Advancing quality: our progress

Fiscal year 2019 | July 1, 2018–June 30, 2019

usp®

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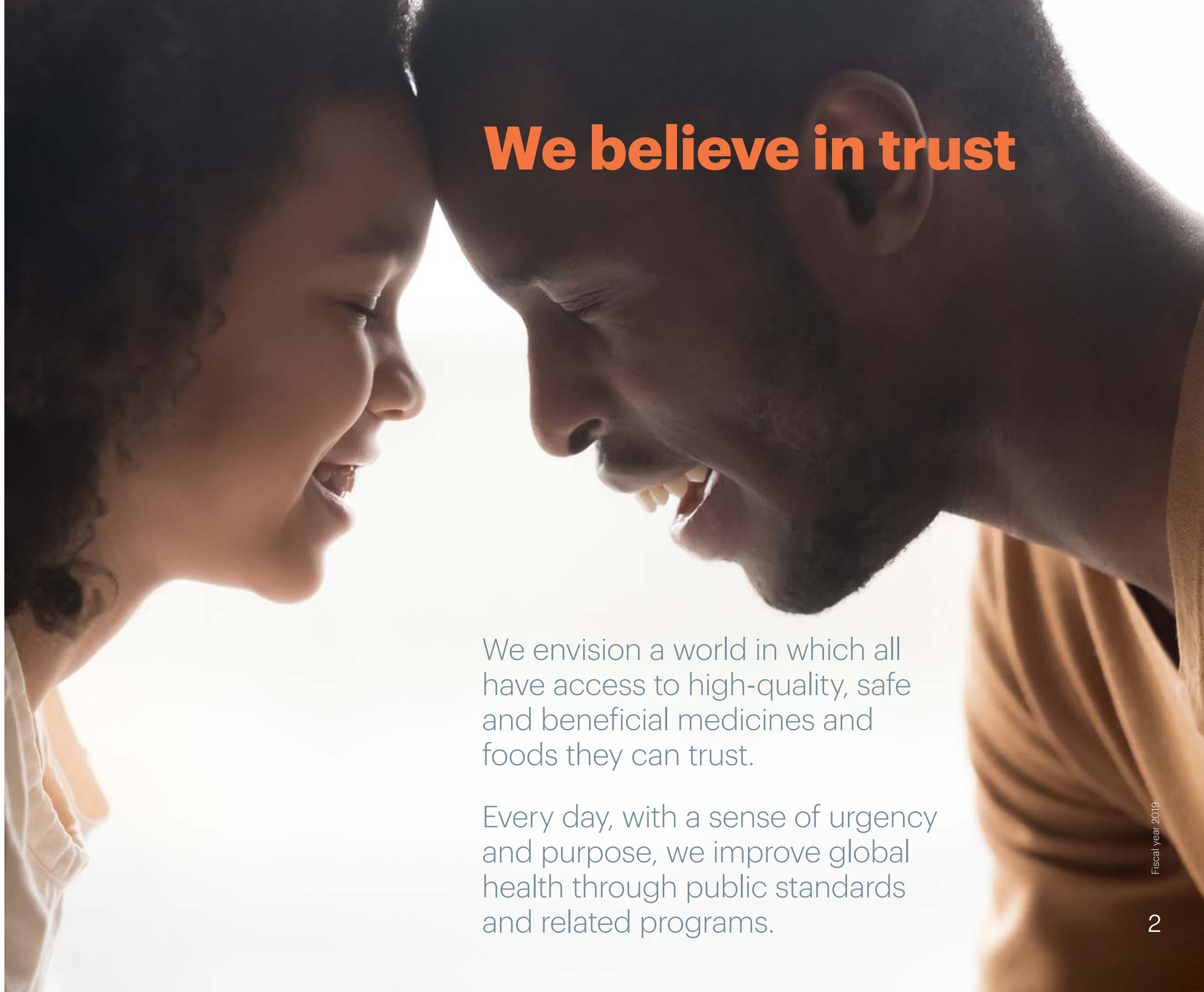


We believe in trust

We envision a world in which all have access to high-quality, safe and beneficial medicines and foods they can trust.

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

What we do

For 200 years, USP has been building trust where it matters most: in the world's medicines, dietary supplements and foods. Through our rigorous science and the standards we set, we have helped protect patient safety and improve the health of people around the world.

Research has shown that trust in the healthcare system leads to healthier behavior and outcomes: patients listen to their doctors, take their medication, and are also more willing to trust new treatments.

