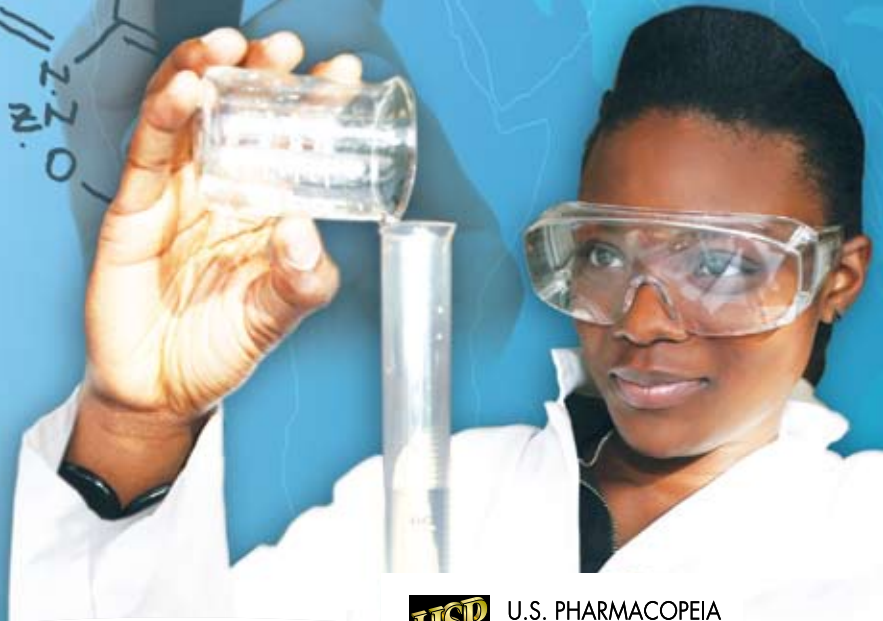
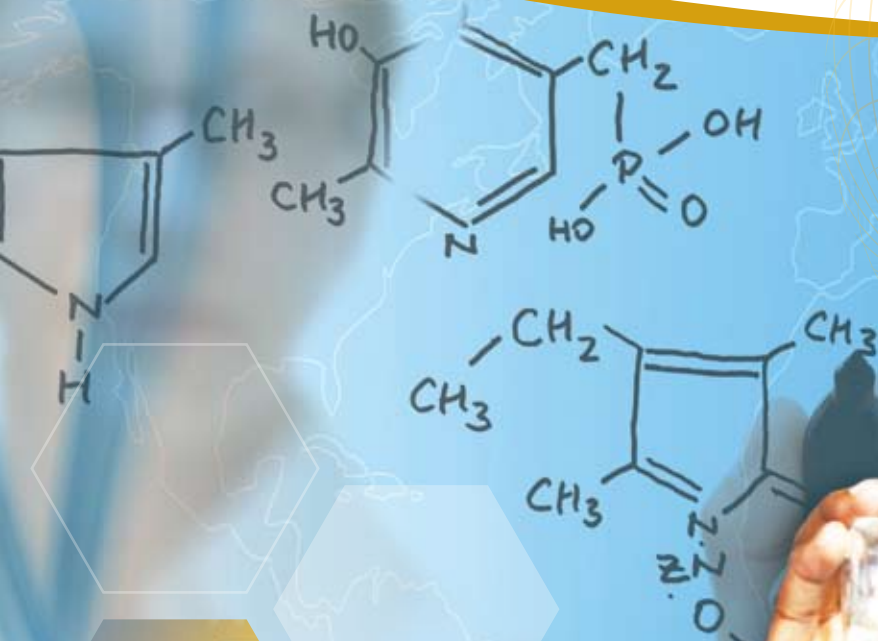


The U.S. Pharmacopeial Convention Strategic Plan



U.S. PHARMACOPEIA
The Standard of QualitySM

QUALITY STANDARDS FOR MEDICINES, SUPPLEMENTS, AND FOOD INGREDIENTS THROUGHOUT THE WORLD

Dear USP **Stakeholder:**

It is a great honor to present to you, our stakeholders, the strategic plan of the United States Pharmacopeial (USP) Convention. This plan serves as a roadmap for USP and describes how the organization will pursue its vision to improve the health of the citizens of the nation and the world by advancing public standards and related programs that help assure high quality, safe, and, where appropriate, beneficial medicines and foods.

This strategic plan includes five key components that form the foundation for USP's activities as the organization prepares to enter the 2010-2015 cycle:

- **Expand** and enhance USP's core compendial activities—the provision of documentary standards and reference materials;
- **Build** and strengthen USP's allied compendial programs—programs that promote development of and access to high quality medicines and foods and build upon USP's core compendial activities;
- **Engage** in other programs that leverage USP's unique capabilities to fulfill the public health needs of its constituencies and support USP's vision and objectives;
- **Operate** both nationally and internationally to help improve the quality, safety and benefit of medicines and foods worldwide; and
- **Manage** all USP's programs, products and services efficiently and effectively to maximize their impact.

