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Empowering a healthier tomorrow

We envision a world where all people have access to quality, safe and beneficial medicines and foods.

Every day, with a sense of urgency and purpose, we improve global health through public standards and related programs.



USP develops scientific standards that help ensure the quality and safety of medicines, dietary supplements and foods. Regulators, manufacturers, healthcare providers and consumers trust USP standards to help protect the public's health. Evolving through transformations in health and science, this quality infrastructure that began with USP's founding in 1820 is one reason why the US drug supply is among the safest in the world. USP standards apply to drug products sold in the US and are used in 140 countries, helping ensure the quality of medicines globally.

USP strives to create quality standards that:



Advance

public health and patient safety priorities



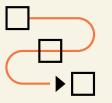
Are practical for

users and enforcers of standards



Are informed by

real-world implications for patients and practitioners



Are developed by

independent experts



Can be measured by

public health impact indicators



Adapt and improve

to keep pace with the evolution of technology and healthcare



Letter from the Board Chair and CEO

This has been a momentous year for USP as we continued the organization's long history of developing standards that help people trust the quality of their medicines, supplements and foods in the US and around the world.

In addition to our ongoing work to develop quality standards, we have been collaborating with a broad range of stakeholders to leverage our standards-setting process; advocate for policy change and provide technical assistance to help build capabilities to positively impact several urgent public health concerns, including the opioid crisis in the US, as well as the global challenges of substandard and falsified medicines, and antimicrobial resistance.

This year is the beginning of the countdown to the USP Convention meeting in May 2020. Every five years, the USP Convention meets, bringing together delegates from member organizations representing scientific and healthcare perspectives from the US and worldwide. Ever since 11 physicians came together in 1820 over concerns about patient harm from inconsistent medical preparations, this body has continuously met to guide our work. Convention members vote on resolutions that help guide the organization over the upcoming five-year period and elect the USP Board of Trustees and the Council of Experts—the group that oversees USP's standards-setting committees.

The year 2020 will mark an extraordinary milestone for USP – our 200th anniversary – and we have many exciting plans underway to recognize the organization's legacy and impact. We often wonder whether

those 11 visionary physicians who gathered in the US Senate to create USP nearly 200 years ago could possibly have imagined the legacy of trust they launched. Their passion for quality medicines has inspired generations of scientists, healthcare practitioners and others who volunteer their expertise to USP to help fulfill that legacy to this very day. Today, more than 750 of the world's best minds in science, healthcare and academia serve on numerous Expert Committees and panels to help develop USP quality standards. We are grateful for their service and hope their critical work inspires others to join us – we simply couldn't do this important work without them.

As we look forward to the 2020 USP Convention, we have launched our Call for Candidates to identify more scientific experts to participate in the standards-setting process for the next five years. If you are interested in opportunities to be a part of this work or know an exceptional candidate to recommend, we encourage you to find out more at usp.org/together.

It is our pleasure to share this report with you. We invite you to visit **usp.org** to learn more about the science behind our standards, our work as advocates for quality around the world and our collaborations to build capabilities essential to ensuring quality.





Susan C. Winckler, R.Ph., J.D.
Chair, Board of Trustees

6,000

More than **6,000 people** attended USP Education courses and workshops

140

140 countries used USP standards

9 in m

9 quality control laboratories

in Africa and Asia earned or maintained ISO accreditation, with technical assistance on testing methodologies and lab

management from USP's Promoting the Quality of Medicine Program (PQM), funded by USAID. Accredited quality control laboratories improve countries' capacity for improving medicines quality through post-marketing surveillance 2,000,000,000

2 billion people around the world have access to quality medicines, dietary supplements and food because of USP standards, advocacy and education

Received 480 donations of methods and materials, to serve as a basis for developing new quality standards

Released 81 new Reference Standards, bringing our current catalog to 3,755

Developed more than 486 new or revised documentary standards, bringing our total number to 6,788

185,000

More than **185,000 square feet of laboratory space** in five countries allow USP to develop and validate testing methods and Reference Standards, as well as offer training on the effective use of these standards



Advancing the science of quality

Scientific expertise and advancement are at the root of USP's work to develop quality standards and are the foundation of all our related activities and programs that help ensure the quality and safety of medicines, dietary supplements and foods around the world. Through the development of Reference Standards for specific ingredients, impurities and finished products, as well as our written standards for processes such as tests, procedures, and packaging and distribution, we set the standard for the science of quality.