USP helps ensure patients can trust their medicines. We work with regulators around the world to help them effectively evaluate medicine quality, bring new life-saving medicines to market, and protect patients from poor-quality medicines. Our technical support and standards also help manufacturers make quality medicines, so they're trusted by patients and healthcare practitioners.

A healthier world requires trust in medicine.

USP's quality standards

As the world gets smaller and more connected, quality issues affect everyone. Diseases travel. Drug resistance grows. Fake medicines kill. The foundation of quality we're building helps address these and other global health issues. Whether decreasing the prevalence of substandard and poor-quality medicines or helping to curb antimicrobial resistance, we're there working to protect the health of people all over the world.

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 impartial, 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

Keeping your word is a matter of trust, integrity, and reliability. At USP, nothing is more important to us.

It's why we've instituted a governance mechanism that holds us accountable to finishing what we start. Held every five years, our USP Convention Meeting gathers more than 500 experts from across the global healthcare community to assess progress to date, elect the leadership of the USP's standard-setting bodies and Board of Trustees, and vote on Resolutions — setting high-level priorities for the next five years.

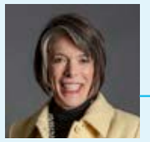
The public health concerns of today require rapid and innovative approaches. Whether it's advocating for increased access to affordable, quality drugs or safeguarding the global supply chain, we leverage our trusted standards-setting process to develop science-based solutions. The adoption of these solutions is in part thanks to the fact that we do not act alone. These issues call for collaborations and partnerships across a variety of stakeholders and decision makers, as well as new ways of thinking to achieve effective solutions.

With science advancing rapidly, so too must the world of medicine. The rapid pace of medical innovation can lead to huge leaps in health and longevity, but it will also bring questions. We're working to help ensure that today's and tomorrow's remarkable innovations can be trusted in the same way we have helped to build trust in quality medicines over the past 200 years.

2020 marks our 200th anniversary. As we embrace this legacy-cementing celebration, we will be taking a deep look at trust in medicine across the centuries.

It is our distinct honor to present this annual report to you. We encourage you to read further about how the trust our standards establish helps ensure the safety of patients and helps make the world healthier one day, one year, one decade, and one century at a time.

Ronald T. Piervincenzi, Ph.D. | Chief Executive Officer



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

By the numbers

Through revolutions in science and medicine, the foundation of quality we build helps scientists keep discovering, manufacturers keep producing, and healthcare teams keep healing. At USP, we work to protect the health of people all over the world, every day.

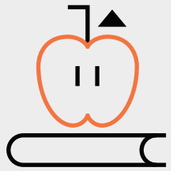
We see our progress measured in tangible gains that renew our commitment to helping people trust the quality of their medicines, dietary supplements and foods.

2,000,000,000

2 billion people across the world had access to quality medicines, dietary supplements and foods because of USP standards, advocacy and education.

7,500+

More than **7,500 people** attended USP Education courses and workshops.



185,000+

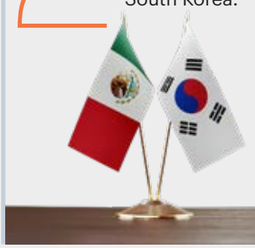
square feet of laboratory space in five countries allowed USP to develop and validate testing methods and Reference Standards, as well as offer training on the effective use of these standards.

150+

More than 150 countries utilized USP science-based quality standards, with over 40 countries integrating these standards into law.

2

Expanded globally to **two countries,** with staff in Mexico and South Korea.



800+

experts in science, industry, healthcare and academia volunteered an estimated 125,000 hours with USP.

234+

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

140

scientific publications including journal articles, *Stimuli* articles, poster and oral presentations at scientific conferences and trade press articles.

6 quality control laboratories in Africa and Asia earned or maintained ISO accreditation, with technical assistance on testing methodologies and lab management from the Promoting the Quality of Medicines (PQM) program, funded by the U.S. Agency for International Development (USAID) and implemented by USP. Accredited quality control laboratories improve countries' capacity for improving medicines quality through post-marketing surveillance.

6

108

Reference Standards were released, bringing our current catalog to 3,809.

478

Convention Member Organizations from 39 countries.

439

documentary standards were developed or revised, bringing our total number to 6,674.

Advancing the science of quality

At its core, science is about using systematic methods to understand the structure and behavior of the physical and natural world. When we think about USP's role in creating standards and building trust in medicines, science is the foundation.

Our approach has always been to bring the world's leading experts together to distill the very best knowledge of the day to create solutions to pressing problems around medicine quality issues. From there, we come to a consensus, informed by science, and create a standard.

