

trust

In fiscal year 2020 we celebrated the role USP has played in building trust in medicines for the past two centuries. From the 11 physicians who founded USP, to our responses to the public health crises that have occurred during the past 200 years, to our plans for helping to ensure the quality of emerging therapeutics, USP has been committed to helping make it possible for people to trust the quality of medicines so they can live longer, healthier lives. When trust is shaken, as has occurred in multiple health crises that were caused by poor-quality medicines, USP's independent, science based, data driven standards have provided a touchpoint that manufacturers and regulators can rely on to test and verify product quality and restore trust.

The COVID-19 pandemic has shaken many people's trust to their core. Early

in the pandemic, lack of information or conflicting information created confusion that caused near panic in grocery stores and uncertainty around the efficacy of existing medicines in fighting COVID-19. Later, as the race for a vaccine accelerated, public officials fomented doubt about the validity of the science and the motivations underlying the pace of development.

What will it take to restore trust? Evidence. Transparency. Collaboration. Evidence of a drug's identity, purity, strength, and performance. Transparency across the medicine supply chain by sharing information that demonstrates the quality of a product from raw materials until the moment it reaches the patient. Collaboration between public and private organizations across the globe, working

together toward a common goal: access to quality medicines for everyone who needs them.

USP is proud of the role it has played in improving public health through public quality standards. As USP delivers on its public health mission, our work, relationships, and partnerships around the globe have never been more critical. Our standards, advocacy, and capability building enable manufacturers and regulators to evaluate medicine quality, bring innovative treatments to market, and protect patients from poor-quality medicines. Healthcare providers and patients will have reason to trust in medicine quality and reap the benefits of scientific and medical advances.



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1820-2020

200usp

The standard of trust



As fiscal year 2020 began, USP was excitedly preparing for two major events: our 200th anniversary and the upcoming convention that would set the stage for USP as it began its third century. We were ready to start the last year of the 2015–2020 cycle with further progress in monograph modernization, establishment of world-class functional capacity, and strong engagement with stakeholders. We embraced the rapidly evolving pharmaceutical and regulatory landscapes, planning for new and innovative ways USP will be relevant and impactful in our next century.

As we celebrated USP’s past, present, and future at the anniversary gala in January 2020, no one could have imagined what lay ahead.

The impact of the novel coronavirus and its disease, COVID-19, continues to reverberate through every corner of the globe, making USP’s mission more relevant than ever. The pandemic exposed vulnerabilities in the global medicine supply chain. Manufacturing is complex, fragmented, and opaque. The pandemic also placed new pressures on the global supply of quality medicines. The potential and ramifications of inequitable and insufficient supply will be felt around the world.

→ **CEO Ron Piervincenzi lifts his glass to toast USP’s 200th anniversary on January 30, 2020, at the Andrew W. Mellon Auditorium in Washington, DC.**



→ **The coronavirus pandemic prompted USP staff to create its first-ever virtual Convention Meeting to set the strategic direction for USP to continue its global health mission.**

As it has for 200 years, USP responded. We worked with government organizations, manufacturers, and healthcare professionals in the U.S. and around the world to help ensure the quality and safety of vaccines and treatments for COVID-19 and building the public’s trust in life-saving medicines. The speed and agility with which we responded is a testament to our operational and institutional strength. USP is well positioned to meet the challenges of delivering on our mission.

We did celebrate USP’s 200th anniversary, albeit not as we had originally anticipated. We celebrated USP’s role in the ability to trust in the quality of medicine for 200 years. We also held our first virtual Convention Meeting, adapting to keep participants safe while enabling Convention Delegates to shape our strategy and guide our areas of impact in the upcoming cycle.

We invite you to read this annual report, which acknowledges significant milestones that USP achieved during FY20 and looks forward into our next cycle and century.

Today’s public health concerns require rapid and innovative solutions that call for collaborations and partnerships across a variety of stakeholders, as well as new ways of thinking to achieve effective solutions. Whether it’s advocating

for increased access to affordable, quality drugs or safeguarding the global medicine supply chain, USP stands ready to meet the challenges of delivering on our mission.


