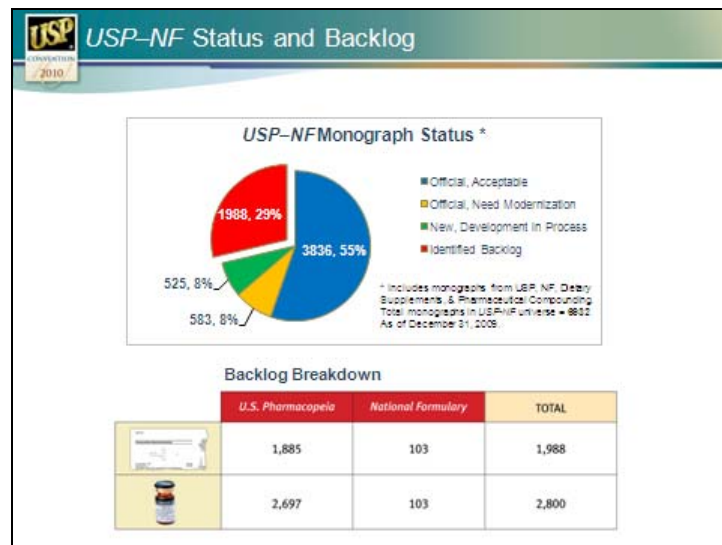
Enhance and Expand Core Compendial Programs

Documentary Standards

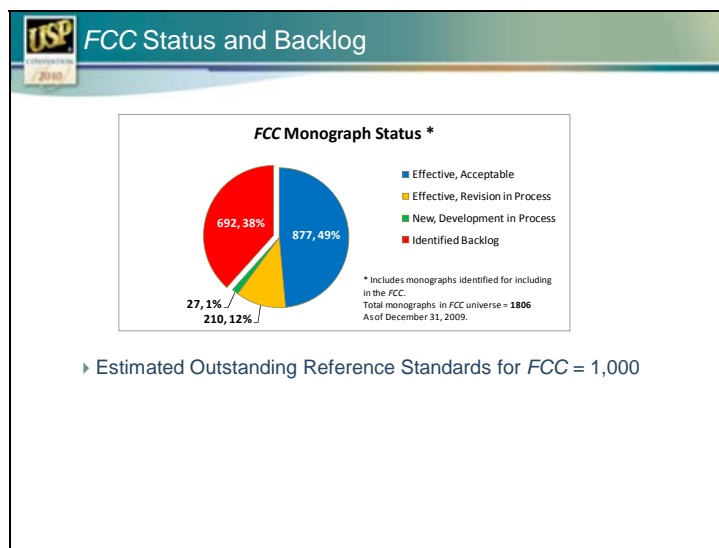
A presentation slide titled 'USP Documentary Standards' with a USP logo and '2010' in the top left corner. The slide features a background image of a red book titled 'USP 33 NF 28 RESUB' and several overlapping white documents. In the bottom left corner, there is a section titled 'Productivity:' with a list of achievements:

- ▶ 370 New Official Monographs
- ▶ 1,201 Revised Official Monographs
- ▶ 43 New Official General Chapters
- ▶ 89 Revised Official General Chapters

Readers of the CEO report, available in the Convention briefing materials, will see that we followed the directives of the Board of Trustees closely—some might say—even with a vengeance. At the close of the 2000-2005 cycle, USP produced the *United States Pharmacopeia (USP)* and the *National Formulary (NF)*. In this cycle, we added three more: the *USP Dietary Supplement Compendia*, the *Food Chemicals Codex*, and the *USP Pharmacists' Pharmacopeia*. At the close of the last cycle, USP's documentary standards were all official—that is they were two of three official compendia of the United States, as specified in the Federal Food, Drug and Cosmetic Act. The third is the *Homeopathic Pharmacopoeia of the United States*. At the close of the last cycle, USP produced little if any authorized text. Now we have several compendial offerings that contain authorized text—and the text in *Food Chemicals Codex (FCC)* is entirely authorized, given that *FCC* is not an official compendium of the United States.