Advancing product performance testing

Jaap Venema, Ph.D. | Executive Vice President and Chief Science Officer

Performance testing is a key part of *USP* monographs for drug products to ensure medicine products perform as expected. For solid-oral dosage forms, dissolution is the standard. The next generation of dosage forms for medicines includes complex and novel dosage forms for medicines, such as implants, nanoparticles, microneedles, chewables, and inhalation devices.

While these innovative approaches are solving drug delivery challenges and bringing a patient focus to drug delivery, they are introducing new challenges in monitoring and ensuring performance.

A new Expert Panel has been formed in this area to address the evaluation and adoption of product performance tests and to develop innovative approaches to novel dosage forms for medicines.

Controlling transport conditions for personalized medicines

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

As personalized therapies have become a reality rather than a distant promise, the tools needed to ensure the quality of these medicines grow increasingly important. Autologous therapies involve processing of an individual's own cells or tissue outside the body before reintroducing them into that person's system to help with wound healing or counteract chronic inflammation. Once produced, autologous therapies must be transported to the recipient. These treatments are very sensitive to changes in their environment, so conditions must be tightly controlled.

That's why this year, we revised *USP* General Chapter <1046> to emphasize how shipping containers for cell therapy products must ensure acceptable temperatures under conditions of use, including temperature extremes inside and outside a shipping container and other shipping challenges, such as X-rays or mechanical vibration.

We're working to help ensure that today's and tomorrow's remarkable innovations can be trusted, in the same way we have helped to build trust in quality medicines over the past 200 years.

Advancing the science of quality

Validating the analytical procedure lifecycle

Introduced a new standard, *USP* General Chapter <1220>, The Analytical Procedure Lifecycle to help with quality control during validation of analytical procedures, which is a critical activity in the pharmaceutical industry to ensure quality.

Collaborating on new over-the-counter standards

Collaborated with the Food and Drug Administration (FDA) and the Consumer Healthcare Products Association to develop innovative compendial pathways for over-the-counter products that are flexible for industry and also meet the FDA's regulatory requirements.

Debuting the *Dietary Supplements Compendium (DSC)* online

Launched a new online resource to help users navigate *DSC* monographs, regulatory guidances, and reference tools used around the world for the dietary supplement supply chain.

Defining supply chain practices for quality products

Initiated development of an information chapter on supply chain practices for products to help improve security for regulatory authorities and the pharmaceutical industry.

Classifying therapeutic uses of covered Medicare Part D drugs

Finalized the agreement with the Center for Medicaid & Medicare Services (CMS) to update the eighth edition of the *Medicare Model Guidelines*, which healthcare plans use to inform drug reimbursement decisions. Along with pharmaceutical benefit managers, USP Expert Panels, and CMS consultants, USP pulls from the USP Drug Classification system to ensure people have access to at least two types of medicines in the drug classes they need that would be reimbursed through Medicare Part D.

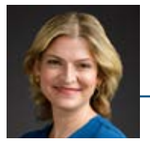
Partnering for accuracy in electronic drug nomenclature

Integrated USP Compendial Nomenclature into the National Library of Medicine's RxNorm, the U.S. vocabulary standard for representing medications within electronic health information, to help ensure that compendial drug names used on manufacturer labels are preserved when they are used in digital environments.

Building strong health systems

Everyone deserves medicine they can trust, but millions of people around the world lack access to quality medicines. Poor-quality medicines—those that are substandard or falsified—put lives at risk, cost economies billions of dollars, and undermine decades of hard-earned health progress.

Working with a variety of stakeholders, USP strengthens medicines quality assurance systems, increases the supply of quality-assured medicines, and develops capacity to detect and remove poor-quality medicines from the market. By sharing scientific expertise and providing technical support and leadership, we help local regulators improve and sustain local health systems and enable manufacturers to supply quality-assured essential medicines for years to come.



Strengthening health systems to take on complex challenges

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

Nearly two billion people worldwide lack access to essential medicines. At the same time, for those living in low- and middle-income countries that have access to medicines, it is estimated that 10 percent of products available are substandard or falsified. For the past ten years, the PQM program, funded by USAID and implemented by USP, has partnered with countries to develop sustainable quality assurance systems that can both increase patients' access to priority products and decrease the prevalence of falsified and substandard medicines.

2019 marked the last full year of our 10-year flagship initiative. Over the past decade, we've partnered with regulators in low- and middle-income countries to sustainably strengthen medical product quality assurance systems, increase the supply of quality-assured medical products and develop capacity to monitor the quality of medical products in national marketplaces. Through these efforts, we were able to help prevent and treat diseases like HIV/AIDS, tuberculosis and malaria, as well as neglected tropical diseases, and improve maternal, newborn, and child health.