CD34+ standard helps with lifesaving transplants

"When patients with leukemia or other conditions need a bone marrow transplant, treatment success depends on choosing a viable transplant sample with the right amount of blood stem cells to rebuild the patient's immune system. Because there are very few stem cells in bone marrow, getting an accurate count can be a challenge.

This year, we made refinements to a standard we had introduced in 2017 so that the testing procedure could be even more useful and impactful. This test relies on the measurement of a marker called CD34+, which is present on the surface of the stem cells. In addition to stem cell transplants, the test is used by researchers to measure stem cells in clinical samples as they work to develop new, lifesaving treatments. This standard helps patients get the most promising transplant of blood-derived stem cells - the very thing which could save their lives."



Fouad Atouf, Ph.D. Vice President, Science, Global Biologics



Protecting the quality of inactive ingredients

"Most people don't think much about excipients, which are considered the 'inactive' ingredients in medicine. But these are actually critically important to how well a drug works in the body, helping the pill hold together or allowing the medicine to be absorbed properly in the body. And poor-quality excipients can be a big risk to patients.

We recently published draft standards seeking comments from international stakeholders revising the standards for three types of saccharin. Today, saccharin is used to help make medicines - which would otherwise taste pretty bad - palatable for patients. It is also used as an excipient for medications delivered intravenously or by aerosol, which means it's critical to control impurities. This work is important because saccharin can contain harmful impurities that can develop during some manufacturing processes."



Catherine M. Sheehan, M.S., M.S. Senior Director, Excipients





Better access to USP standards

Launched a new platform for USP-NF Online, offering users a wide range of new functionalities so they can find what they need more quickly.



Improving testing for insulin

Published the first cell-based assay for insulin products, which provides an alternative to animal testing and aligns with USP's commitment to replace animal testing wherever possible. This major advancement is faster, less costly and more accurate and reliable than animal testing.



Quality of "inactive" pharmaceutical ingredients

Harmonized standards internationally for commonly used excipients, including glycerin, povidone, polyethylene glycol and several types of cellulose. Also known as inactive ingredients, excipients can harm patients if their quality is poor. This work supports the FDA's priority to help stakeholders select the appropriate excipient for intended use, as well as our work to harmonize standards with the European Pharmacopeia and the Japanese Pharmacopeia.



Addressing impurities in medicines

Introduced a new standard to control elemental impurities (also known as heavy metals) in medicines. This advanced technology replaces techniques that had been in use for more than 100 years and has tremendous impact for pharmaceutical manufacturing and medicines quality around the world.



Quality of over-the-counter products

Introduced several new and revised standards for over-the-counter products including those used for coughs and cold, pain relief, dental care and skin care through successful collaborations with our stakeholders, which include regulators and industry representatives.



Protecting the health of children and vulnerable populations

Introduced a new standard for the quality of multivitamin-multimineral powder to help improve the quality of products used around the world to help children and other vulnerable populations with anemia and vitamin and mineral deficiencies. Requested by UNICEF, the monograph covers 15 critical ingredients and will be used as its international standard.



Quality of compounded medications

Published proposed revisions to standards for sterile and nonsterile compounding for public comment. Millions of compounded medications are prepared by pharmacists and other healthcare practitioners to meet individual patient needs, and their proper preparation is important for patient safety.



Tackling new issues with food adulteration

Formed new Expert Panels to address critical quality issues related to dietary proteins and honey, which are particularly susceptible to economically motivated adulteration.