But this progress tells only part of the story. The further story is that we have monograph backlogs in all our compendia, including *USP-NF*—both missing monographs and monographs that need updating. USP is working diligently to solve this challenge. We developed the flexible monograph to give more opportunities for manufacturers of the same article to use different tests, procedures, and acceptance criteria. And we created the ‘Pending’ monograph approach to allow manufacturers to work on a public monograph at USP pending the FDA’s review of their application. And while the *Non-USP* approach does not solve missing monographs or monographs needed in *USP-NF*, it nonetheless fills a gap for similar articles marketed in other countries and regions of the world. In the coming years, USP might develop ways to build monographs working more independently.



And here are the backlog numbers for FCC. The bottom line is that more than 40,000 medication names are marketed outside of the United States (Drugs.com). New and updated monographs are needed for thousands of food and drug articles nationally (in the *USP*, *NF*, and *FCC*) and internationally. Plus many thousands of reference materials also are needed.



And beyond our expansion of compendia offerings, we advanced our publications of *USP-NF* into other languages, including Spanish and Russian with plans for a Chinese translation as well. With Arabic and French added, the line-up would be complete for the languages in which the World Health Organization presents its information. One might argue that analytical chemists speak English well enough to conduct the tests, procedures, and acceptance criteria of the monograph. USP does not believe this is true, and its growing experience in translations indicates that at times that the meaning of a monograph can be obscure even when read by experienced analysts in their own language.



Despite the expansion in compendia offerings, *USP-NF* remain our core publications, and we made good progress in bringing new monographs to official status and updating existing monographs in these two compendia.

In Summary—Documentary Standards

A slide titled "USP Strategic Plan: Documentary Standards" with a "2010" logo. It contains a bulleted list of activities and goals.

- ▶ **What's Going On Now**
 - Work on New Monographs/Monograph Updating
 - More Translations: Chinese in Progress
- ▶ **What's Possible**
 - French? Arabic?
 - USP Works More Independently for New/Missing Monographs
 - Non-U.S. Monographs/Reference Materials
 - Strengthened Harmonization

Reference Materials



USP Reference Standards

- ▶ USP Offers More Than 2,500 Reference Standards for Use in the Full Range of *USP–NF* Tests and Procedures
- ▶ USP Reference Standards Have Been Rigorously Tested by USP, Industry, and Government Scientists

Productivity:

- ▶ 728 New Reference Standards
- ▶ 931 Replacement/Continuing Reference Standards



U.S. PHARMACOPEIA
The Standard of Quality

Earlier in the day I spoke to you about Phoenician rocks. USP’s Phoenician rocks—our publicly available official USP Reference Standards used in weighing the active ingredient in drug substances and products—occupies a great deal of our attention. We expend about 60% of our resources to bring these marvels of science to the world. We recently crossed a high water mark—2,500 reference materials in commerce throughout the world. While it is hard to estimate how many reference materials are needed for public documentary standards for food and drugs in the world, it could be a very large number--perhaps as many as 20,000 reference materials or more. That is a lot of Phoenician rocks! And some of these are not easy to come by. The suite of reference materials for heparin now includes the deadly adulterant, over-sulfated chondroitin sulfate, as well as dermatan, a chondroitin type of impurity, as well as the heparin drug substance itself with others as well for a total of seven.



At the close of the last cycle, USP stood eagerly at the brink of a beautiful new headquarters building that would consolidate our offices on the Twinbrook campus. USP’s existing laboratories at the time, occupying leased space, clearly were not state-of-the art!



We also dreamed of expanding our laboratory capabilities to sites around the world. You might ask—why does USP need so many laboratories? Candidate reference materials, typically achieved through generous donors, undergo rigorous testing, and we need multiple, independent laboratories to do this.

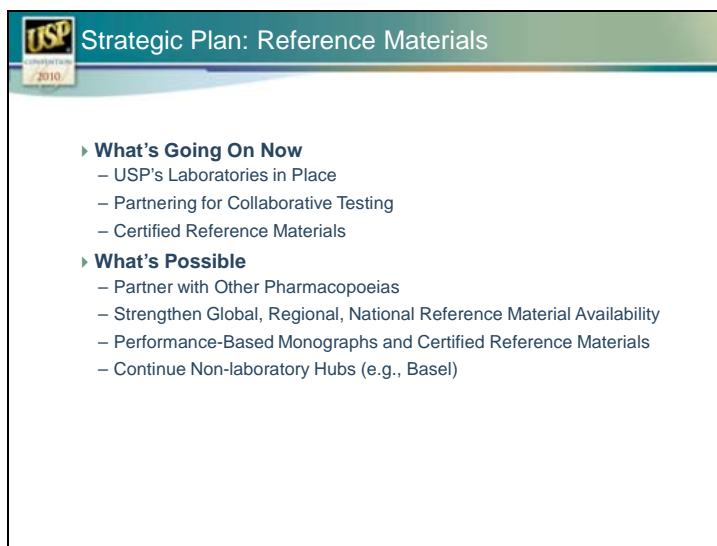


Our new building now exists—and it is indeed beautiful. We moved into the new building in August 2007 and celebrated its opening at our Spring Governance meeting in March 2008. The building is not only beautiful, it is highly functional as well, with excellent space for meetings, offices and laboratories.