The successful close of this chapter foreshadowed USP's being selected by USAID to implement PQM+ and continue our work addressing the proliferation of poor-quality medical products that put millions of people at increased risk of illness or death and waste precious health system resources.

Assuring quality in medicines procurement

Anthony Lakavage, J.D. | Senior Vice President, Global External Affairs and Secretary, USP Convention

To achieve universal health coverage, medical products must reach patients with their safety, identity, strength, quality, and purity intact. Standards for procurement of quality-assured medical products exist, but adherence to them has not been uniform due to contextual and environmental conditions. Unfortunately, substandard and falsified medicines are highly prevalent in countries where under-resourced regulatory authorities cannot adequately oversee medicines along complex, globalized supply channels.

During the 72nd World Health Assembly in Geneva, USP co-hosted, alongside the government of Belgium, the Bill & Melinda Gates Foundation, the Swedish International Development Cooperation Agency, and the Republic of South Africa's Department of Health, an event to discuss openly how to ensure quality in medicines procurement. The collaboration resulted in a report with five specific calls to action for all stakeholders, including philanthropic organizations; NGOs; global financing and procurement mechanisms; financial institutions; and technical, scientific, and academic organizations.

The public health concerns of today require rapid and innovative approaches. Whether it's advocating for increased access to affordable, quality drugs or safeguarding the global supply chain, we leverage our trusted standards-setting process to develop science-based solutions.

Building strong health systems

Reducing infant mortality in developing countries

Provided technical assistance on assuring quality when administrating chlorhexidine, a life-saving antiseptic to prevent umbilical cord infections in newborns who are delivered at home in regions with a high neonatal mortality rate, through our PQM program, which is funded by USAID.

Leveraging global partnerships to safeguard the supply chain

Disseminated the supply chain toolkit to regions in Asia and Latin America to help implement best practices to secure the supply chain, including strengthening the integrity of e-commerce. Under the Asia-Pacific Economic Cooperation (APEC) Supply Chain workstream, USP conducted training in Chile, with support from U.S. FDA, the Council of Europe, and the Alliance for Safe Online Pharmacies, to train over 40 regulators from across South, Central, and the Caribbean region of the Americas.

Protecting against future Ebola outbreaks

Helped the Academic Consortium to Combat Ebola in Liberia strengthen laboratory services for the prevention, detection, and surveillance of Ebola virus diseases (EVD) and other emerging infections in the country.
USP conducted SWOT analysis of medical laboratory logistics systems, blood safety services and prevention and infection control (IPC) capacity, and recommended policy and guideline changes to align laboratory services with international best practices.
USP conducted training of trainers in laboratory quality management systems and undertook forecasting and quantification of key laboratory reagent and consumables, blood safety products and IPC commodities to prevent stock outs and service disruption when responding to future EVD outbreaks.

Strengthening regional quality assurance systems for medicines

Collaborated with the Pan American Health Organization to provide technical assistance for the Caribbean's regulatory system toward assessing and positioning its drug testing laboratory in the context of a regional post-marketing surveillance program.

Supporting Brazil's new regulatory framework for dietary supplements

Provided technical support in the establishment of new regulatory guidelines for dietary supplements in the country, helping to ensure the quality of products in the market.

Advocating for quality

Every day, all over the world, people take medicine, choose a dietary supplement, or eat a meal. Many of us don't worry that what we rely on for our health can harm us or even be deadly. With USP quality standards in place to set the bar for how these quality products are made, we are safer and healthier.

We work with our partners—policymakers and stakeholders who implement USP quality standards—to facilitate multifactorial approaches to quality medicines. We build a foundation of quality that protects our health, because everyone should have access to quality medicines, dietary supplements and foods.

Driving evidence for why quality matters in healthcare systems

Anthony Lakavage, J.D. | Senior Vice President, Global External Affairs and Secretary, USP Convention

"There's no lack of evidence for instances when poor-quality medicines resulted in recalls, sicknesses, and deaths. What's much harder to pinpoint are examples of when good-quality medicines saved lives and prevented tragedy. In the past year, the USP Quality Institute more than doubled its academic partners to help meet this need.

Working with graduate fellows, we've expanded from an initial theme of investigating the link between poor-quality medicines and antimicrobial resistance (AMR) to studying how vulnerabilities in procurement may be affecting medicine quality. This is game changing. We often look to regulators to enforce quality but overlook the responsibility of procurement agencies to make sure that the medicines they buy are safe and effective for patients. Beyond looking for best practices here, we started research on another underappreciated quality challenge. That is how excipients—the inactive ingredients in medicines—may contribute to poor health outcomes.