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


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



2020 HIGHLIGHTS

As the magnitude of the global health crisis of the pandemic began to unfold early in 2020, USP quickly identified ways to support efforts in the battle against COVID-19. We took swift action to ensure that manufacturers had uninterrupted access to the reference standards they needed to continue producing quality medicines. We expanded existing services and developed new solutions to support the availability of essential protective products and support the development of treatments and vaccines.

USP also recognized that the vulnerabilities in the global medicine supply chain that the pandemic brought to light would remain a threat without remediating action. To that end, USP has identified factors that contribute to those vulnerabilities and ways to strengthen the supply chain in the future. Details are found in USP Global Public Policy Position: **Key Elements to Building a More Resilient Supply Chain**.



As demand for hand sanitizer skyrocketed, USP released a **Hand Sanitizer Toolkit** that provided manufacturers, pharmacies, and other facilities with compounding information so they could **help alleviate shortages**.



Overcoming shipping, delivery, and communications challenges posed by COVID-19 travel restrictions, **USP went above and beyond so customer orders were fulfilled**.



USP developed actionable insights on current weaknesses in the **global medicine supply chain** that can inform future changes leading to **improved resilience**.



USP extended the official date for compendial standards *USP 43-NF 38* and *FCC 12th* edition and *USP 43-NF 38, First Supplement*, **giving industry and regulators additional time to meet compliance requirements** as they dealt with unprecedented challenges resulting from the pandemic.



To **help accelerate the development of safe and effective COVID-19 vaccines, medicines, and other treatments**, USP technical experts were available to scientists, developers, and manufacturers worldwide.



With the quality of medicines being more critical than ever, USP scientists were able to continue their laboratory research to advance development of new standards, thanks to **USP's designation as an essential business**.



USP worked with agencies in more than 20 countries to help supply Reference Standards and **facilitate the supply of quality medicines across the global supply chain**.



Nearly 200 manufacturers, labs, and healthcare practitioners from nine countries benefited from USP's educational offerings by taking advantage of a **75% discount to help in the battle against COVID-19**.



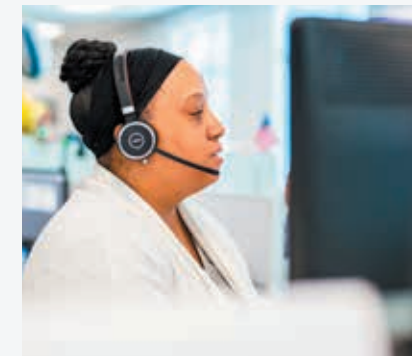
Over 140 manufacturers, academicians, and regulators leveraged our six-month complimentary access to **USP-NF** monographs and documentary standards to **support the development of COVID-19 vaccines and treatments**.



To help address shortages while protecting front-line healthcare workers, USP's Compounding Expert Committee **issued strategies for the use of personal protective equipment and garb**.



To protect patients during the pandemic and beyond, USP issued guidance to help regulators in low- and middle-income countries **mitigate medical product quality and availability issues**.



Working remotely, USP Customer Support teams responded to the higher-than-usual volume of inquiries with tracking and support services that helped **ensure customers had the standards they needed to continue production of quality medicines**.



USP has raised awareness among thought leaders in industry, academia, and regulatory bodies about the need for increased diversity, greater transparency and data sharing, and other key actions to **strengthen the upstream global medicine supply chain**.

QUANTIFYING THE IMPACT OF USP STANDARDS

A **research study** conducted by Johns Hopkins University and published in the journal *PLOS ONE* evaluated the impact of quality standards on the supply of medicines. The study found that the availability of a quality standard increases competition and reduces prescription drug costs in the U.S. On average, drugs with a USP public quality standard had approximately 50% more generic manufacturers compared with medicines without such a standard. Not only did these standards increase competition in the generic medicines market but researchers also estimated that they reduced overall prescription drug costs by \$11 billion in 2015 and 2016.

The Johns Hopkins study provides evidence in support of USP's **Generics Access Plan** to help increase access to medicines by facilitating generic competition through new and revised quality standards and related activities. USP's Generics Access Plan supports the U.S. Federal Drug Administration (FDA) in its efforts to encourage development of **new generic medicines** to promote competition, help reduce drug prices, and improve access to medicines for Americans.



