200 years of building trust

Proposed Resolution 15

Impact Expansion

Resolution white paper developed by USP staff, with input from the Council of the Convention

200 usp The standard of trust | Convention The 2020 Meeting

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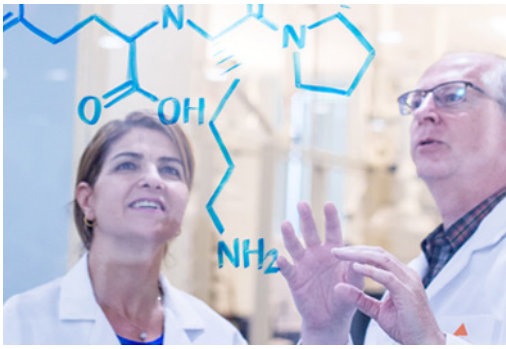
Impact Expansion

USP will expand its public health impact by reaching more people in more geographies with USP standards, capability building, and advocacy.

Summary

When USP was founded, and throughout much of its early history, the organization focused primarily on medicines quality in the United States. Today, the increasingly global nature of medicines development and production, economic development, and expanding health systems around the world has created numerous opportunities to help advance patient safety, public health, and access to quality medicines in nearly every part of the world. One of USP's greatest impact opportunities is to further harness and leverage its 200 years of commitment to, and investment in, robust, science-based quality standards for the benefit of people wherever they live, whether in the United States or elsewhere in North America, Latin America, Asia, Africa, or Europe. This Resolution proposes that USP apply its capabilities proactively, intensively, and in collaboration with public agencies and stakeholders, to help advance patient safety and public health worldwide.

Background

At its founding 200 years ago, USP's mission was to help ensure that safe, quality-assured medical products were available in the United States. Over time, and increasingly for the past 10 years, USP has invited

dozens of government, industry, practitioner, and consumer groups from outside the United States into the USP Convention. In addition, the composition of USP's standards-setting Expert Committees has become more global. Through this combination, USP has made important strides forward in integrating the global healthcare community into the framework of USP's governance and standards-setting mechanisms. Today, as part of a global community, USP has broadened its mission to encompass improving global health through public standards and related programs that help ensure the quality of medicines. This expanded mission will be accomplished through USP standards, capability building, and advocacy.

USP's achievements include modernized quality standards for medicines that benefit patients around the world. As part of its modernization efforts, USP relied on research that examined the World Health Organization (WHO) Model List of Essential Medicines and identified those medicines lacking public quality standards.[1] Informed by these data, *USP-NF* includes greater coverage of medicines on the WHO list, and the organization has established a mechanism by which to prioritize monograph revision or development for high-burden medicines. Additionally, USP has developed and deployed education and training programs to expand the capability of regulators, industry, and others to optimize the impact of USP standards. USP has invested in both laboratory capacity and collaborative efforts with government and industry in countries on every continent; more than 30 percent of USP staff are based in locations outside the United States. In addition, USP has implemented U.S. Agency for International Development (USAID)-funded programs, including the Promoting the Quality of Medicines (PQM) program. Through these programs USP has worked with regulators and industry in nearly 40 countries over a 26-year period. USP has also launched research initiatives to help inform public policy and regulatory policy making, and USP forms coalitions of stakeholders to raise awareness and increase urgency and political will to invest in regulatory systems and policy reforms to help ensure the quality of medicines. These steps have positioned the organization to build global perspectives and insights as well as incorporate global expertise into its work, which allows USP to expand its impact significantly around the world.

A Brief History of USP's Impact Expansion

USP's presence as a key actor in the global health community is not new. International demand for USP's reference and documentary standards increased dramatically at the end of the 20th century. In 1969, USP standards were recognized in 27 countries, serving as the sole standard in Costa Rica, El Salvador, and Panama. By 1990, the list of countries officially recognizing the *U.S. Pharmacopeia–National Formulary* (*USP–NF*) had risen to 46. From 1995 to 2000, the Convention also reached agreements with the pharmacopeias of Argentina, Brazil, and Mexico to adopt and adapt USP standards. These initiatives served to build relationships with other agencies and enhanced awareness of USP as a global leader in quality standards. Since 2000, USP has expanded its impact by creating its global sites, establishing modern translations of *USP–NF*, developing and formalizing multiple alliances with collaborator organizations, and launching a globally accessible digital platform for *USP–NF*, among other activities.