We are proud to share that we had the first dissemination of the USP Quality Institute findings at the Medicine Quality & Public Health conference in Oxford, England."

Increasing access to medicines by facilitating generics competition

Carrie Harney, J.D | Senior Director, Government Affairs, Policy and Advocacy

"Generic medicines have benefited millions of Americans and saved $1.5 trillion dollars in the past 10 years. Patients have more access to affordable alternatives of the medicines they need when there is generic competition. And while there has been much progress, there are still many off-patent medications that have limited or no generic options. This year, USP launched the Generics Access Plan to close this gap by developing new public standards through a collaborative process, working with independent experts from healthcare, academia and industry, as well as representatives from the FDA.

Since its inception, the Generics Access Plan has developed and updated quality standards supporting FDA's Drug Competition Action Plan priorities and offered training and education for generics manufacturers worldwide. Over the inaugural year of the program, we have been actively convening regulators, industry representatives, patient groups, payers, healthcare practitioners, and others to identify additional ways to support generics development through the standards-setting process and educational programming."

Advocating for quality

Advocating for quality and innovation in biologics

Met with 60+ congressional offices to discuss how quality standards drive biologic and biosimilar competition. The meetings stemmed from organizing in response to a draft provision that proposed removing requirements that biologic medicines meet USP quality standards, making adherence to these transparent public standards optional. USP upheld its conviction that when it comes to families' health, quality and safety should never be optional.

Mitigating drug shortages

Supported public health efforts to develop new and refine existing compendial processes that may represent approaches to mitigate current complex problems such as drug shortages and quality medicines access issues. This included focused outreach to stakeholders during the monograph development process, particularly for product characteristics associated with drug shortages, such as having a limited number of manufacturers.

Shaping frameworks to combat antimicrobial resistance

Included in a resolution by the World Health Organization's Executive Board and the World Health Assembly in its actions requiring member states to protect medicines quality to prevent AMR.

Advocating use of public standards in India

Signed a memorandum of understanding with the Food Safety and Standards Authority of India to support the recent recognition of USP standards in India's health supplement regulations.

Highlighting the human impact of poor-quality medicines

Established and supported the Medicines We Can Trust global campaign as a platform for policymakers, patient organizations, global health groups, and standards-setting organizations, such as USP, to talk publicly about the impact that poor-quality medicines have on patient safety and public health.

2020 marks our 200th anniversary. As we embrace this legacy-cementing celebration, we will be taking a deep look at trust in medicine across the centuries.

Exploring the future of quality

Science is advancing rapidly, and so is the world of medicine. We're working to help ensure today's and tomorrow's remarkable innovations can be trusted in the same way we have helped to build trust in quality medicines over the past 200 years.

To deliver greater impact on medicine quality in the future, USP is embracing disruptors in healthcare, including the digitization of healthcare, new medicine modalities, shifts in approaches to ensure quality, a more complex supply chain, and innovative manufacturing technologies.

USP works with key stakeholders including regulatory and industry experts to anticipate and assess how new medical and technological breakthroughs may impact existing USP standards and monographs to address potential challenges or risks.

Integrating quality standards into digital systems

Michael Levy, M.B.A., M.S. | Vice President, Head of Research & Innovation

"USP joined the Allotrope Partner Network to explore how quality standards can be better integrated into digital systems. Massive volumes of data are generated by sophisticated lab instruments, factory sensors, and the use of machine learning. In light of this data revolution, structured and interoperable data models can be leveraged for insights, predictive analytics, and improved quality."

Convening manufacturing expertise to foster innovation

Jaap Venema, Ph.D. | Executive Vice President and Chief Science Officer

"Pharmaceutical Continuous Manufacturing (PCM) is the next major evolution of manufacturing. A significant departure from "batch" production that has been the mainstay of pharmaceutical manufacturing for decades, continuous manufacturing has long been used in other industries to help streamline production, improve quality controls, decrease time to market and, ultimately, lower costs.

In light of this new quality paradigm, USP volunteers from several USP Expert Committees and the USP Quality Standards for PCM Expert Panel are working to ensure the development and implementation of compendial quality standards for medicines manufactured using PCM. One of the Expert Panel's first tasks has been to propose standardized terms and definitions used in the domain of PCM. The panel recently completed the first phase of this effort with the publication of "USP (Pharmacopeial) Perspective for Pharmaceutical Continuous Manufacturing," a *Stimuli* article in *Pharmacopeial Forum* 44(6). The article covers the definition of continuous manufacturing, material properties and characterization techniques, process analytical technology applications in PCM, risk management, and regulatory landscape and consideration.

