

Rising to
global health
challenges



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FY 2021 Annual Report

Just before the start of USP's 2020–2025 cycle, the global public health landscape changed with the onset of the COVID-19 pandemic. Responding to the crisis became a top USP priority. We strategically leveraged our expertise, volunteer bodies, and global footprint to help strengthen the supply of trusted, quality-assured vaccines, treatments, and preventatives.

At the same time, USP's core obligations still required our attention. Staff and volunteers continued to advance that essential work while urgently mobilizing to address the global public health crisis.

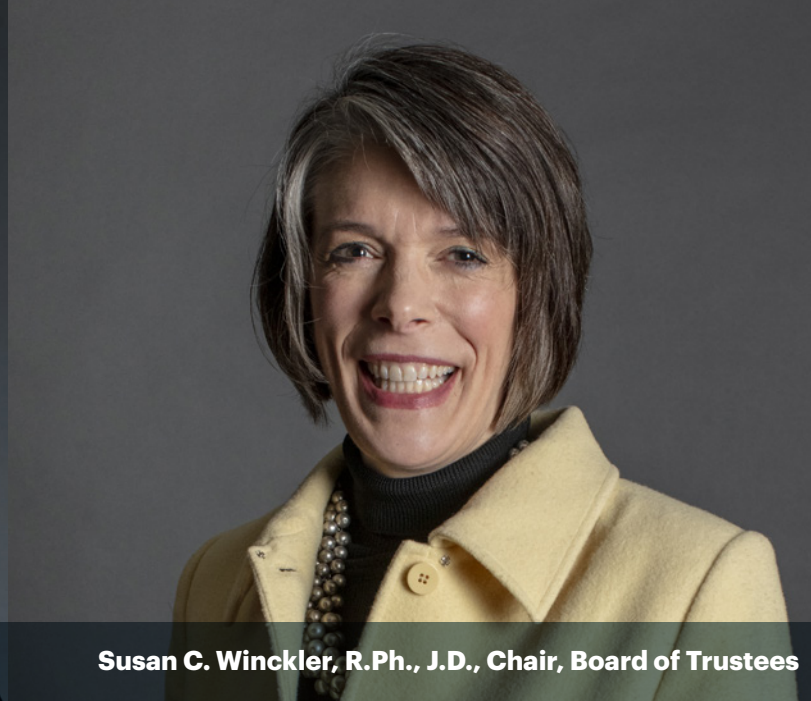
Throughout the fiscal year that closed on June 30, 2021, USP worked to advance our mission and activate our strategy to deliver impact through standards development, advocacy, and capability-building efforts that help ensure global access to quality-assured medicines, dietary supplements, and foods.

We are proud to share this report on the progress USP has made during the fiscal year.





Ronald T. Piervincenzi, Ph.D., CEO



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



When USP's 2021 fiscal year began in July 2020, the vast and devastating impact of the COVID-19 pandemic was fueling both closed behaviors but also global cooperation and innovation with which the world would respond. At USP, we determined early on that our work to partner with stakeholders on the pandemic response would be our top organizational priority.

During the year, development, distribution, and administration of new COVID-19 vaccines, treatments, and preventatives moved at a pace and scope never before experienced. At USP, we worked with our expert volunteers to deliver essential tools and resources to support these efforts and ensure access to quality-assured products. Together, we helped expand access to safe hand sanitizers, minimize vaccine waste, maximize shots in arms, and address the potential for substandard and falsified vaccines and treatments.

These and other USP efforts helped strengthen the medicine supply chain and trust in critical medical products at a time when public misinformation was rampant and resulting uncertainties only served

to further undermine already lagging public trust. It's exactly the kind of practical, solutions-oriented approach that USP has taken since its founding over 200 years ago to advance its public health mission.

Throughout the pandemic, we also continued to advance our broader strategy to deliver impact through standards development, advocacy, and capability building efforts that help ensure global access to quality-assured medicines, dietary supplements, and foods. We continued to transform our digital fluency and the way we work to maximize our impact, help ensure the safety and wellbeing of our staff and volunteers, and further support a culture of inclusion and diversity where everyone feels empowered and valued for their contributions.

At the close of the 2021 fiscal year, we are proud of what we've accomplished. Through this annual report, we invite you to learn more about how our ongoing efforts are helping to strengthen the medicines supply chain and improve public health in the U.S. and around the world.