Beyond this achievement, USP opened state-of-the-art laboratories in leased space in Hyderabad (2006), Shanghai (2007), and Sao Paulo (2008) in this revision cycle.

In Summary—Reference Materials

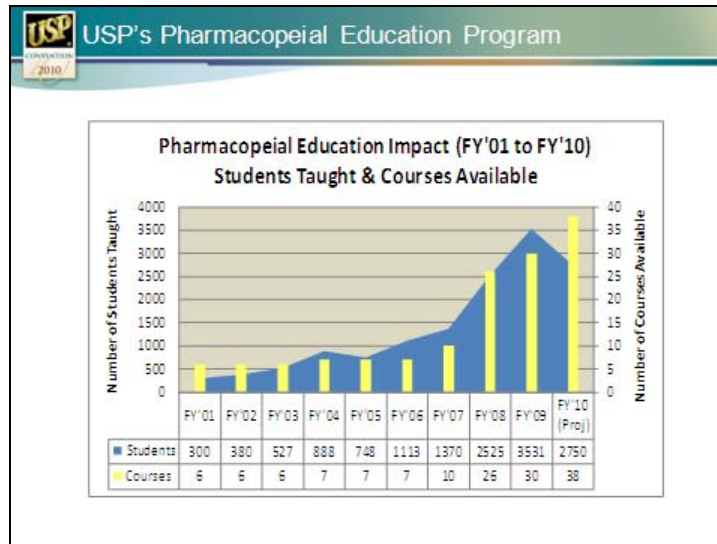


I emphasize the importance of public documentary and reference materials standards as a means of assuring the public trust. Just as we wouldn't be too pleased if the scales at our grocery store were maintained by produce sellers, we should be equally concerned if public national standards were missing for the food and drugs we use in our everyday life. USP wishes to work with all regulatory and pharmacopoeial bodies of the world, with food and drug manufacturers, and with all stakeholders to come to good public documentary and reference material standards. There is far more that we can do in the coming cycles, and indeed the availability of a public reference material, preferably certified, opens the door to compendia harmonization in ways that we can perhaps now only imagine. I do urge Convention delegates and observers—and the public at large—to better understand the value of public standards in advancing practitioner and patient/consumer confidence in assuring the quality and benefit of food and drugs—just as you now know this, implicitly or explicitly when you purchase goods by weight at the grocery store.

Build and Strengthen Allied Compendial Programs

At the close of the 2005-2010 revision cycle, USP maintained three allied compendia programs: Pharmacopeial Education, Verification, and USAID’s Promoting Quality of Medicines Program.

Pharmacopeial Education



USP began the Pharmacopeial Education program in the 2000-2005 cycle, in response to a Convention Resolution. There 35 Pharmacopeial Education courses with several more under development. We recently formed a curriculum committee to assist in updating and adding new courses. Overall, USP’s pharmacopeial education program has had steady growth, until the financial crisis began impeding travel, and has been found to be particularly useful in major ingredient and product manufacturing countries like India and China. In these settings, the desire to enter the US market is strong but the understanding of at times complex U.S. requirements is difficult. Indeed it seems likely that the value of many of USP’s pharmacopeial education courses lies more overseas than it does in the US, and numbers in the CEO report confirm this observation.