Building capabilities to strengthen systems that protect quality

USP supports the public health safety net, helping ensure the quality of medicines, dietary supplements and foods - from manufacturing to distribution to use by consumers. We facilitate the exchange of ideas and engage partners in discussing how poor-quality medicines impact the today's major public health threats. From providing training on planning and implementing risk-based post-marketing surveillance, to sharing best practices for protecting quality throughout the global supply chain, we help build the capabilities of manufacturing and regulatory systems around the world to improve medicines quality.

Improving medicines quality around the world

"Poor-quality and falsified medicines are a very serious public health threat in many parts of the world, delivering little or no therapeutic benefit to patients. Rather than getting better, patients can get sicker or die.

USP's work to improve medicines quality in low- and middle-income countries is born from the same reasons that this organization was founded nearly 200 years ago. For the past 10 years, we have been proud to be an implementing partner for the Promoting the Quality of Medicines Program, funded by USAID, and proud of the work we have accomplished. As this program draws to a close in 2019, we look forward to continuing this important work, building new partnerships with USAID and others to help patients everywhere have access to the quality medicines we all deserve."



Emily Kaine, M.D. Senior Vice President, Global Health



Helping protect the global supply chain

"Protecting the integrity of the global supply chain for medical products is critically important for medicines quality and public health around the world. This year, USP was endorsed as a Center of Excellence on Quality in the Supply Chain by the Asia Pacific Economic Cooperation (APEC). USP is working with medicines regulators from the APEC member economies to share best practices, standards and guidance for protecting the supply chain within these 21 economies that border the Pacific Ocean. As part of this work, USP held a series of stakeholder meetings in Asia that provided an opportunity to share the FDA's Roadmap for Supply Chain Integrity Toolkit, developed with USP and other partners to help APEC member economies strengthen their regulatory systems to improve medicines quality."



Katherine Bond, Sc.D. Vice President, International Policy and Regulatory Affairs





Making a difference in malaria

Lauded by the CEO of Ghana's FDA, Delese Mimi Darko. She credited USP-Ghana and technical assistance through USP's PQM Program – funded by USAID – as playing a significant role in reducing the prevalence of poor-quality antimalarial medicines from 30 percent in 2008 to 1.4 percent last year. USP-Ghana has provided quality systems training for over 300 regulators, manufacturers and academics from across the continent.



Responding to urgent global health needs

Helped gain WHO prequalification for praziquantel (an active pharmaceutical ingredient used to treat parasites) and capreomycin and amikacin solution (medicines used to treat tuberculosis), through our PQM Program, which is funded by USAID.



Workforce development in India

Introduced the new USP Training Institute in Hyderabad, India, which prepares recent university graduates and pharmaceutical professionals in India to contribute to a culture of quality in pharmaceutical manufacturing.



Quality medicines and the global health agenda

Awarded official relations status by the World Health Organization, became a Center of Excellence at the Asia Pacific Economic Cooperation organization and renewed official status with the Pan American Health Organization. USP also remains an official observer at the International Conference on Harmonization and has special consultative status with the United Nations Economic and Social Council.



Supporting quality medicines in China

Marked USP-China's 10th anniversary with a celebration in Shanghai, and with the 9th ChP-USP Joint Forum in Beijing, co-hosted with the Chinese Pharmacopeia – a leading international drug standards event.



Protecting healthcare workers

Introduced two programs to empower healthcare workers to best use USP standards related to compounding medicines and safe handling of hazardous drugs. Our new HazRxTM Mobile App helps healthcare workers quickly identify which drugs need special handling to help reduce health risks. We also trained more than 2,000 healthcare workers on USP's standards to help increase patient and healthcare worker safety.



Helping stakeholders with formulary benefits

Published the USP Drug Classification system (USP DC), which can be used to design, review or compare formulary benefits – the medicines that may be prescribed to patients within certain health plans. Updated yearly, the USP DC was developed in response to stakeholder feedback to the USP Medicare Model Guidelines, used by the Centers for Medicare & Medicaid Services to support its formulary to support Part D benefits as part of the Prescription Drug Improvement and Modernization Act of 2003.

avancing quality: our progress

Advocating for quality

Harnessing a broad coalition of diverse partners, USP advocates in the US and around the world for public policies that support the public health safety net.