Critical to this plan and the achievement of USP's vision are the volunteer scientists and healthcare professionals who form the chairs and members of the Council of Experts and its Expert Committees. These volunteers make the scientific decisions for USP's compendia — the *United States Pharmacopeia*, the *National Formulary*, the *Food Chemicals Codex*, and allied publications — and accompanying reference materials. They assure that USP's compendial activities and other public health programs proceed in the most rigorous, scientifically-defensible way, through an open and transparent public process with strict safeguards against conflicts of interest. Equally critical are USP's Convention members, who support and promote USP's mission and reflect USP's values and character as a practitioner-based organization. These volunteers and members are supported by a dedicated staff working in USP's headquarters in Rockville, Maryland and in sites outside the United States including Europe, India, China, and Brazil.

USP's compendial and other public health programs are proven avenues through which USP can help improve the quality, safety and benefit of medicines and foods, and benefit practitioners, patients and consumers in the United States and throughout the world. This strategic plan will guide us in advancing these important programs, and will provide a springboard for USP's work in the future.

The USP Board of Trustees
September 2008

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VISION

USP envisions a world in which all citizens have access to high quality, safe and beneficial medicines and foods. USP approaches this vision with a sense of urgency and purpose, strengthened by its cadre of dedicated and expert volunteers, members, and staff, and working collaboratively with key stakeholders across the globe.

MISSION

To improve the health of people around the world through public standards and related programs that help ensure the quality, safety, and benefit of medicines and foods.

Sustaining Principles

To ensure USP's ability to continue to promote and serve the public health, USP will:

- **Honor** the contribution and dedication of USP volunteers by striving for scientific excellence and rigor in the development of public standards and all its activities.
- **Maintain** its legacy as an independent, self-supporting, practitioner-based organization.
- **Adhere** to established principles and policies that ensure USP's impartiality and objectivity and support its open, transparent, and participatory processes.
- **Foster** an environment of professionalism, collaboration, and mutual respect among volunteers, members, stakeholders, and employees.
- **Undertake** strong stewardship by operating on sound business practices with fiscal prudence and management discipline.



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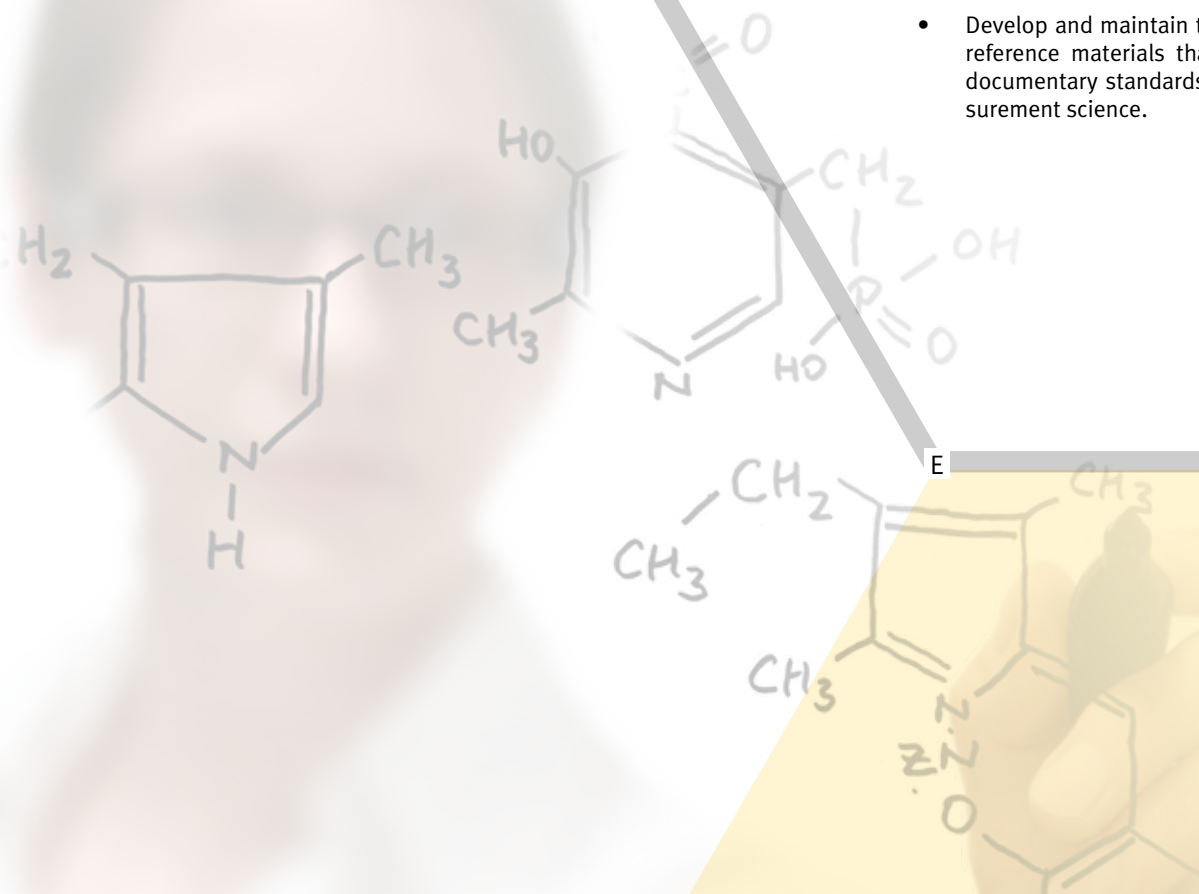
Strategic Plan

To achieve its vision in concert with its sustaining principles, USP will implement a strategic plan containing five main elements.