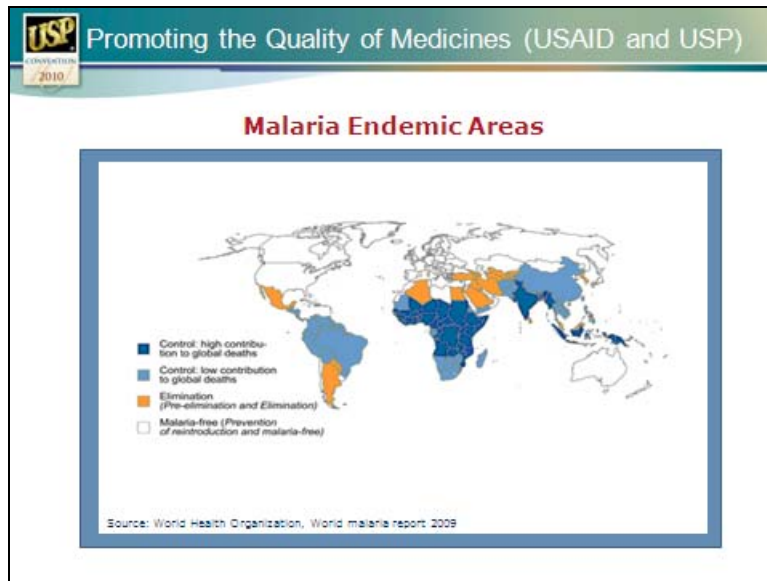
Verification

- 
USP Dietary Supplement Verification
 Launched 2002
 Dietary Supplements
- 
USP Dietary Ingredient Verification
 Launched 2004
 Dietary Ingredients (Vitamins, Minerals, Amino Acids, Botanicals, Non-botanicals)
- 
USP Pharmaceutical Ingredient Verification
 Launched 2006
 Drug Substances and Excipients


USP began its verification programs in the early part of the 21st century as a means of filling a regulatory gap. For dietary supplements, GMPs did not then exist, so USP's programs were designed to include review, audit, and test, activities that are typically conducted by a regulatory agency. The manifestation of success after USP's evaluation is a special mark that is distinguishable from USP's typical compendia marks.

USP's verification program for dietary supplements has been promoted by retailers who wish to assure their customers that they are selling good quality dietary supplements. And they do this by insisting that sellers in their stores engage in our Dietary Supplement Verification Program. This program now is applied to approximately 360 million bottles, providing assurance that what's on the label of a dietary supplement is in fact in the bottle. USP expanded beyond dietary supplements to dietary supplement and pharmaceutical ingredients, with the overall intent of all programs of supplementing scarce regulatory resources. And much more can be done. While USP's verifications programs are comprehensive, component parts can be offered as well to good purpose. For example, USP could conduct only an audit to assist with a subsequent regulatory inspection, or engage in testing alone as a means of facilitating market access, batch release, and/or market surveillance.

USAID's Promoting Quality of Medicines Program




USP is honored to be the recipient of funds from USAID over a period of almost 20 years to produce first drug information and now drug quality information to assist countries and regions throughout the world. Through expert leadership from USAID, the transition of the program to quality could not have been timelier. Increasingly, the world is challenged with counterfeit and substandard medicines, and the new Promoting Quality of Medicines program has worked diligently to understand and combat merchants who hawk their deadly wares.



Quality of Antimalarials in Sub-Saharan Africa

2010

- ▶ **Joint USAID/WHO Study**
 - USP DQI Surveyed 3 of 10 Countries Involved
 - Sampled Most Sold/Used in Public, Private Markets
 - Tested with Minilab® in Field, Confirmed at USP Labs
- ▶ **Findings**
 - Revealed 26–44% Failed to Meet Quality Standards
 - Gave Specific Data on Problem Types, Brands, Regions
 - Made Actionable Data Available to Country MRAs
- ▶ **Impact and Implications**
 - Improve Quality of Meds to Improve Malaria Treatment
 - Need Quality Component in Government Policies



Here is an example from a QAMSA study of the quality of anti-malarials. As you can see, the problem of poor quality anti-malarials is a devastating and has many negative repercussions. USP has a special team of international quality specialists who drive the PQM program from our Headquarters working with in country experts around the world.