From our work with partners raising awareness of the impact of quality, to generating evidence that can inform effective policymaking, to elevating the use of public quality standards as critical tools to advance worldwide progress on health priorities, USP uses our voice to help build a stronger public health safety net.

Generating data to inform policymaking on medicine quality

"This year, USP launched the USP Quality Institute, a new research and advocacy initiative developing evidence to support policy decisions related to medicines quality. In the past year, we have established two academic partners, at Georgetown and Boston Universities, and fellows have begun their first research projects.

These initial fellows are focused on demonstrating how poor-quality antimicrobials can create or accelerate resistance to important treatments such as antibiotics and antimalarials. In the coming months, we also will announce new academic partnerships and additional investigational thematic areas, expanding our efforts to develop an evidence base for why quality medicines matter."



Anthony Lakavage, J.D.

Senior Vice President, Global External Affairs and Secretary, USP Convention



Supporting the FDA's efforts to encourage new generics

"USP has a long history of developing quality standards that help more generic medicines get to the market. In 2017, the FDA began directing applicants for FDA approval of new generic medicines to reach out directly to USP to resolve any potential issues complying with USP quality standards. Through this Pending Monograph Program, USP facilitates new generics entering the market by accelerating revisions to existing USP monographs to ensure they include the applicants' specifications for their product. This helps ensure these new generics are in compliance with USP quality standards so they can be legally marketed in the US."



Elizabeth Miller, Pharm.D. Vice President, US Regulatory Affairs

Sincral year 2001

Raising awareness of poor-quality medicines

Launched the Medicines We Can Trust campaign to inspire collective action and unify a diverse and broad coalition of partners around the world to address this problem that puts millions of lives at risk, costs economies billions and undermines trust in health.



Poor-quality medicines and drug resistance

Urged nations to include steps to ensure medicine quality in antimicrobial resistance national action plans, including publishing an analysis of national action plans. As part of this advocacy, the WHO Bulletin, a leading peer-reviewed public health journal, published Medicines Quality Assurance to Fight Antimicrobial Resistance, authored by USP experts Jude Nwokike, Aubrey Clark and Phillip Nguyen.



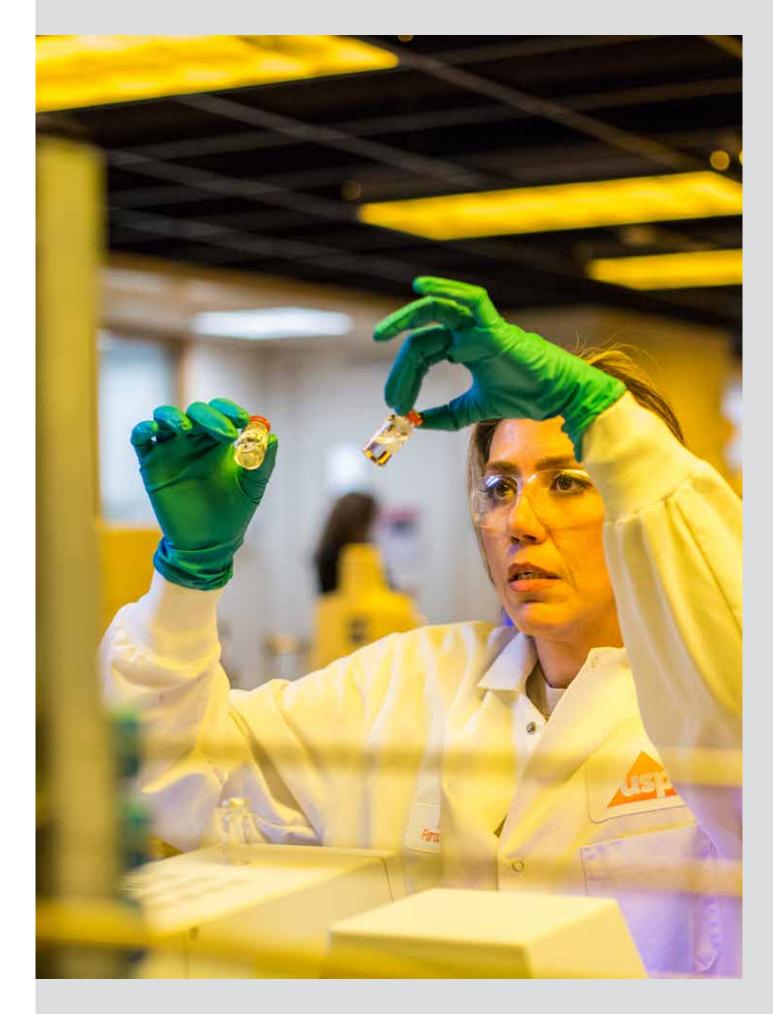
Advocating in the US for quality dietary supplements