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

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

USP by the numbers

From the number of standards we develop, to the number of volunteers and collaborators we work with, to the number of people who attend our education courses and workshops, to the number of countries that use USP standards, numbers help tell the story of how USP's work supports trust in the quality of medicines, dietary supplements, and foods around the world.



24,000+

people

attended USP Education courses and workshops



99%

experts

in science, industry, healthcare, academia, and government liaisons from 41 countries

501

convention members

from 44 countries



675

new or revised documentary standards

bringing our total number to 7,514

125

new reference standards

bringing the current catalog to 4,025

470+

donations

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

250+

scientific publications

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



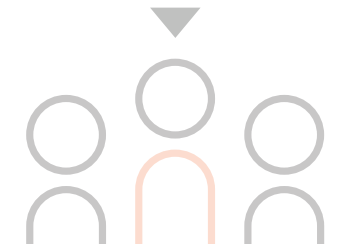
178

countries and territories

received shipments of USP standards

1,150+

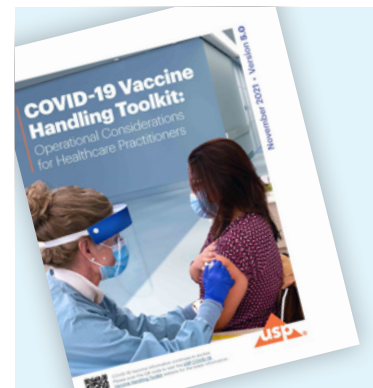
staff members globally



Responding to COVID-19

To help healthcare practitioners, manufacturers, and other stakeholders deliver vaccines to billions of people, prevent disease, and treat the sick, USP worked with our expert volunteers from the onset of the pandemic to quickly identify and address related needs. During the year, we developed a suite of tools and resources to address quality challenges and potential efficiency gaps in the delivery of COVID-19 vaccines, treatments, and preventatives. These resources helped to support trust, get more shots in arms, and save lives.

Throughout the year, we also worked in concert with allied organizations, including USP Convention members, to promote awareness of these essential tools and resources among healthcare practitioners, manufacturers, regulators, educators, government officials, and other key stakeholders.



USP's COVID-19 [Vaccine Handling Toolkit](#) brings together in a single resource essential strategies to address efficiency gaps, help maximize doses per vial, and minimize waste while maintaining safety and quality.



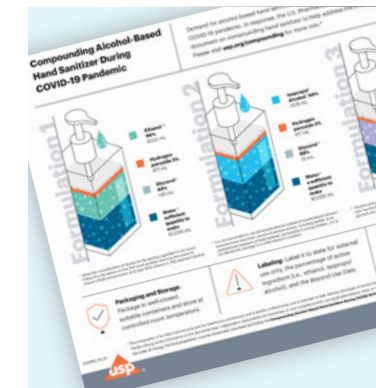
USP resources for ensuring the quality of health products during the COVID-19 pandemic include [learnings about substandard and falsified \(SF\) medicines and vaccines](#) from past pandemics as well as tools developed either by USP or in cooperation with other organizations.



USP's [resources](#) for addressing the potential for SF COVID-19 treatments include a [Toolkit](#) for determining the identity and purity of remdesivir. This [Toolkit](#) also features USP's first NMR-based digital spectra when using either high field or benchtop NMR instruments.

“
Development of USP's toolkit for detecting falsified remdesivir antiviral COVID-19 treatment could not have been done without the collaboration and support of manufacturers, other pharmacopeias, and organizations that provided essential materials, information, guidance, and support.”

Jeffrey Moore, senior director, USP Scientific Affairs & Strategy



USP's [Hand Sanitizer Toolkit](#) addresses quality challenges for production and use of alcohol-based hand sanitizers. The Toolkit includes free access to standards and information on producing quality hand sanitizers and addressing the potential for potency issues and methanol contamination. [Alcohol](#) and [dehydrated alcohol](#) monographs were also updated with a limit-of-methanol test to address the issue.



Pandemic-related USP trainings included a [webinar](#) held in conjunction with the World Health Organization and Sabin Vaccine Institute for immunization-experts dialog on delivering COVID-19 vaccines globally; webinars on USP Toolkits for vaccine quality assessments targeting regulators in low- and middle-income countries; a [seminar](#) focused on helping stakeholders ensure quality alcohol-based hand sanitizer production and supporting safe use of the products; and a [forum](#) addressing regulatory and quality issues in the manufacture of alcohol used in drug products more broadly, including hand sanitizers used to combat the public health emergency.