Building on this progress, we've partnered with the Center for Structured Organic Particulate Systems at Rutgers School of Engineering to develop a full training module on PCM that will be available in 2020."

Exploring the future of quality

Identifying future paradigm shifts in the pharmaceutical industry

Brought the world's leading experts in quality—both in medicine and other industries—together as a Quality Advisory Group to identify the main paradigm shifts in the pharmaceutical industry in the next 10–15 years, as well as their impact on pharmacopeias, industry, regulators, practitioners, and patients. The group will provide recommendations for how pharmacopeias and regulators should evolve and develop forward-looking strategies to ensure the relevancy of quality standards in a global environment.

Honing DNA methods for botanical and probiotic identification

Published study findings in a peer-reviewed article titled "Improving End-User Trust in the Quality of Commercial Probiotic Products" in *Frontiers in Microbiology* to help improve understanding of quality probiotics.

Scientific experts

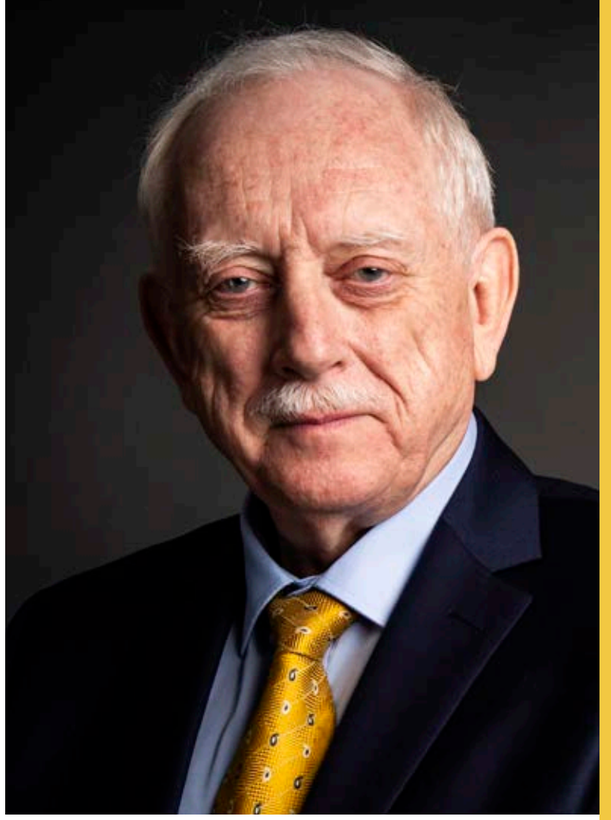
Central to USP's achievements are the contributions of over 800 experts who volunteer their time and knowledge in our Council of Experts. USP standards are in a continuous process of review and revision based on new evidence, emerging public health concerns, and public requests for revision. Input from volunteers is crucial for maintaining these high standards and preserving public trust.

This year, we continued recruitment efforts for our Call for Candidates for the next 2020–2025 Convention cycle. Every five years, USP invites qualified candidates—scientists, academicians, regulatory professionals, healthcare practitioners, and others who work with medicines and foods—to apply to serve as decision makers on USP's Council of Experts and Expert Committees. This past year, we've explored new ways to attract, engage, and retain leading experts and harness their spirit of volunteerism to help advance USP's science and public health mission. This included experimenting with more flexible time commitments and allowing volunteers more options to engage in work that best leverages their unique expertise.

Outstanding scientific and public health volunteer experts

Ever since 11 physicians who were concerned about how inconsistent medical preparations were harming patients came together in 1820 to found USP, our mission has been carried forward thanks to the many hours generously contributed by our Expert Volunteers.

Propelled by an estimated 125,500 hours in 2019, we extend our heartfelt gratitude for the unparalleled show of commitment and remarkable contributions of the USP volunteer bodies. We honor the work they do to advance global health through public standards and related programs through USP's Volunteer Awards and Recognition Program.



Jacob Bigelow Award

The Jacob Bigelow Award was presented to Chris Moreton, Ph.D., in 2019 in recognition of his dedication and exemplary leadership as a member of the USP Excipients Monographs 1 Expert Committee.