- ***Modern Translations of* USP–NF:** Almost a century after the first *USP* Spanish translation, USP resumed its translation efforts and began publishing an official, annual *USP–NF* Spanish Edition in 2005. In 2009, a Russian edition of *USP 29–NF* 24 was published. While not official or intended for regulatory compliance, the translation is a useful reference for the growing Russian pharmaceutical industry. A new effort has just begun to translate a more recent version of the *USP–NF* into Russian and keep it current. USP has also started working on Chinese translations of the *USP–NF*.

- ***Alliances:*** Throughout its history, USP has had strong relationships with international bodies, pharmacopoeias, and regulatory authorities in many countries (for more information about these relationships and USP efforts, review the white paper on the proposed Resolution, Pharmacopeial Cooperation and Convergence). USP has advanced these relationships by jointly hosting annual science meetings and symposia in various parts of the world. These meetings facilitate the exchange of scientific information and strengthen collaborative relationships. Since 2000, USP has partnered with organizations to host meetings and stakeholder forums in India, China, Latin

America, the Middle East, and North Africa. Formal agreements signed with standards-setting groups, government agencies, and industry organizations in 2008 and 2009 have solidified these partnerships, fostering collaboration in the development of standards, verification activities, training, and visiting scientist programs.

- ***Investing in Laboratory Infrastructure:*** In 2000, USP implemented the USAID-sponsored Drug Quality and Information (DQI) program, focused on improving the quality of medicines and their appropriate use in resource-limited countries. It concentrated on malaria, HIV/AIDS, and tuberculosis in Latin America, Africa, and Asia, working with national governments and global agencies to combat counterfeit medicines. The first Official Medicines Control Laboratory (OMCL) Network—the External Quality Control Programs (EQCP) network—was created in 2001 through the collaboration of USP, the Pan American Health Organization (PAHO), and OMCLs from Latin American and Caribbean countries.
- ***Promoting the Quality of Medicines (PQM) Program:*** In 2009, USP was awarded a five-year $35 million USAID grant to support a new expanded program that transitioned DQI efforts and resources into the PQM program. PQM's focus was to strengthen medicines quality assurance systems, combat substandard and counterfeit medicines, and support global efforts to improve public health. PQM supports the prevention of substandard and counterfeit medicines by developing monographs, providing collaborative testing, and offering technical assistance in the form of reference standards, documentary standards, and training. PQM has helped communities in more than 35 countries in Africa, Asia, Eastern Europe, and Latin America.

Expanding Impact

USP's efforts have grown consistently in response to increasing complexities and risks in global health. USP now has in place an infrastructure that allows the organization to work with both local stakeholders and global entities to leverage its capabilities to help protect patient safety and public health around the world. These capabilities include:

- Formation of a matrixed leadership structure using the best of both a global, centralized approach to function and a decentralized, regional leadership for collaboration and execution;
- Recruitment of locally based staff to engage with regulators, practitioners, and industry concerning local needs and public health priorities;
- Establishment of USP as an officially recognized nongovernmental organization in multilateral forums including the Asia-Pacific Economic Cooperation

USP 2025 Impact Strategies

Standards:

USP will continue to be a definitive source of medicines quality standards using several new strategies

- Remain up-to-date
- Adopt a more flexible, agile, and iterative approach to standards development and delivery
- Address new and emerging therapeutic classes, including biologics and biosimilars.

Capability Building:

USP will be a leading provider of services that are essential to improving patient access to quality medicines

- Collaborate with regulators
- Provide training for industry
- Engage practitioners
- Facilitate adoption of new technologies

Advocacy:

USP will be a global institutional leader advancing medicines quality

- Generate and disseminate evidence
- Build trust in USP standards
- Integrate USP standards into frameworks for biomedical innovations and emerging areas of medicine

(APEC), New Partnership for Africa's Development (NEPAD), PAHO, WHO, and as well as collaborations through Memorandums of Understanding with most of the major pharmacopeias and regulatory agencies in the world;

- Geographically expanded training and education platforms to reach stakeholders on every continent;
- Implementation of the Promoting the Quality of Medicines Plus (PQM+) program funded by USAID, which will expand the capabilities of governments and manufacturers in low- and middle- income countries around the world.