USP's pandemic response efforts have had a quantifiable impact. From its initial release in January 2021 and throughout the year, USP's COVID-19 Vaccine Handling Toolkit helped stakeholders accelerate the pace of vaccinations, prevent waste while maintaining quality, and build confidence in becoming a vaccine administrator.

Over 50 million additional COVID-19 vaccine doses were made available in the U.S. as of July 2021 with the help of strategies outlined in USP's Vaccine Handling Toolkit.

- More than 76,000 COVID-19 vaccine network providers across the U.S. at large retail and independent pharmacies, hospitals, and public health entities received the Toolkit.
- Toolkit strategies and best practices were shared with all 50 U.S. state pharmacy associations, 60+ boards of pharmacy, and over 160 schools of pharmacy by healthcare practitioners, government officials, institutions, and others across the U.S.
- The international version of the Toolkit reached over 50 countries.

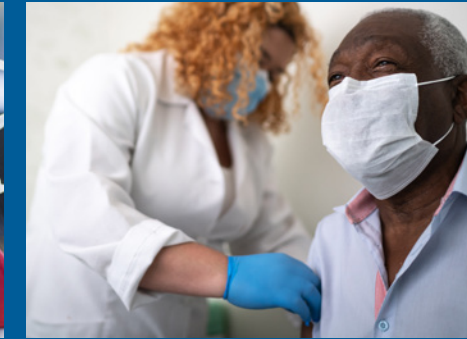
Meanwhile, we reached 4 million people globally with our Hand Sanitizer Toolkit to increase the world's supply of safe, quality hand sanitizer.

“
Using the strategies from the USP Vaccine Handling Toolkit for pre-drawing syringes and streamlining our processes and workflow, we increased shots in arms by 50% per day.”
Patricia Slattum, Pharm.D., Ph.D., BCGP, vaccine administrator for the Virginia Medical Reserve Corp and Virginia Commonwealth University



“USP's Toolkit facilitates sharing of best practices with colleagues, including at other institutions we work with, to help ensure confidence that vaccine handling procedures are consistent regardless of practice setting.”

Kevin Hansen, Pharm.D., M.S., BCPS, BCSCP, assistant director of pharmacy, pharmaceutical compounding, The Moses H. Cone Memorial Hospital, Cone Health



“Diverse front-line experiences helped us appreciate the spectrum of stakeholder needs in developing the Vaccine Handling Toolkit. What was familiar for one type of expert may be entirely novel to a volunteer in a rural setting, and we needed to accommodate each perspective.”

Lindsey Clawson, MBA, USP lead of COVID-19 vaccine strategy



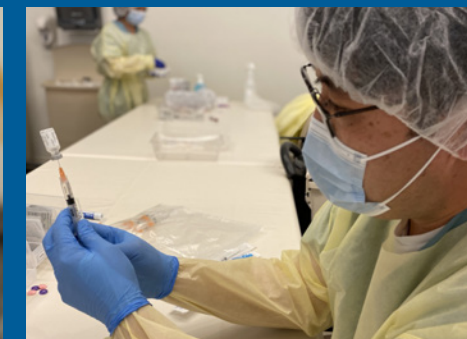
“I'm proud to work alongside such dedicated USP expert volunteers and staff who continue to contribute to the Vaccine Handling Toolkit in response to user feedback and new information, and the agile, collaborative approach we took to addressing a public need in real time.”

Nakia Eldridge, Pharm.D., MBA, USP senior manager, healthcare quality, safety, and information



“With expanded authorization for use of COVID-19 vaccine in children, more people will now be seeking vaccination appointments. USP's Toolkit will help pediatricians and other vaccine administrators consistently maximize doses and minimize waste while maintaining quality.”

Lisa Ashworth, B.S. Pharm., R.Ph., BCSCP, FACA, system compounding specialist and clinical pharmacist, Children's Health System of Texas



“Inova started using the Toolkit as soon as it was available. We standardized our workflow and processes to optimize vaccine prep. Standardization guarantees doses are always maximized and waste is minimized while ensuring vaccine is prepared following the best, safest practice.”