Dr. Moreton was selected for his remarkable knowledge and selfless dedication. He coauthored a *Stimuli* article and was responsible for key insights for new and revised monographs. He was also recognized for serving as a USP Call for Candidates Recruitment Ambassador and for his contributions as Co-Chair of the <1059> Excipient Performance Expert Panel, where he expertly managed the overall strategy of the chapter revision. Dr. Moreton exemplified what it means to be a USP Volunteer. He sat on more than a half dozen excipient-related committees and went above and beyond for USP standards setting.

Award for Outstanding Contribution to the Standards

The 2018 Award for Outstanding Contribution to the Standards was presented to two Expert Panels. The Residual DNA Expert Panel was honored for its work on developing a new general chapter to address measurement of residual DNA in recombinant therapeutic products toward improved drug quality, safety and affordability. Wes Workman, Ph.D., chair of the Residual DNA Expert Panel, accepted the award on behalf of its members.

Members of the Residual DNA Expert Panel include:

- Wes Workman, Ph.D., Chair
- Pascal Anger, Ph.D.
- Jon Borman
- Donna Christner
- Scott Kuhns, Ph.D.
- Judy Shimoni, Ph.D.
- Weihong Wang, Ph.D.

The Compounding–Radiopharmaceuticals Expert Panel, responsible for developing a new test chapter for the preparation, compounding, dispensing and repackaging of radiopharmaceutical products, also received the 2018 USP Award for Outstanding Contribution to the Standards. James Ponto, M.S., Chair of the Compounding–Radiopharmaceuticals Expert Panel, accepted the award on behalf of its members.

Members of the Compounding–Radiopharmaceuticals Expert Panel include:

- James Ponto, M.S., Chair
- David Barnes, B.S. Pharm
- Allegra DePietro, M.S.
- Wendy Galbraith, Ph.D.
- Fred Gattas, Pharm.D.
- Richard Green, B.S. Pharm
- Kim Huynh-Ba, M.Sc.
- Brenda Jensen, M.A.
- Ravindra Kasliwal, Ph.D.
- Patricia Kienle, M.P.A.
- Vivian Loveless, Pharm.D.
- Paul Mahan, B.S. Pharm
- Rezaul Mannan, Ph.D.
- Sara Rothman
- Steve Zigler, Ph.D.

Governance and leadership

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

USP Convention Meeting

Held every five years, the USP Convention Meeting provides overall governance spanning five-year cycles. Representatives of over 460 Member Organizations convene in Washington, D.C., 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, USP's scientific leadership and the Council of Experts.

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 non-governmental standards-setting organizations. Convention Members work together on priority issues throughout the cycle, bringing together diverse perspectives to address some of healthcare's most pressing issues.

Editor's note: In light of the COVID-19 pandemic, and with the health and safety of our Convention Member representatives, stakeholders, and staff as our priority, USP made the decision to hold the USP 2020 Convention Meeting virtually May 4–6.

Board of Trustees

The Board of Trustees meets quarterly throughout the year to guide USP's policies, finances, and strategic direction, as set by Convention Member Organizations every five years. The volunteer board is composed of two trustees who represent the medical sciences, two trustees who represent the pharmaceutical sciences, four trustees who serve in an at large capacity, and one trustee who represents the public interest.

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At Large Trustee

Gail R. Wilensky, Ph.D.
At Large Trustee

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

Council of Experts

The Council of Experts consists of the Chairs of the Expert Committees (currently 25) and the Chief Science Officer. They are responsible for several overarching sections in the USP Compendia, such as General Notices, and are the scientific governing body of USP. They meet three times per year to discuss and guide USP's scientific policies and strategies.

Executive Leadership Team

Ronald T. Piervincenzi, Ph.D.
Chief Executive Officer

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

Stan Burhans, M.B.A.
Chief Financial Officer

Bruk Alemayehu, M.B.A.
Senior Vice President, Science, Chemical Medicines

Amanda Cowley, J.D.
Senior Vice President, Strategy & Business Development

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

Salah Kivlighn, Ph.D.
Senior Vice President, Global Strategic Marketing & Program Operations

Anthony Lakavage, J.D.
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Senior Vice President, Global Human Resources

K.V. Surendranath, Ph.D.
Senior Vice President, Global Sites

Hermes van der Lee
Senior Vice President, Global Laboratory Operations

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Senior Director and General Manager
Latin America

Alessandro Slama
Senior Director and General Manager
Europe, Middle East, Russia and NIS Countries

Anthony Tann, M.B.A.
Senior Director and General Manager
Asia-Pacific

Sireesha Yadlapalli, P.G.P.
Senior Director and General Manager
South Asia

Geoff Tsen, M.B.A., Ph.D.
Vice President
USP China

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.