In Summary—Allied Compendial Programs



Strategic Plan: Allied Compendial Programs

2010


- ▶ **What's Going On Now**
 - Pharmacopeial Education
 - Verification Certification
 - Promoting the Quality of Medicines (PQM)
- ▶ **What's Possible**
 - Expand Education and Training with National and International Partners
 - Strengthen Testing Capabilities (e.g., Marketplace Surveillance)
 - Expand Support to National Food and Drug Control Laboratories and Pharmacopoeias (If Present)
 - Expand Non-laboratory Hubs (Basel)
- ▶ **Combating Counterfeits**
 - Spectral Libraries
 - ▶ Confirm the 'Good'
 - ▶ Detect and Deter the 'Bad'

Engage in other Public Health Programs that Fulfill Unmet Needs

Drug Information and Reporting Programs

Beginning in the 1970s, USP engaged in creation of drug information and reporting programs in innovative and thoughtful ways. USP's drug information and reporting programs are now concluded, but many live on, having been taken up by other groups, including the Federal government. USP regrets the termination of these programs, but acknowledges their remarkable success—created at times when national approaches were uncertain. They paved the way for more concrete action by others. Their legacy lives on the Patient Safety Organizations now building and in many other ways as well.

Model Guidelines

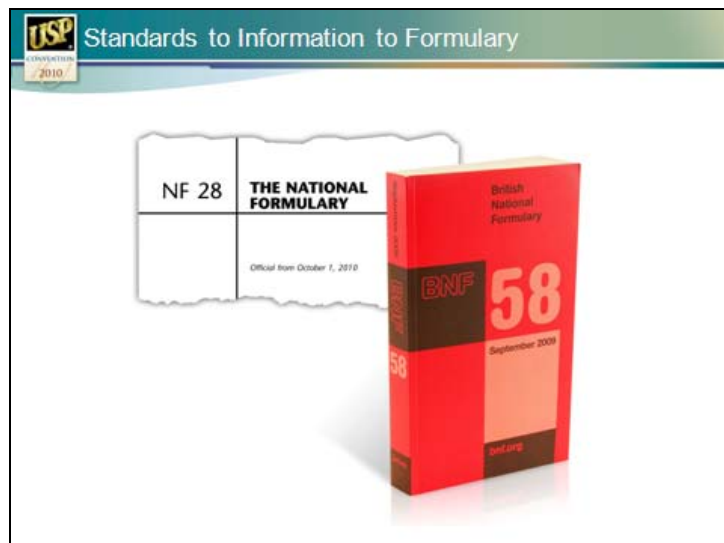


Model Guidelines

Model Guidelines and Formulary Key Drug Types V 4.0

Therapeutic Category	Pharmacologic Class	Formulary Key Drug Types
Analgesics	Nonsteroidal Anti-inflammatory Drugs	
	Therapeutic Category	Opioid Analgesics, Long-acting Opioid Analgesics, Short-acting
Anesthetics	Local Anesthetics	
Antibacterials	Aminoglycosides	
	Beta-lactam, Cephalosporins	Cephalosporin Antibacterials, 1st Generation Cephalosporin Antibacterials, 2nd Generation Cephalosporin Antibacterials, 3rd Generation Cephalosporin Antibacterials, 4th Generation
	Beta-lactam, Penicillins	Amino Derivative Penicillins


USP was honored to be requested by Congress under the Part D provisions of the Medicare Modernization Act to help assure beneficiary access through creation of Model Guidelines. USP's Model Guidelines are now in Version 4.0 and are used by the Centers for Medicare and Medicaid Services as part of a suite of voluntary standard used in yearly evaluations of drug plans offering the Part D benefit. USP will now work shortly, at the beginning of the 2005-2010 revision cycle, on Version 5.0 to the Model Guidelines. USP acknowledges the remarkable work of the Council's Model Guideline Expert Committee beginning in 2004 and in subsequent years. Some of the solutions arrived at in the Committee's work not only protected beneficiary access but also avoided situations where only one drug would be in a particular category and class. This possibility might have added to cost and was solved through creation of a third category termed Formulary Key Drug Types.



USP's work on Model Guidelines is a potential re-entry into the world of standards for drug information and drug information itself. In this view, the Model Guidelines themselves create a

table of contents for information about the drugs that fit within its framework, and standards to support this additional information could be created as well.

In Summary—Other Programs




Strategic Plan: Other Programs

- ▶ **What's Going On Now**
 - Reduction in Practitioner Programs
 - Model Guidelines
- ▶ **What's Possible**
 - Enhance Practitioner Standards
 - Voluntary Consensus Standards-setting Body
 - Drug Standards, Drug Information, 'National Formulary'

Operate Nationally and Internationally

Via the Board of Trustees strategic plan, USP encourages to work both nationally and internationally to promote availability of standards to assure good quality and beneficial food and drugs. With this directive, USP embraced its international opportunities with enthusiasm and commitment. Some of this change was begun in response to the amplified availability of drug products into the US from overseas, a change arising as non-US manufacturers learned the intricacies of the U.S. regulatory processes. Some arose because of USP's interest in partnering countries with increasingly strong capability in manufacturing for food and drugs. And some arose because of concern for counterfeit and substandard medicines. In earlier years, USP was a visitor to many countries overseas. Then through careful Board decision-making, we expanded with creation of sites now five continents, including North America.