Melanie Massiah-White, B.S. Pharm., M.H.A., vice president, chief pharmacy officer, Inova Health System



“It was an honor to collaborate on development of the Toolkit. This effort, led by USP's Healthcare Safety & Quality Expert Committee with input from other committees and liaisons from CDC and FDA, and in coordination with Operation Warp Speed, helped increase COVID-19 vaccine availability by over 50 million additional doses.”

Farah Towfic, Pharm.D., MBA, director, USP CEO Operations

Commitment to supply chain resilience

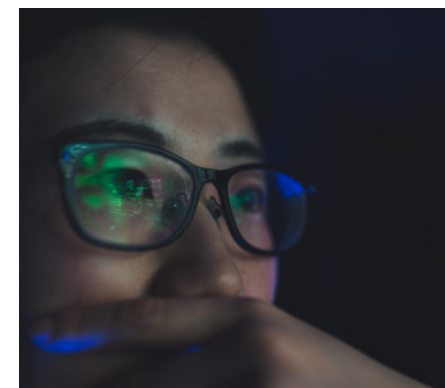
USP's standards and related programs play an important [role](#) in almost every stage of the [global medicines supply chain](#), helping governments and manufacturers increase the availability of safe, quality medicines, and building patient and healthcare provider trust. During the year, USP advanced initiatives to address long-standing supply chain vulnerabilities that became more obvious during the pandemic.

“
USP developed the Medicine Supply Map to help identify, characterize, and quantify risks in the upstream supply chain. It can help direct government investment in improving supply chain resiliency and support decision-making to mitigate the impact of drug shortages.”

*Vimala Raghavendran, senior director,
USP Pharmaceutical Supply Chain Center*



USP leveraged its role as a convenor to co-host a [five-day summit](#) on global pharmaceutical manufacturing and supply chain security with the American Hospital Association, American Medical Association, and American Society of Health-System Pharmacists. Aided by input from government agencies, regulators, and other stakeholders, the coalition started [shaping solutions](#).



USP worked to aid [modernization of pharmaceutical manufacturing](#) to increase production capacity, expand manufacturing to more regions, reduce over-reliance on a few countries, and help ensure medicine quality. We forged a strategic [alliance](#) with Phlow to certify and validate pharmaceutical continuous manufacturing (PCM) processes and partnered with Rutgers University on a [course](#) to aid understanding of PCM requirements.

USP developed a series of white papers and other stakeholder resources to advance policies to increase [visibility](#) into the medicines supply chain, harness the power of [PCM](#), and make the supply chain more [resilient](#).



USP transformed the way we work to ensure the safety of our personnel while navigating logistical challenges to continue to deliver public quality standards and other essential products and services to manufacturers in over 150 countries to help ensure the safety and quality of medicines.



USP worked to glean insights from disparate data sources to develop an [early-warning capability for potential disruptions](#) in the upstream medicines supply chain, and to better understand and identify weaker links in the supply chain.

USP is committed to building global capacity to produce quality-assured medicines. During the year, this included advancing educational programs and other initiatives to expand USP's public health impact and reach more people in more geographies around the world. By promoting collaboration and engagement across key sectors, USP is helping to strengthen capabilities among national medicines regulatory authorities to help ensure medicine quality and expand patient access to essential medicines.

USP Education

USP completed an education program refresh and refocused resources where they could have the most impact, supporting those who are implementing USP quality standards. During the year, we hosted industry, regulatory, and healthcare professional education and training for over 21,000 attendees, including significant participation outside the U.S., and we expanded digital access to USP training materials. Of those completing training course surveys, 88% reported the program would have a positive impact on the quality of their work.