677

DOCUMENTARY STANDARDS

developed or revised, bringing our total number to 7,236

147

REFERENCE STANDARDS

released, bringing the current catalog to 3,932

283

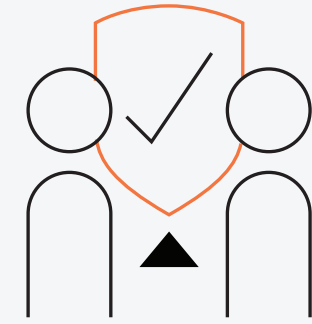
DONATIONS

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

900+

EXPERTS

in science, industry, healthcare, academia, and government liaisons from 31 countries



490+

CONVENTION MEMBERS

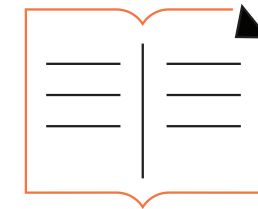
from 40+ countries



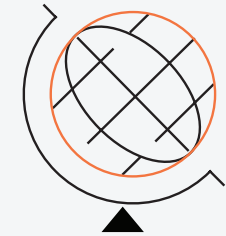
214

SCIENTIFIC PUBLICATIONS

including journal articles, *Stimuli* articles, industry press articles, posters, and more



COUNTRIES



150

have used USP standards

50

recognize USP standards in law

18,000+

PEOPLE

attended USP Education courses and workshops



Trust

200 YEARS OF BUILDING

For USP's 200th anniversary, we showcased our impact on public health and looked ahead to USP's role in enabling trust in future therapeutic innovations.

Trust CoLab

USP partnered with the Massachusetts Institute of Technology (MIT) Center for Collective Intelligence to engage over 100 global leaders in health and science using MIT's unique online platform. The Trust CoLab participants collaborated to explore the medical breakthroughs that will shape people's health between now and 2040, and what it will take to build trust in these innovations. The final report, ***Trust or Consequences 2040: Will Innovations in Health and Medicine Deliver?***, was released in May 2020.

TEDMED

To reach thought leaders in industry, medical research, think tanks, and governments, in March 2020 USP sponsored TEDMED, an annual event focused on innovations in health and medicine.



USP's CEO Ron Piervincenzi moderated a discussion on trust in medicine between investigative journalist Katherine Eban, consumer advocate Ralph Nader, and vaccine trust anthropologist Heidi Larson. During an animated exchange of ideas, Dr. Larson expressed concerns about COVID-19



vaccine adoption due to lack of public trust. Nader pointed to commercialism and outsourcing of drugs as well as misinformation as the causes of distrust. Eban countered that the public may have too much trust and confidence in the federal agencies in place to protect them. USP executive leaders hosted a Jeffersonian dinner at which nearly 40 experts in health and medicine discussed the future of medicine and how to build trust in medical innovations. Participants focused on transparency, the importance of evidence, and making drugs available cheaper and faster.

Additionally, USP shared early results of the *Trust or Consequences 2040* report, an insightful perspective on the future of innovation in health and medicine, with TEDMED participants.

Trust eXperience

USP premiered its ***Trust eXperience***, an interactive visualization exhibit, enabling TEDMED attendees to explore how USP public quality standards build trust and increase access to medicines for cancer, cardiovascular diseases, diabetes, HIV/AIDS, malaria, and tuberculosis. From the standards used to designate a medicine's identity, strength, purity, and performance to the work of the expert scientists who set those standards, TrustX offered a look

into the complexities that help ensure medicine quality and safety worldwide.



Trust TV

While at TEDMED, nine experts in health and medicine were filmed in a remote studio for ***USP's Trust TV*** series. They were asked to consider trust's role in the future of medicine and provide their perspectives on current and emerging therapeutics including vaccines, precision medicines, and generics, as well as technologies such as machine learning and gene editing. These physicians, scientists, and business leaders agreed that trust will be essential for patients to accept innovative approaches to preventing, diagnosing, and treating disease. Building that trust will require public and private sectors to work in tandem and robust evidence from independent sources that demonstrates the safety and effectiveness of innovative treatments.