Regionalization

		USP World Region								
		North America	Latin America/Caribbean	West Europe	East Europe (CIS)	Middle East, North Africa (MENA)	Sub-Saharan Africa	South Asia	East Asia (Pacific)	
		USP Headquarters	USP Brazil Site	USP India Site				USP India Site	USP China Site	
Partners										
U.S. FDA International Offices		HQ-Maryland	Costa Rica, Mexico, Chile	Belgium, U.K., Italy	HQ-Maryland	HQ-Maryland	HQ-Maryland	India	China	
Ministries of Health/Regulatory/Regional Authorities		Agreement-Health Canada	MOU-PANU/WHO	MOU-NBSC	MOU-Russia Rosdravnadzor	MOU-Jordan FDA	African NET Ref. Std. & Harmon. Initiatives (Develop.)	Infrastructure Agreement: Andhra Pradesh	MOUs: China: NCPSP; Singapore: HSA; ASEAN: RSWG	
Official Medicines Control Laboratories (OMCLs)		FDA	PANDRH				African Med. Quality Control Lab Network		MOUs-China & Provincial Municipal Agencies	
Pharmaceutical Commissions			MOU-Mexico	Council of Europe/EDQM				MOU-India	MOU-China; MOU-Vietnam	
Manufacturers		Stakeholder Forums, Advisory Groups	MOU-Sindusfarma SH Forums	Stakeholder Forum			WHO prequalification	India Advisory Group, SH Forum	China Advisory Group	
Activities		<ul style="list-style-type: none"> • Convention Membership/Observer • Agency (MOU, Outreach, Standards) 			<ul style="list-style-type: none"> • OMCLs (MOUs, Outreach, Standards, Proficiency, Accreditation) • Annual Scientific Meetings 		<ul style="list-style-type: none"> • Stakeholder Forum • Advisory Groups • Marketing & Sales 		<ul style="list-style-type: none"> • USAID Program • Verification • Education/Training 	

Moving beyond even this intensive activity, USP began a set of activities in USP-defined regions. Most countries of the world do not have pharmacopoeias, and in these countries USP offers its documentary and reference material standards as a public good. In countries where pharmacopoeias exist, USP works as a partner and collaborator through formal and informal agreements. The posters in the visitors hall in the Convention center give a glimpse of how USP's works in our eight regions of the world. I encourage you to view them at your leisure over the coming several days. USP's home base is North American region defined with only two countries--the United States and Canada. USP values its relationships both with FDA and with Health Canada and has especially appreciated the opportunity to strengthen relations with FDA in the 2005-2010 revision cycle. New opportunities are arising as well with Health Canada, and USP looks forward to advancing these in the coming cycle.



And just as we stood at the brink of a beautiful new building in Rockville at the close of the last cycle, we stand now at the brink of a beautiful new building in Hyderabad at the close of this cycle, which the USP Board of Trustees resolved to construct at one of its closing meetings of the cycle. Ground-breaking occurred in February 2010 in Hyderabad, and we expect to occupy this building in about a year. In some sense, USP's overseas sites could have been built in the U.S., but USP chose far-distant countries for its sites as to better reach out to global manufacturers and compounding professionals, our partner pharmacopoeias, regulatory and other conformity assessment bodies, and patients and practitioners. In some ways this work has just begun, through our regionalization efforts, but it promises to bring USP's greatest growth and opportunities in coming revision cycles—as we work to partner in countries across the globe in advancing optimal public standards and assuring good conformity assessments to them—by first, second, and third parties.