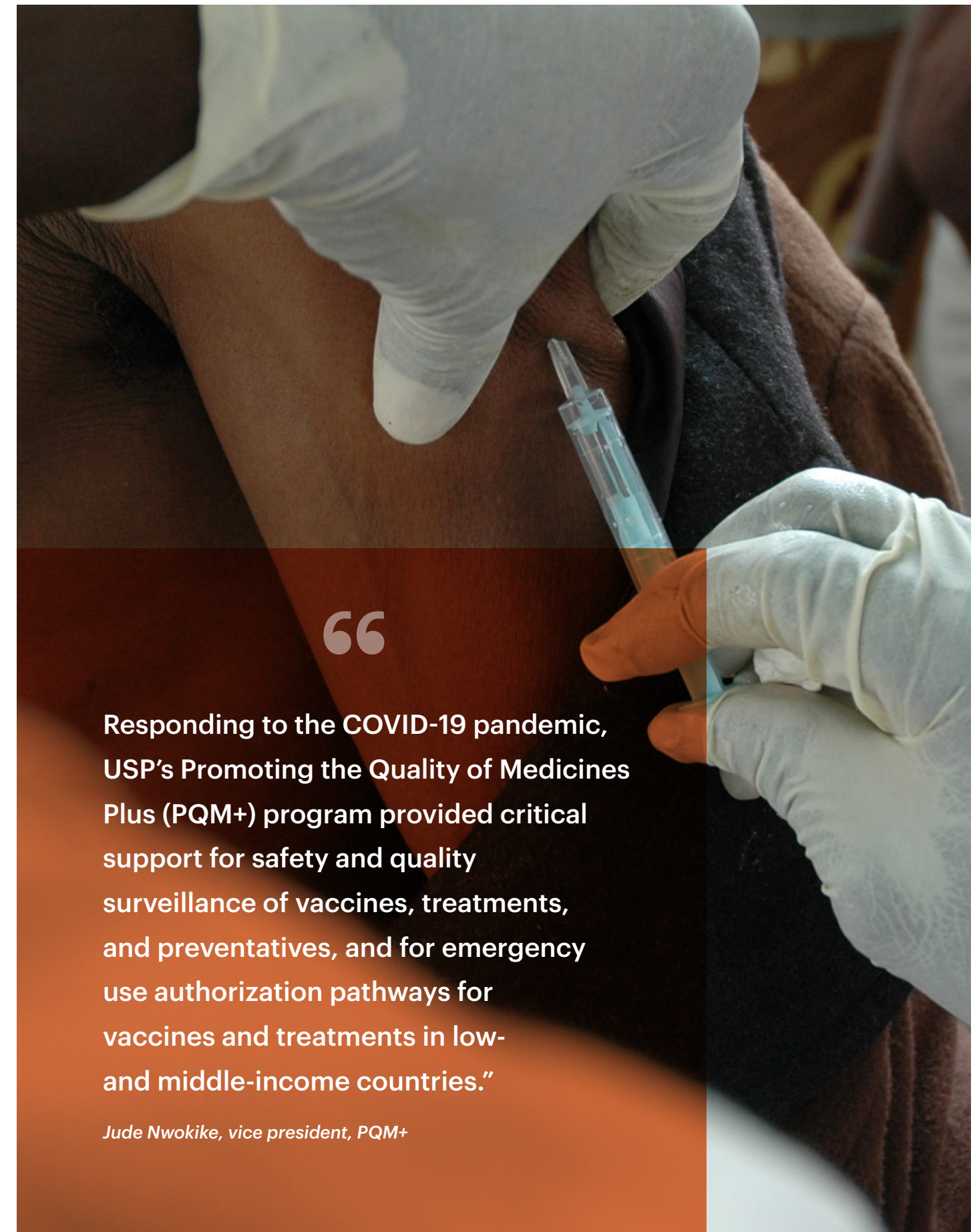


USP worked throughout the year to expand global health and manufacturing services, including groundwork to acquire [Pharmatech Associates](#). Completed early in fiscal year 2022, the acquisition extends our capability-building portfolio to deliver on our mission to expand the supply of quality medicines.

Promoting the Quality of Medicines Plus (PQM+)

USP expanded the reach of its flagship [Promoting the Quality of Medicines Plus](#) (PQM+) program, which aims to strengthen regulatory systems, apply use of quality assurance standards, and access to quality-assured medicines in low- and middle-income countries (LMICs). Funded by the U.S. Agency for International Development, the program added Guinea, Mozambique, the Democratic Republic of the Congo, Madagascar, and Tajikistan as we continued to expand our circle of partners and donors to amplify our efforts.

Under the program, we deployed risk-based product surveillance guidelines and tools to 20 countries, improved the capacity of 37 manufacturers in LMICs to produce quality-assured medicines, and supported manufacturers in development of 11 critical and life-saving products for tuberculosis, malaria, neglected tropical diseases, and maternal/child health.