Worked with partners in the Dietary Supplements Quality Collaborative, a multi-stakeholder group recently founded by USP to improve the quality and safety of dietary supplements. The Collaborative's white paper describing dangers to consumers of illegal products masquerading as dietary supplements identified key actions that stakeholders could take individually and cooperatively to help address this public health problem.



Working worldwide for quality dietary supplements

Continued our work with Brazil's health regulatory agency, ANVISA, including sharing information about ensuring the quality of dietary supplements and food ingredients as ANVISA formulated new dietary supplement regulations. Pharmacopeial standards have an important role in the agency's new guidelines for dietary supplements' quality, which recognize USP compendia within the new regulatory framework.



Exploring the future of quality

As science and technology continuously evolve, so must quality standards. This is as true today as it was when USP was founded nearly 200 years ago. In the 19th century, spectrometry was introduced as a new way to assess molecules, and was adopted into standards as the technology matured. Today, we continue to explore new technologies to consider their potential implications for quality standards.

Our collaborations with a diverse set of organizations, academics and researchers are key to USP's work envisioning the future of quality including exploring the quality implications of new approaches, such as 3D printing of medicines, continuous pharmaceutical manufacturing, and digital therapeutics that use software as therapy.

Bridging from batches to continuous manufacturing

"The pharmaceutical industry is beginning to adopt continuous manufacturing approaches, which promise to improve flexibility and efficiency, compared to traditional 'batch' manufacturing methods. Of course, new technologies bring new quality challenges. USP is collaborating with experts from academia and industry to best understand the implications on medicines quality of this complex manufacturing approach.

That's why USP launched our Pharmaceutical Continuous Manufacturing Initiative this year - to help ensure the quality of medicines that are manufactured in a continuous process, as this approach becomes more broadly adopted by industry."



Jaap Venema, Ph.D. Chief Science Officer and Chair, Council of Experts



Exploring quality needs for new technologies

"Exciting new technologies are creating treatment options for patients with certain conditions - such as attention deficit hyperactivity disorder and substance dependency - that are based entirely on software. This means that instead of taking medicine, a patient can interact with an app on his or her phone or tablet to achieve positive clinical outcomes. The FDA has recently approved several of these digital therapies, which treat substance use disorders, type 2 diabetes, respiratory disease, schizophrenia and other chronic conditions.

Along with the Digital Therapeutics Alliance, we co-hosted a roundtable discussion with USP experts and leading companies in the digital therapeutics field. Through this convening and our ongoing work, we are exploring the meaning of quality in the context of these therapies and how quality standards can be applied to digital therapeutics."