In Summary—Operate Nationally and Internationally

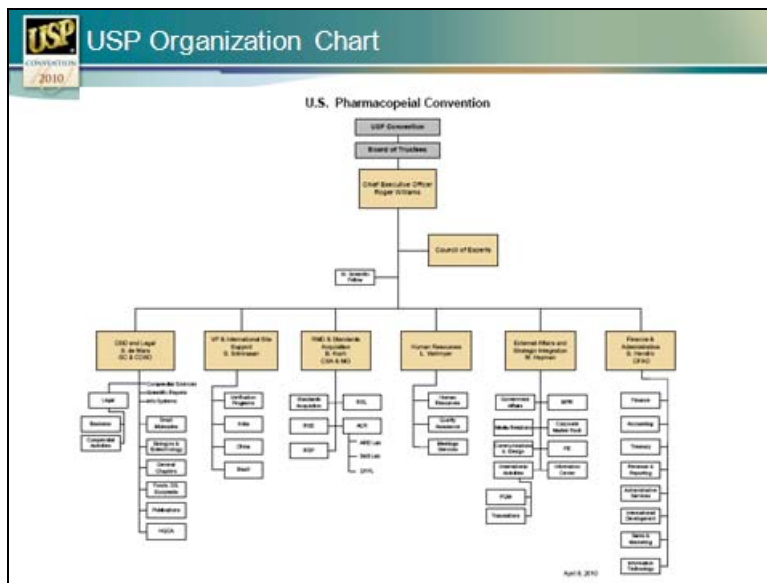
USP Strategic Plan: Work Nationally/Internationally
CONVENTION 2010

- ▶ **What's Going On Now**
 - International Sites/Hub
 - Regionalization
 - Harmonization (PDG)
 - Strengthen Global Links: WHO, BIPM, Codex
- ▶ **What's Possible: Drugs**
 - Strengthen MOUs
 - Global Harmonization
- ▶ **What's Possible: Foods**
 - Build Reference Materials for Food Ingredients
 - Add Translations

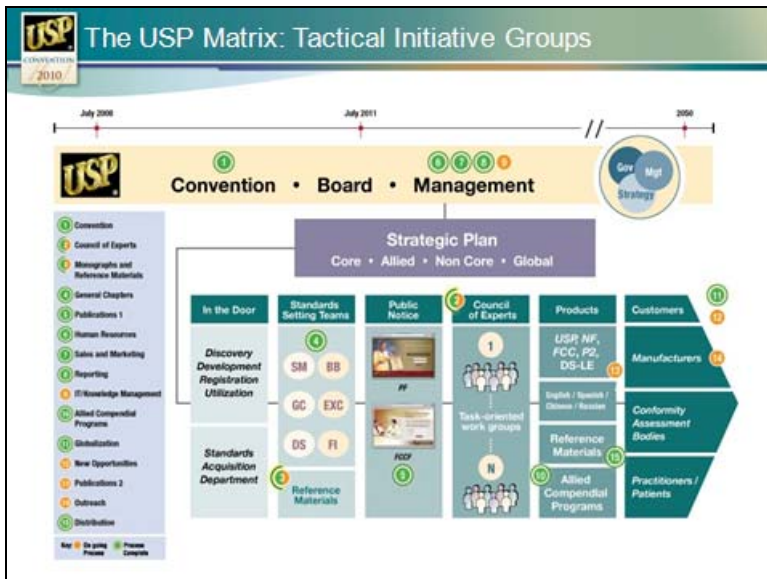
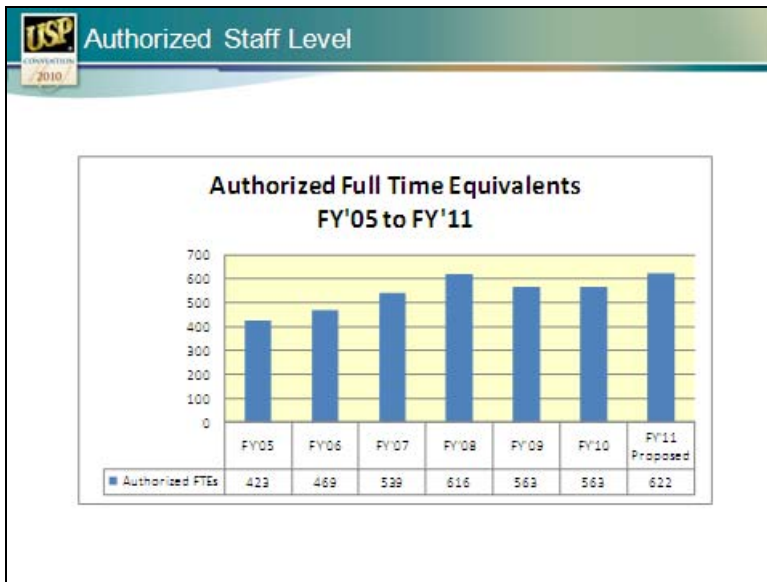
Manage USP Programs, Products and Services Efficiently and Effectively

Staff

Sixty years ago, this part of my presentation would have been easy. It would have been given by Lloyd Miller, and he would have talked about himself—as the sole staff member of USP.