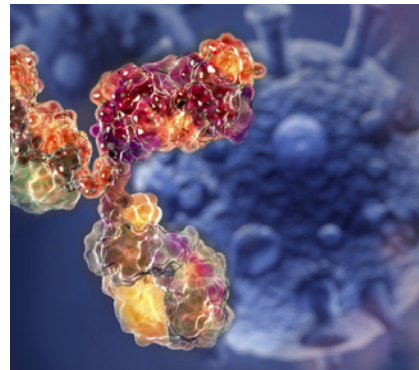
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Responding to the COVID-19 pandemic, USP's Promoting the Quality of Medicines Plus (PQM+) program provided critical support for safety and quality surveillance of vaccines, treatments, and preventatives, and for emergency use authorization pathways for vaccines and treatments in low- and middle-income countries.”

Jude Nwokike, vice president, PQM+

Responding to emerging quality challenges

USP standards play an essential role in addressing emerging quality challenges to support trust in medicines and help prevent related, potential drug shortages before they occur. Beyond our work to address the pandemic in 2021, USP continued to develop science-based standards and related programs that support the development, manufacture, distribution, and administration of medicines to help ensure they are safe and work as they should.



To support biopharmaceutical innovation and monoclonal antibody therapy in particular as a growing class of biotherapeutics, USP launched a new set of monoclonal antibody performance standards to support assessment of multiple analytical methods used to evaluate product quality attributes, including identity, post-translational modifications, and aggregation.



Impurities can affect the efficacy and safety of drug products because they can occur at any stage of the drug development and manufacturing process. The new Pharmaceutical Analytical Impurities were released through a USP quality process designed to ensure identity and quality appropriate for analytical applications. The growing portfolio is used in analytical testing for drugs in oncology, cardiovascular, psychiatric, gastrointestinal, and other therapeutic areas.

“**USP’s nitrosamine impurities general chapter and associated reference standards have helped stakeholders ensure appropriate control of these impurities while our education courses and training materials have helped raise awareness about related regulatory requirements globally.**”

Mrunal Jaywant, USP senior director of R&D

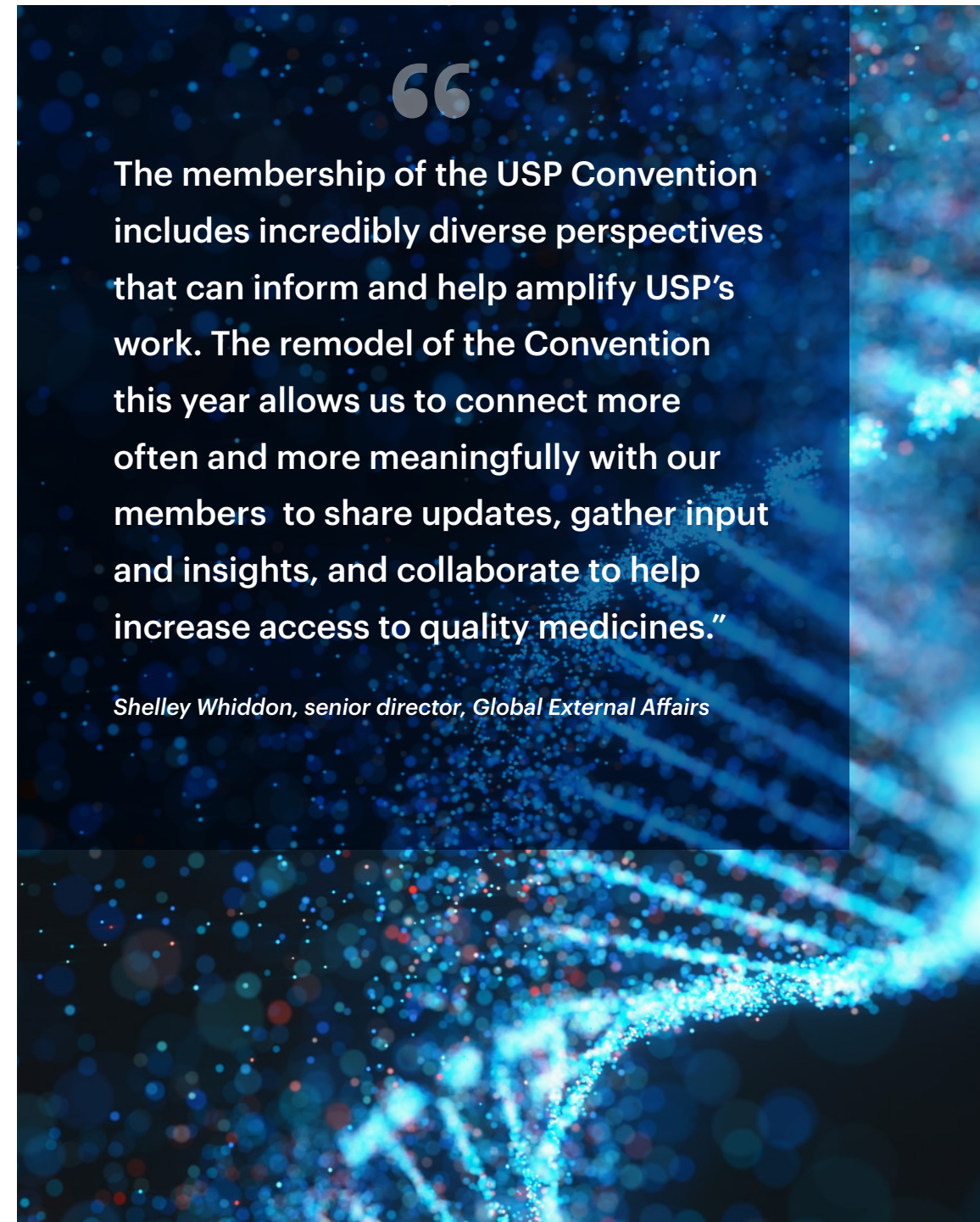
To expand and support stakeholder awareness and dialog around the science of quality, USP initiatives included:

- Launch of the Our Science website to showcase the science behind our standards, the innovative work of USP scientists and volunteers, and opportunities for emerging leaders in science such as student fellowships and programs.
- Open Forum stakeholder events to facilitate information exchange and discussion among manufacturers, regulatory agencies, and the broader scientific community on key topics to help USP address emerging challenges.
- Publication of 258 USP scientific publications during the year, including journal articles, *Stimuli* articles, industry press articles, scientific posters, and presentations.

To help drug manufacturers and regulators worldwide address the potential for cancer-causing [nitrosamine impurities](#) in medicines, USP engaged with thousands of stakeholders to help control the risks. This included development in record time of new standards, educational courses, webinars, and workshops through collaboration with our Expert Volunteers to address the pressing health concern. USP launched an [online knowledge hub](#) community on nitrosamines to facilitate information exchange, engaging 400+ stakeholders from 63 countries.



Since the time of USP's founding over two centuries ago, to our responses to the many public health crises that have occurred over the years and the emergence of countless new therapeutic modalities, USP has been committed to helping make it possible for people to trust the quality of medicines that help them live longer, healthier lives. Achieving this goal has required a culture of constant innovation and transformation. In fiscal 2021, this included transforming the way we work to increase the impact of our standards, maximize volunteer engagement on key priorities, and further operational excellence.



USP maximized the power of the [USP Convention](#)—a governing body with over 500 members from around the world—by adding opportunities for more frequent and meaningful engagement on shared priorities through creation of regional and sector-based chapters. These included new regional chapters for South Asia, Latin America, and greater China, and new sectors for biologics, generic medicines, healthcare practice, and dietary supplements. USP also redesigned its model for volunteer engagement to increase flexibility when leveraging expert advisors for standards development.



USP launched the Digital & Innovation (D&I) division to accelerate and amplify our digitally-enabled public health initiatives and digital fluency for long-term public health impact. D&I will help make more of USP's content available through digital processes and platforms, and create new digital experiences when interfacing with USP standards and other content. As part of this work, USP started the transition to new platforms to create, manage, and disseminate content accessible at the fingertips of healthcare providers and other stakeholders.



USP's broader preparations for the future are reflected throughout our [2020–2025 Resolutions Progress Report](#), which further details progress in fiscal year 2021 and worked planned for fiscal year 2022.



USP worked to further integrate advanced technologies and their applications into our reference standard operations, including quantitative nuclear magnetic resonance (qNMR) analytical procedures to help ensure quality. qNMR methods were included in USP's [Toolkit](#) for addressing the potential for substandard and falsified remdesivir treatment of COVID-19.