Michael Levy Vice President, Head of Quality Institute, Head of Research & Innovation

Exploring the future of quality



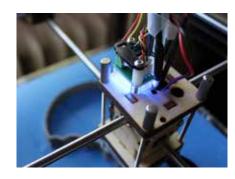
DNA for dietary supplements standards

Assessing the use of DNA identification techniques for herbal dietary supplements to determine the technology's potential to identify material from particular plant species. This approach could be used together with other analytical methods to ensure the composition of herbal dietary supplements, and potentially others types of supplements, such as probiotics, in the future.



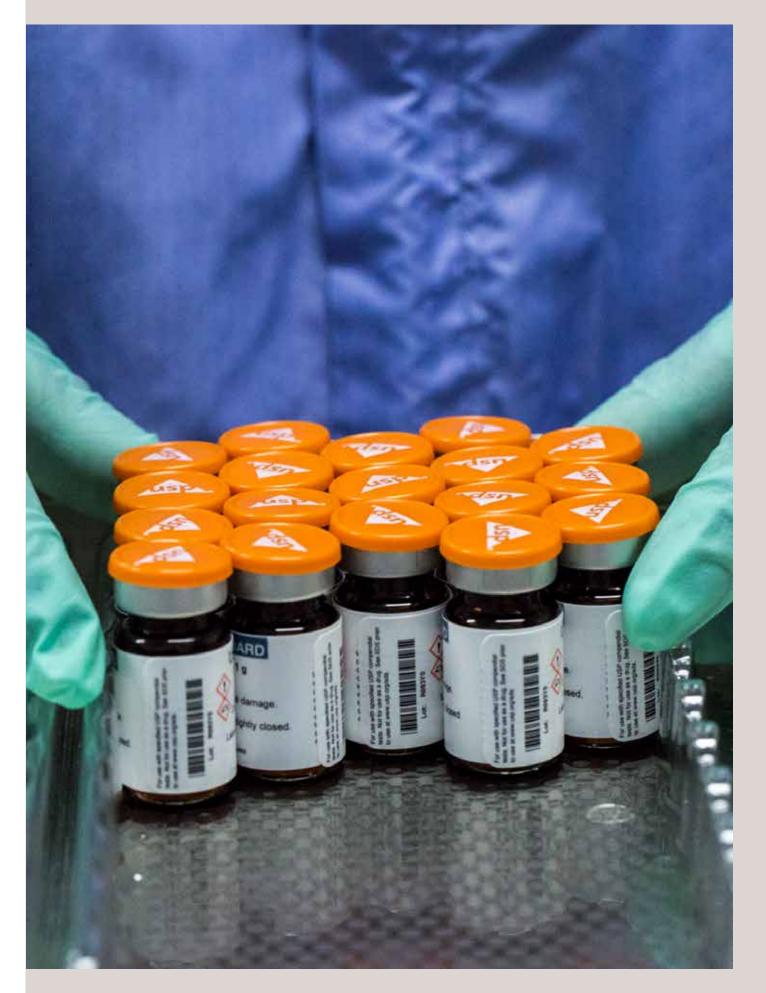
Exploring the use of qNMR spectroscopy

Exploring the use of quantitative nuclear magnetic resonance (qNMR) spectroscopy, an emerging analytical method based on the same underlying technology used in MRI scans, for use in determining the identity, and potentially the purity, of pharmaceutical materials.



Emerging technologies' role in standards

Screening 11 emerging technologies to assess potential quality implications and areas for potential future explorations, including how recent advances in 3D printing, bioreactors and the use of bacteriophage might impact medicines quality.



Join our volunteers

USP quality standards are developed by our Council of Experts – more than 750 independent experts in science, healthcare and academia who have a passion for quality and public health. These dedicated volunteers contribute their expertise as members of USP Expert Committees and panels to develop and revise quality standards that help billions of people worldwide trust their medicines, dietary supplements and foods.

These experts consistently tell us how meaningful this work is to them, as a way to contribute to strengthening the global public health safety net. This year, we launched the official Call for Candidates for volunteers to serve on these critical committees for the 2020–2025 Convention cycle. It may seem early to start thinking about the experts on our standards-setting committee in 2020, but this serious effort takes time. Learn more about volunteering at usp.org/together.