Scaling the tried and true.



Dangerous uncertainty.



A world of difference.

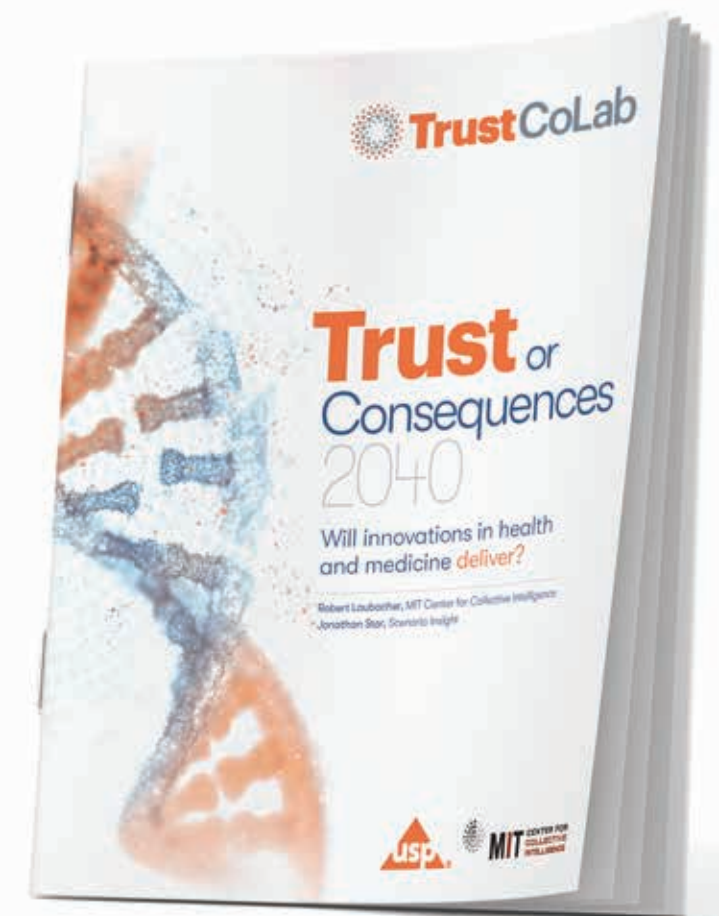


Solving tomorrow's problems.



The Trust CoLab explored four scenarios that will shape people's health between now and 2040 and how trust will be critical in making sure developments help people everywhere live longer and healthier lives.

The report, *Trust or Consequences 2040: Will Innovations in Health and Medicine Deliver?*, presents four potential worlds that could emerge by the year 2040. The report also raises critical questions about how current choices may influence healthcare in 20 years.



OUR global health

WORK COMBATS SUBSTANDARD AND FALSIFIED MEDICINES

USP's Global Public Health division concluded 25 years of work with USAID on the Promoting the Quality of Medicines (PQM) program. Led by USP and funded by the U.S. Agency for the International Development (USAID), the PQM program improved quality assurance systems in more than 40 countries to increase access to quality-assured priority medical products and decrease the prevalence of substandard or falsified medicines. The [final report](#) goes into greater detail about the program's accomplishments.



PQM+

After a competitive bid process, USP's global health impact work continues under USAID's [Promoting the Quality of Medicines Plus \(PQM+\)](#) program, which is implemented by USP and its consortium of partners. PQM+ builds on the PQM program's legacy of strengthening quality assurance systems and provides technical assistance to manufacturers and medicines regulatory authorities in low- and middle-income countries. PQM+ has made [significant strides](#) in strengthening regulatory systems that assure the quality of essential medical products.



Since the beginning of the pandemic, the PQM+ program has already made significant strides in strengthening quality-assured supplies of essential medical products. [The following are two notable examples.](#)

In January 2020, the World Health Organization (WHO) pre-qualified the first medicines quality control laboratory in Central Asia.

To fight COVID-19, the Government of Bangladesh expanded access to quality-assured personal protective equipment (PPE). Working with the Directorate General of Drug Administration (DGDA), WHO, and local manufacturers, PQM+ developed visual inspection checklists based on international standards for gowns, coveralls, fabric masks, surgical masks, and N95/KN95 respirators. DGDA inspectors use the new checklists to inspect manufacturing facilities to ensure quality standards are met.