90–95%

Approximately **90 to 95 percent** of every dollar the organization receives is used to fund programs to develop public quality standards, advocate for quality throughout the medicines supply chain, strengthen regulatory systems, and educate healthcare practitioners and pharmaceutical industry stakeholders.

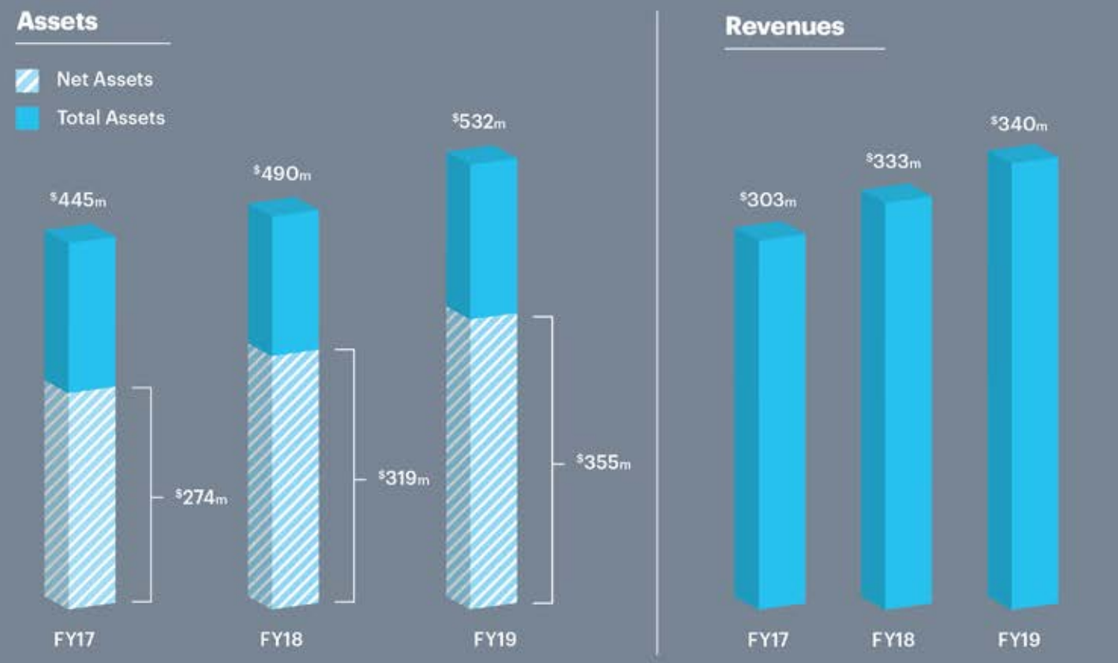
The remaining **5 to 10 percent** of revenue is set aside each year to be held in reserve to help ensure USP is able to mitigate risks in the event of unexpected financial challenges and continue our work.

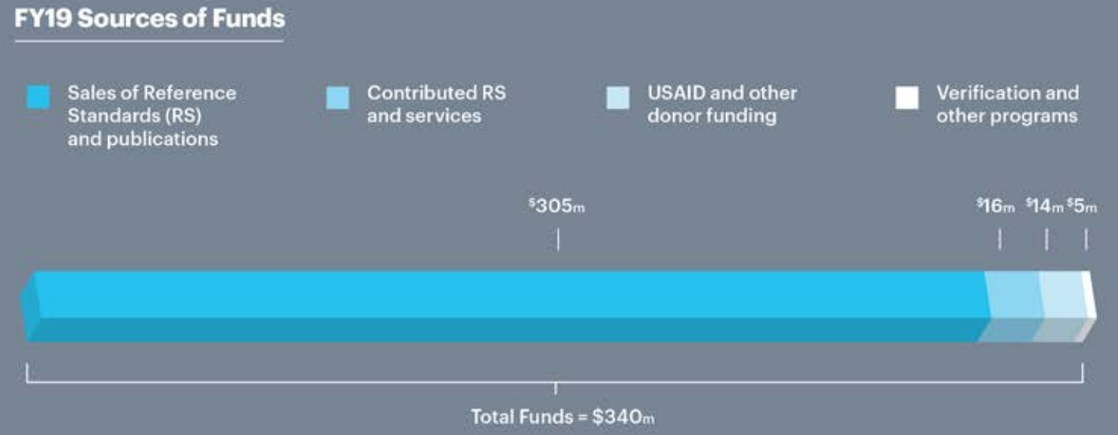
5–10%

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 that ended June 30, 2019.

Financial Highlights





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