Outstanding scientific and public health volunteer experts

Since its very beginning nearly 200 years ago, USP has benefited from the expertise of the world's top experts in science, healthcare and academia – who volunteer to serve on our Expert Committees and panels in five-year cycles. We are grateful for their contributions, as well as their passion and dedication, and simply could not do our important work without them.

With more than 750 remarkable scientific experts who volunteer for USP, it is not an easy matter to select those for special

recognition. This year was no exception, especially as we introduced a new honor – the Jacob Bigelow Award. Named for one of the visionary physicians who founded USP, this award recognizes the outstanding contribution by an individual volunteer and complements the Award for Outstanding Contribution to the Standards, which acknowledges the exceptional contribution of a team of volunteers. Both awards were presented during the USP Midcycle Meeting for our governing body leadership, held in Phoenix in February 2018.

Jacob Bigelow Award

The inaugural Jacob Bigelow Award was presented to Charles G. Thiel in 2018 in recognition of his dedication and exemplary leadership as a member of the former USP Aerosols Expert Committee and the USP Advisory Panel on Aerosols.

Mr. Thiel, who volunteered as a scientific expert for USP for over 20 years, was responsible for a number of technological advances that drastically improved how inhalers delivered lifesaving medicine to people with asthma. First available to patients in 1957, Mr. Thiel's inhaler design was easier for patients to use and was the first device able to aerosolize asthma medicine so it was better able to reach deep into the lung. During his time with the advisory panel, Mr. Thiel applied his expertise to developing standards for a number of innovative and widely used devices improving inhalers – helping the more than 200 million people living with asthma today.



Charles G. Thiel (left) accepts the Jacob Bigelow Award from Jaap Venema, Ph.D., Chief Science Officer and Chair, Council of Experts

Award for Outstanding Contribution to the Standards

The 2017 Award for Outstanding Contribution to the Standards was presented to the Expert Panel responsible for evaluating portable screening technologies and accepted by its chair, Andy Stergachis, Ph.D. The Expert Panel was honored for its work evaluating screening technologies that assess the quality and authenticity of medicines and the widespread dissemination of those findings.

Members of the Review of Surveillance and Screening Technologies for the Quality Assurance of Medicines Expert Panel include:

Andy Stergachis, Ph.D., Chai

JaCinta Batson, M.B.A.

Stephanie Crawford Ph D

Facundo Martin Fernandez, Ph.D

Eliangiringa Kaale, Ph.D

Ravi Kalvanaraman Ph [

Wilherforce Kwiringira M.:

Paul Newton, Ph.

Bernard Olsen, Ph.I

lason Rodrigue.

Benjamin Wilson, Ph.[

Stephen John Young, B.Sc

Anthony Zook, Ph.D







Governance and leadership

USP is governed by leaders from science, healthcare and academia coming from around the world who serve on two governance bodies - the USP Convention and the Board of Trustees. The vision of these governing bodies is executed by the organization's executive leadership team.

USP Convention

Held every five years, the USP Convention provides overall governance spanning five-year cycles. Representatives of member organizations convene in Washington, DC, to carry out critical governance activities, including discussing issues important to USP constituents, setting organizational strategy, voting on resolutions that help guide USP's work and electing the Board of Trustees.

Member organizations represent a variety of valuable perspectives from around the world, including academic institutions, health practitioner and scientific associations, consumer organizations, manufacturer and trade associations, government bodies and associations, and nongovernmental standards-setting organizations.

Board of Trustees

The Board of Trustees meets quarterly throughout the year to guide USP policies, finances and strategic direction, as set by the Convention. The volunteer board is comprised of two trustees who represent the medical sciences, two trustees who represent the pharmaceutical sciences, three trustees who serve in an at-large capacity, and one trustee who represents the public interest.

Todd K. Abraham, Ph.D., M.B.A.

At-Large Trustee

Gregory E. Amidon, Ph.D.