Access to medicines alone, without quality assurance, is not enough.

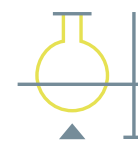
Dr. Matshidiso Moeti,
WHO Regional Director for Africa

Building

ON OUR SCIENTIFIC FOUNDATIONS



USP's foundation has been the science and the scientific rigor that underlies everything we do. In this final year of the five-year cycle, we reflect on the progress we've made and the impact we've had. Below are some of the other important scientific milestones and accomplishments that USP has achieved in FY20.



Our up-to-date initiative is nearly complete.

We have eliminated outdated techniques and ensured that hazardous chemicals are identified and removed from processes.



A two-year collaboration with FDA culminated in issuance of FDA draft guidance

titled "**Harmonizing Compendial Standards** With Drug Application Approval Using the USP Pending Monograph Process." The Pending Monograph Process (PMP) provides a transparent and efficient pathway to align the development of monographs with FDA approval of the associated applications. By the end of FY20, USP had processed 112 PMP requests.



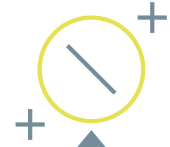
The Cannabis Expert Panel of the Botanical Dietary Supplements and

Herbal Medicines Expert Committee published a **manuscript** defining quality parameters for cannabis inflorescence. This scientific resource may serve as the basis of public quality specifications for cannabis inflorescence in the future.



The USP Biologics standards portfolio was expanded and diversified with

standards to support the performance of methods and processes applicable to classes and families of products throughout their lifecycle. Among the notable additions in FY20 were Monoclonal Antibody Performance Standards and USP General Chapter <127> *Flow Cytometric Enumeration of CD34+ Cells* and a CD34+ Cell Enumeration System Suitability Reference Standard.



To help protect patients from exposure to potentially harmful nitrosamine impurities

in medicines, the Chemical Medicines program unit began developing Reference Standard materials for all six nitrosamine contaminants identified by FDA in angiotensin II receptor blockers and other drugs. Chemical Medicines also continued its work developing a general chapter framework of test procedures and approaches for controlling **nitrosamine impurities**.



USP Excipients scientists published

the results of a novel excipients survey that explored views on the current state of excipient innovation. The **survey results** will help shape USP's future strategy for excipient standards development.

THE PAST LIGHTS A PATH TOWARD THE future of quality

Central to USP's achievements are the contributions of countless experts, who volunteer their time and knowledge in USP's Council of Experts (CoE) and Expert Committees and Panels.

A dynamic recruitment campaign during FY20 invited new volunteers from around the world. Applicants from over 30 countries and representing more than 30 fields of study were willing to apply their knowledge

and experience to develop quality standards. Deliberate efforts were made to recruit new members representing emerging topics, such as advanced therapies in biologics and health information and technology.