USP Will Be a Definitive Source of Quality Standards

USP will expand its impact by continuing to work with regulators, sharing its legacy of scientific expertise to support local regulatory efforts and build confidence in USP standards among regulators (to learn more, please read the papers on Efficiency in Standards Development and Revision and Collaboration with FDA and Other Stakeholders on Health Priorities). Additionally, USP will work toward greater convergence in public quality standards (to learn more, please read the paper on Pharmacopeial Cooperation and Convergence). USP will also prioritize new or revised standards that meet stakeholder needs or address medicines quality issues where people are most at risk; these may include performance standards for biologics or standards for antibiotics and vaccines, among others (to learn more, please read the paper on Access to Biologics). Finally, USP will strive to ensure that its standards remain up-to-date and will encourage and support the use of innovative technologies such as new analytical methods for improving the quality of medicines (to learn more, please read the papers on Innovation and Digital Transformation of Standards). USP will develop and revise standards in a manner consistent with the best scientific knowledge available through increasingly global and flexible networks of expertise (for more information, please read the paper on Quality Standards). By taking a more flexible, agile, and iterative approach to standards development and delivery, USP can deliver standards that are fit-for-purpose in more geographies, in an efficient manner, and responsive to the needs of USP stakeholders (to learn more, please read the paper on Culture of Excellence).

USP Will Be a Leading Provider of Services That Are Essential to Improving Access to Quality Medicines

Another way USP can impact more people is as a leading provider of services that are essential to improving medicines quality. This involves collaborating with regulators, providing training for industry, engaging practitioners, and facilitating the adoption of new technologies. USP offers unique and tailored education and training programs to students as well as stakeholders in industry and regulatory agencies worldwide (to learn more, please read the paper on Education and Training for Industry and Healthcare Practitioners). Trainings are available in person and through multimedia digital platforms. USP also provides direct support to governments in countries around the world to build regulatory and quality assurance systems. For example, USP works with governments and regulators in low- and middle-income countries through APEC and the USP Center of Excellence for Securing Medicines Quality Across the Supply Chain (to learn more, please read the paper on Regulatory Systems Strengthening).

USP Will Be a Global Institutional Leader Advancing Medicines Quality

As a global organization focused solely on advancing patient safety, public health, innovation, and access to quality medicines through science-based standards, USP is uniquely positioned to lead and convene stakeholders around medicines quality. In doing so, we support stakeholders around the world by helping make the broader community mindful that the quality of medicines is foundational to healthcare and requires focused financial and human resource investments and prioritization among policy initiatives. USP brings together stakeholders in coalitions to advocate for policies that will ensure patient access to quality medicines in the United States and around the world (to learn more, please read the paper on Coalition Building). In addition, as a science-based and mission-driven organization, USP generates evidence that can help policy makers and regulators worldwide make informed decisions about investments and policy reform (to learn more, please read the paper on Evidence Generation to Inform Policy). Finally, by leveraging digital media and other innovative forums, USP can build awareness and create a sense of urgency about quality in the interests of patient safety and public health.

Alignment with USP Mission

The complexities of our interconnected world impact patient safety and public health, both in the United States and abroad. The medicines supply chain for all countries is global, making adherence to science-based standards more important than ever. Patients, regardless of where they live, remain vulnerable to the safety risks of poor-quality medicines. With globalization has come shared societal public health risks that can accompany medicines quality challenges. An urgent example is antimicrobial resistance, driven partly by poor-quality antimicrobials. USP begins its third century ready to make a greater impact on public health than ever before. USP will accomplish this by leveraging its capabilities in collaboration with partners around the world, along with an expanded commitment to advance access to quality medicines. USP has the greatest impact on medicines quality when it brings together USP standards, advocacy, and capability building. By cultivating critical success factors that focus on people, continuous improvement, digital optimization, and investment and sustainability, USP will fulfill its mission and expand its impact to reach more people in more areas around the world.

Resource Assessment

Modest incremental investments required to supplement resources currently in place.

In the second half of the 2015–2020 cycle, USP invested in externally facing functions and staff on five continents, worked with stakeholders to identify needs, and has begun to implement programs to leverage USP's 200 years of investment and expertise in collaboration with, and in support of, stakeholders around the world. We will optimize this foundational investment to support medicines quality across the global supply chain for the benefit of patients and consumers around the world.

References and Notes

[1] Roth L, Adler M, Jain T, Bempong D. Monographs for medicines on WHO's Model List of Essential Medicines. Bulletin of the World Health Organization 2018;96:378–385. doi:http://dx.doi.org/10.2471/BLT.17.205807.