Pharmaceutical Sciences Trustee

Satyanarayana Chava

At-Large Trustee

Paul Chew, M.D.

Medical Trustee

John E. Courtney, Ph.D.

Treasurer

Timothy R. Franson, B.S. Pharm., M.D.

Past President, USP Convention

Jesse L. Goodman, M.D., M.P.H.

President, USP Convention

Laura Herman, M.B.A., M.A.

Public Trustee

Robert J. Meyer, M.D.

Medical Sciences Trustee

Ronald T. Piervincenzi, Ph.D.

Chief Executive Officer, ex officio member

Marilyn K. Speedie, Ph.D.

Pharmaceutical Sciences Trustee

Thomas R. Temple, B.S. Pharm., M.S., FAPhA

Past Chair, At-Large Trustee

Gail R. Wilensky, Ph.D.

At-Large Trustee

Susan C. Winckler, R.Ph., J.D.

Chair, At-Large Trustee

Executive Leadership Team

Ronald T. Piervincenzi. Ph.D.

Chief Executive Officer

Jaap Venema, Ph.D.

Chief Science Officer and Chair, Council of Experts

Anthony Lakavage, J.D.

Senior Vice President, Global External Affairs and

Secretary, USP Convention

Stan Burhans

Chief Financial Officer

Amanda Cowley, J.D.

Senior Vice President, Strategy &

Business Development

Scott Henderson, M.S.

Senior Vice President, Global Information Services

Emily Kaine, M.D.

Senior Vice President, Global Health

Salah Kivlighn, Ph.D.

Senior Vice President, Global Strategic Marketing

& Program Operations

Christine Stunyo

Senior Vice President, Global Human Resources

K.V. Surendranath, Ph.D.

Senior Vice President, Global Human Resources

Hermes van der Lee

Senior Vice President, Global Laboratory Operations

Financials

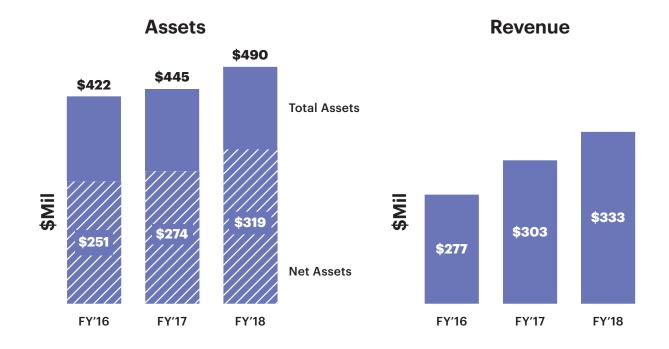
As a scientific nonprofit focused on advancing public health, USP applies the organization's resources to advance our mission in many ways, including developing quality standards, advocating for policies that support quality and working with governments to help build some of the most critical capabilities needed to help ensure the quality of medicines. As part of our commitment to protect public health, USP prioritizes the robust stewardship of our resources, including the revenue we use to fuel our public health work.

USP receives funds from multiple sources, primarily the sale of Reference Standards and publications, as well as from quality verification services and grants from public and philanthropic organizations, which support our work to advance our mission. Approximately 90–95 percent of every dollar the organization receives is used to fund programs to improve global health in the current period, while 5–10 percent of revenue is set aside each year to be held in reserve to help ensure USP is able to mitigate risks in the event of unexpected financial challenges and continue our work. The USP Board of Trustees oversees our strategic plan, operating goals and budgets, and investment reserves, to ensure alignment with our mission.

This summary of financial information has been extracted from the USP audited consolidated financial statements for the fiscal year ending June 30, 2018. To view the full 2018 audited consolidated financial statements, visit www.usp.org/financials-fy18.



Financial highlights



FY'18 Sources of Funds	\$Mil
Sales of Reference Standards and publications	\$293
Contributed services	\$17
USAID and other donor funding	\$17
Verification and other programs	\$6
Total Revenue	\$333

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