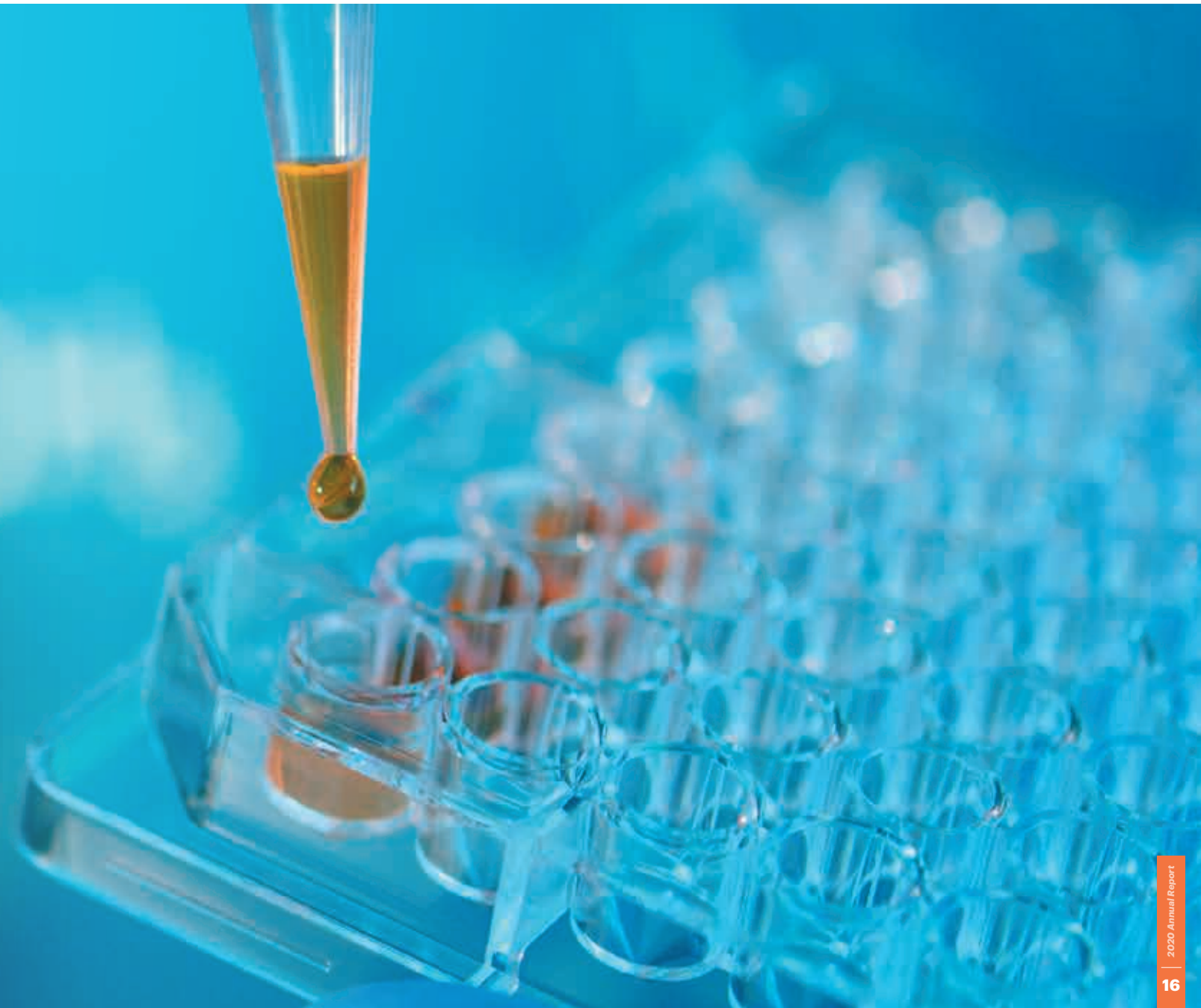
The CoE piloted a more agile and flexible volunteer model for engaging volunteers and leveraging their time and expertise in the next cycle. The new model was designed to help attract a broader, more diverse audience and increase

volunteer engagement and retention. The newly created Expert Advisor role is a short-term opportunity for experts to contribute to specialized topics as the need for their expertise arises.

The **CoE report** describes the activities and achievements of the CoE, its Expert Committees, and its Expert Panels during the 2015–2020 cycle. The following are examples of the CoE's accomplishments in FY20.

- ▶ **Exploring novel pathways to monographs for over-the-counter medicines**
- ▶ **Responding to the COVID-19 pandemic**
- ▶ **Collaborating with the FDA to expedite generic drug development and improve patient access to medicines**
- ▶ **Recruiting for a new Scientific Fellows program**
- ▶ **Delivering on monograph modernization**
- ▶ **Adding global health monograph information to General Notices**

Volunteer applicants from **30** countries
representing **30+** fields of study



future

EMBRACING OUR

“
Our strategy also includes four Enabling Ambitions — People, Quality, Digital, and Investment and Sustainability — which are critical success factors that must be cultivated for us to fulfill our mission and deliver the greatest impact.”

While committed to a strong finish of the 2015–2020 cycle, USP also looked ahead during FY20, developing a strategy with which to embark on a new fiscal year, a new cycle, and a new century.