Over the past sixty years, the growth of USP’s staff has been impressive, with projected staffing in our fiscal year 2011 possibly at over 600. But of course these numbers don’t tell the whole story. What is much more important is that USP’s staff is now highly skilled and international in character—probably one of the most diverse and talented group of experts I have ever seen. And their skills sets are enormous, including language skills. USP staff members are fluent in over a dozen languages—and for many of them their first language is not English.



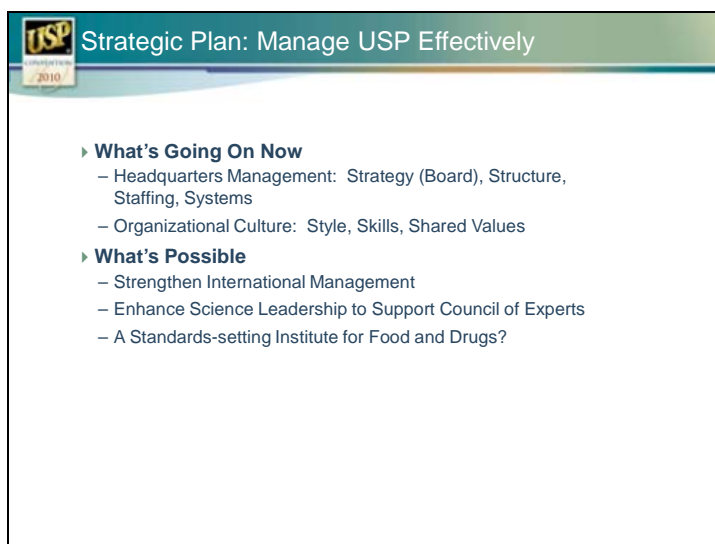
Beyond growth of USP staff, USP was required to change its structure, staffing, and systems to advance the Board's directives in its Strategic Plan. This is a multiyear effort that has many ramifications so that even now, at the close of the 2005-2010 revision cycle, much remains to be done. But great progress has been made in our rules and procedures, our finance and accounting practices, and our human resource commitments. And equivalent work is underway for our quality assurance, information technology, marketing and sales, external affairs and strategic integration, and other key management areas.

Further, USP now works in a highly matrixed way that depends on optimizing organization culture, strengthens cross-functional communications, values a lessons-learned approach, and builds high performing teams wherever needed.



In May 2009, USP purchased 2.2 acres of land adjacent to USP Global Headquarters in Rockville, Maryland to allow future expansion opportunities of up to 150,000 square feet of space. Pending formal utilization, the site was refurbished to provide additional parking and a setting for employee events until it is used for expansion.

In Summary—Manage USP Effectively



Close

As I close my CEO presentation, I turn now to you, the delegates to the USP Convention as well as observers and other guests. Our time as leaders of the USP Convention in the 2005-2010 cycle is coming to an end, but your work now is just beginning. Shortly you will hear a report from the Resolutions Committee so that you can conclude Resolutions to guide us in the coming years. You will then select a new Board of Trustees and a new Council of Experts, and you may choose to amend our Constitution and By-laws. As you ponder these decisions, please understand the value of public standards and know that achieving them is fraught with difficulty.

The public monograph with allied reference materials is our core activity from which all else stems and on which USP's mission is based.



At the close of my CEO presentation at the 2005 Convention, I spoke of Greek temples where Athenian democracy flourished two thousand years ago.



Some of these temples were the motivation for the Spalding Conference Room, which now exists. In some ways, USP is stronger and more committed to serving practitioners, patients and consumer than ever before. We think of the Golden Age in Greece as a time when the voice of the people could be heard in the Athenian forums. USP is like that—we are a forum where different voices can be heard, where dissent can be raised, and understanding can progress. We are stronger now, yet perhaps somewhat vulnerable, because the strength and value of a public forum can be harmed either knowingly or unknowingly. We need your knowledge and wisdom to move forward, and your time is now.