Expand and Enhance USP's Core Compendial Activities

To increase the availability of public standards that will help ensure the quality, safety, and efficacy of medicines and the quality, safety, and, where appropriate, benefit of foods, USP will:

- Create comprehensive, relevant and timely documentary standards for medicines, dietary supplements and corresponding traditional medicines, food ingredients and other articles, revising these standards as necessary to account for new products and ingredients, new analytical procedures and methods, and new opportunities arising from the advance of science.
- Develop and maintain the quality and availability of reference materials that support new and revised documentary standards based on advances in measurement science.





Engage in Other Public Health Programs that Fulfill Unmet Needs and Leverage USP's Unique Capabilities

For USP to have the greatest public health impact, its compendial programs and services must take priority and receive the resources needed to achieve their purpose and potential. To complement these programs and services and further advance USP's vision, USP will:

- Monitor advances in science and technology and other changes in the healthcare environment.
- Engage continuously with stakeholders in order to identify unmet public health needs where USP can make an important contribution.
- Leverage USP's unique strengths and capabilities to respond to needs of USP's constituencies.
- Undertake activities outside the compendial area that are expected to have a strong public health impact and are synergistic with compendial programs and services.

Build and Strengthen USP's Allied Compendial Programs

To promote the effective use of quality public standards worldwide and encourage compliance with such standards, USP will:

- Develop, strengthen, and deliver relevant and timely pharmacopeial education programs that assist manufacturers, compounding professionals, practitioners, regulators, patients and consumers in understanding and implementing USP standards.
- Establish and expand verification programs that will provide assurance to manufacturers, regulators, practitioners, patients and consumers that products and ingredients consistently meet optimal quality standards.
- Provide technical assistance, training, and other programs in developing countries to help improve the development, registration, and utilization of medicines and foods and their ingredients in such regions.
- Support anti-counterfeiting programs and other efforts that help ensure the quality, safety and benefit of medicines and foods in commerce in the United States and in other countries around the world.

B





Manage All USP Programs, Products and Services Efficiently and Effectively

To ensure that USP's programs successfully fulfill their important public health goals and at the same time assure the organization's sustainability, USP will:

- Ensure that its core compendial activities continue to be self-sustaining, reinvesting in such activities where necessary to strengthen and expand them to achieve the greatest public health benefit.
- Invest in allied compendial programs, recognizing their value in promoting the use of public standards to improve the quality, safety and benefit of medicines and foods, while seeking grants and other third-party funding to allow expansion of such programs domestically and in developing countries.
- Engage in programs outside of the compendial area that are self-sustaining or fully supported by independent sources of revenue consistent with USP's mission and vision.
- Engage in fiscally responsible decision making consistent with USP's existing financial commitments, investment policies, and budgetary goals.

Operate Both Nationally and Internationally to Maximize the Public Health Benefit of USP's Programs and Services throughout the World

To fulfill its commitment to improving quality worldwide, USP will:

- Seek ways to work effectively throughout the world while maintaining its relevance and importance to, and fulfilling its historical role and responsibility in the United States.
- Partner in a collaborative spirit with industry, pharmacopeias, regulators, practitioners, patients and consumers in the United States and abroad to help accelerate the mutual development of public standards, build and strengthen local capabilities and infrastructure, and improve the quality of products used domestically and exported.
- Seek opportunities to customize and deliver its compendial programs and services to best meet the needs of individual countries and regions, focusing in particular on developing countries where local resources and capabilities are most constrained.
- Establish facilities and sites in other countries and regions as appropriate to expand USP's presence and enable it to work more closely and effectively with key stakeholders in such countries and regions to improve the quality of medicines and foods.
- Build and expand relationships with domestic and international organizations and other stakeholders to identify potential areas of collaboration to further shared public health goals.

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USP and **the Path Ahead**

When its journey began nearly two centuries ago, USP was committed to utilizing the most current scientific knowledge to improve the public health through the promulgation of public standards. That same commitment holds true for USP today—in fact, it is stronger than ever before. USP has a recognized responsibility to provide public standards for medicines and foods, and our history calls us to be true to that core mission. The importance and relevance of USP as an independent standards-setting compendial body is increasingly important in today's global marketplace, where patients and consumers may have access to medicines and foods of undocumented safety and effectiveness, and uncertain or even fraudulent quality.

The stewardship of this organization brings a responsibility that is both broad and deep, but one we shoulder with enthusiasm and determination. We approach the path ahead with confidence, and we are energized by the commitment and the caliber of USP's volunteers, members, and staff who symbolize USP's legacy of contribution.



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