With rapidly emerging new medical modalities, new manufacturing, analytical and digital technologies, and an increasingly complex global and regulatory landscape, we recognized that the challenges of ensuring a global supply of quality medicines are acute. The pandemic accelerated the pace of these changes and placed new pressures on the global supply of quality medicines. Our strategy would be built on the foundation of our mission while moving agilely toward work that will be relevant and impactful in addressing these emerging issues.

By embracing the challenges that we identified as opportunities, USP approaches the future from a position of strength. Our mission priorities focus on ways to continue building trust in medicines. Those priorities are informed by our own experience and insights, as well as by the perspectives of our Convention member organizations that represent a cross-section of academia, government, healthcare, and industry from around the world. We are committed to building trust in COVID-19 vaccines and treatments by supporting their development, manufacturing, and distribution, and strengthening supply chain resiliency to help ensure the supply of quality medicines for all.

Our 2025 strategy establishes three Impact Ambitions — Standards, Advocacy, and Capability-Building —

that will allow us to produce new and definitive standards for medicines; make it easier for stakeholders to use our standards and raise our voice to continue to advocate for quality. Our strategy also includes four Enabling Ambitions — People, Quality, Digital, and Investment and Sustainability — which are critical success factors that must be cultivated for us to fulfill our mission and deliver the greatest impact.

Difficult but inspiring work lies ahead. We are eager to begin.



Setting the stage

FOR USP'S THIRD CENTURY



Convention
The 2020 Meeting



Anthony Lakavage, USP
Senior Vice President,
Global Affairs and
Secretary, USP Convention
and Board of Trustees
welcomes Convention
Delegates from more than
40 countries



FDA Commissioner
Stephen Hahn, M.D.,
addresses USP
Convention Delegates
from around the world.



As the 2015–2020 cycle drew to a close, USP convened Delegates from its nearly 500 member organizations at the **Convention Meeting** in May. Originally planned as an in-person event with a special celebration of USP's 200th anniversary, the meeting was transitioned to USP's first ever virtual Convention Meeting. Key governance duties and important elections proceeded, and the meeting's virtual format didn't diminish the seriousness with which Delegates approached their responsibilities. Convention Delegates adopted 15 **Resolutions** that align with USP's 2020–2025 strategy and elected USP's Board of Trustees and Council of Experts that

will help guide USP's priorities and maximize its impact. As the 2020–2025 cycle begins, the **Council of the Convention** (CoC) will be established. The CoC is a global governance committee that represents the full USP Convention Membership throughout the five-year cycle, making decisions that help shape USP's governance, the Convention's Membership, and the Resolutions that contribute to USP's strategic direction.

Building a sustained connection
The Council of the Convention and **Board of Trustees** worked with USP to shape a new model for connecting with Convention

Membership designed to build sustained engagement throughout each five-year cycle. This new model consists of Convention Sectors and Regional Chapters that aim to harness the full breadth and depth of perspectives within the USP Convention. Convention Sectors are built around broad areas of standards setting, such as Biologics, Generic Medicines, and Innovation, engaging Members around shared priorities. Regional Chapters are in areas of the world where USP works, including Latin America, South Asia, Greater China, and Asia Pacific, to bring together Members with common public health concerns and regulatory environments.

<p>I Resolution</p> <p>Collaboration with FDA and Other Stakeholders on Health Priorities</p>	<p>II Resolution</p> <p>Efficiency in Standards Development and Revision</p>	<p>III Resolution</p> <p>Quality Standards</p>	<p>IV Resolution</p> <p>Access to Biologics</p>	<p>V Resolution</p> <p>Research and Innovation Within USP</p>
<p>VI Resolution</p> <p>Digital Transformation of Standards</p>	<p>VII Resolution</p> <p>Education and Training for Industry and Healthcare Professionals</p>	<p>VIII Resolution</p> <p>Regulatory Systems Strengthening</p>	<p>IX Resolution</p> <p>Compounding</p>	<p>X Resolution</p> <p>Cannabis</p>
<p>XI Resolution</p> <p>Pharmacopeial Cooperation and Convergence</p>	<p>XII Resolution</p> <p>Evidence Generation to Inform Policy</p>	<p>XIII Resolution</p> <p>Coalition Building</p>	<p>XIV Resolution</p> <p>Culture of Excellence</p>	<p>XV Resolution</p> <p>Impact Expansion</p>

As a nonprofit organization committed to helping protect public health, USP prioritizes responsible stewardship of our resources to advance our mission. Looking ahead to the new cycle, we laid foundations in FY20 that will enable us to face the rapidly advancing pharmaceutical and technical landscapes from a position of strength. To sustain our ability to deliver on our mission, we sought to protect our existing revenue base while directing our growth energies in areas that will maximize our relevance to the broad future of quality medicines.

While the pandemic has impacted the way we work, USP has been resilient in meeting our goals and sustaining our operations and mission critical activities. We are committed to a long-term strategy that will enable global integration and response to public

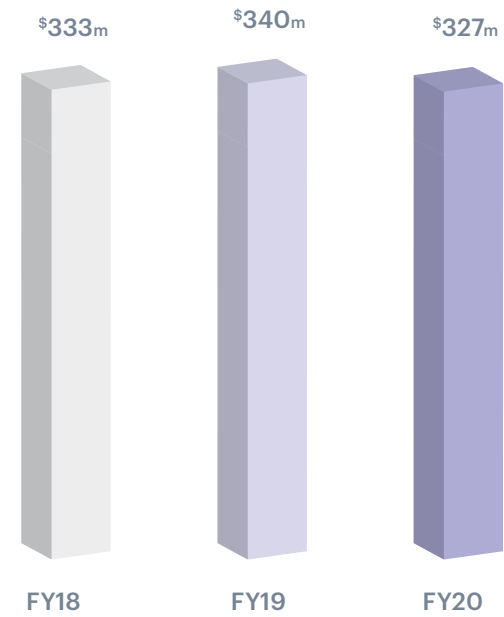
health needs. We recognize the need to invest in significant cross-functional opportunities with major commitments of management focus and resources.

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, that support our work to advance 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, 2020. The USP Board of Trustees oversees our strategic plan, enterprise risk management, operating goals and budgets, and investment reserves to ensure alignment with our mission.

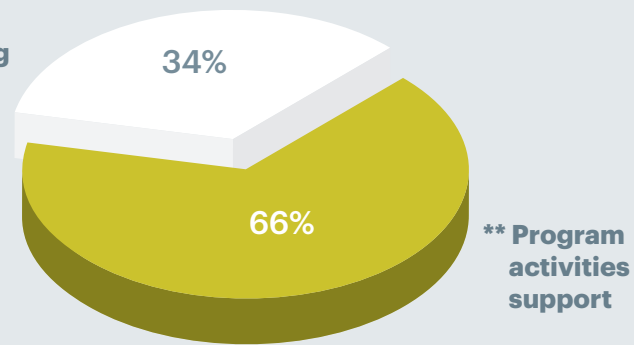
Summary

Revenue



Revenues Contribute to USP Mission-Driven Programs

* Supporting activities



USP invests approximately 95 percent of every dollar USP received in the development of public quality standards and programs that advocate for quality throughout the medicines supply chain, build stronger regulatory systems, and educate healthcare practitioners and pharmaceutical industry stakeholders.

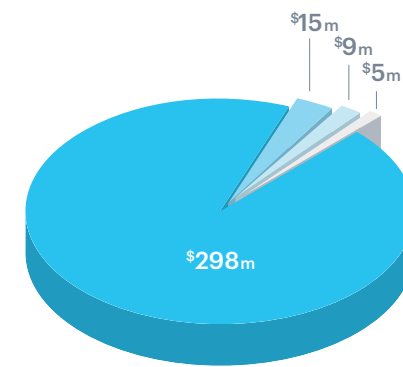
The remaining 5 to 10 percent of revenue is held in reserve each year to help mitigate risk in the event of unexpected financial challenges and ensure that USP can continue its work.

* Supporting activities include management and general expenses.

** Program activities support standards development, regulatory system strengthening, public health advocacy, and education.

The 2020 audited financial statement is available [here](#).

FY20 Sources of Funds



Sales of Reference Standards (RS) and publications

Contributed RS and services

USAID and other donor funding

Verification and other programs

Assets

Net Assets

Total Assets