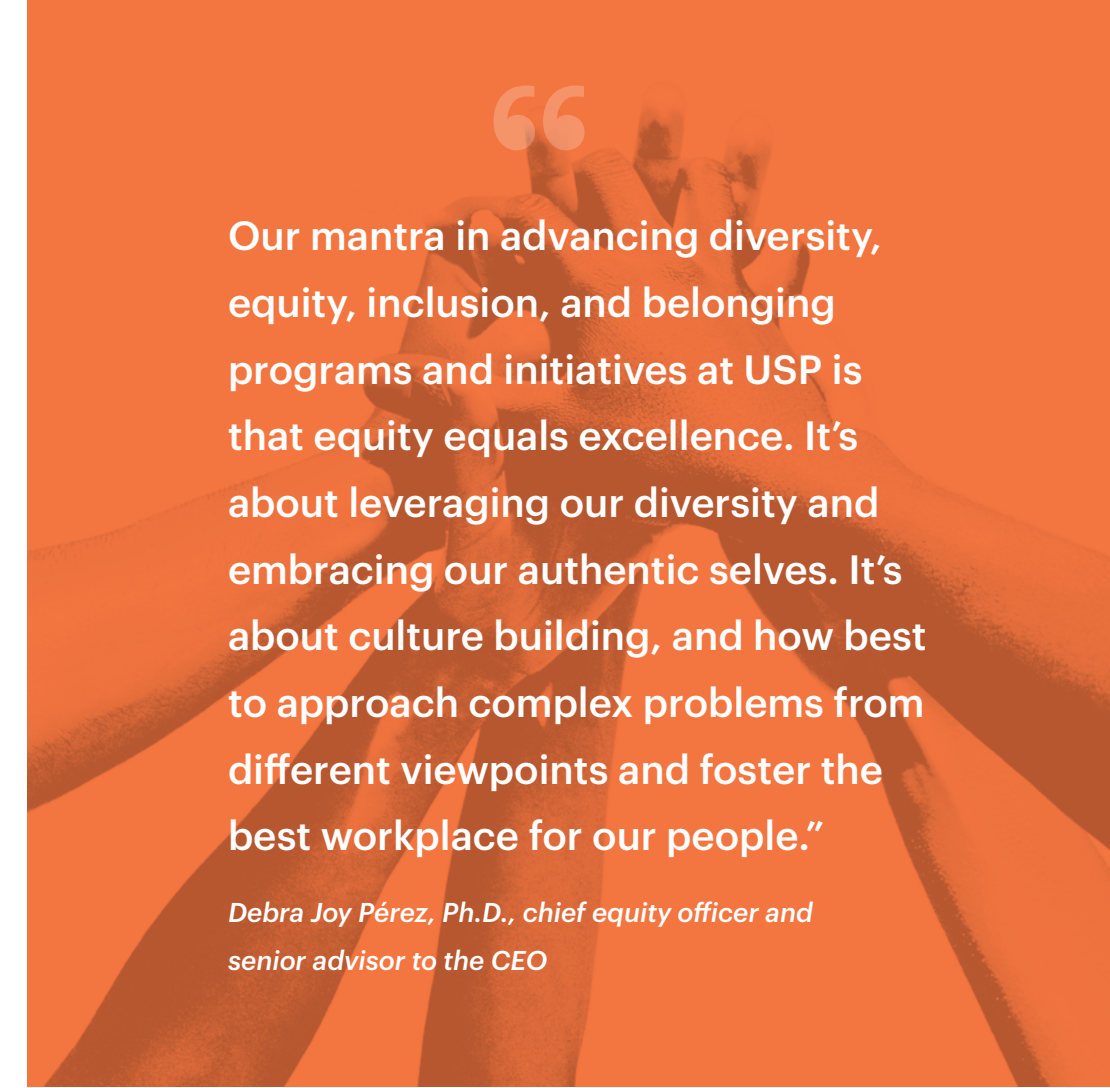
Leveraging our diversity

Evidence shows that when more diverse perspectives are included in organizational cultures and processes, there is more innovation and creative thinking, and better problem solving. At USP, these are critical drivers in applying our science to fulfill our public health mission.

In fiscal 2021, USP launched its Office of Organizational Culture, Equity and Inclusion Excellence (the USP Equity Office) to shape and implement diversity, equity, inclusion, and belonging (DEIB) programs and initiatives across USP operations and mission activities, and to serve as a resource for USP's worldwide volunteers and staff.

The USP Equity Office team is led by a newly hired [chief equity officer and senior advisor to the CEO](#) on DEIB. The team's work is supported by the organization's executive suite, a DEIB Council, and other leadership, and is extended via a variety of affinity groups across the organization. USP affinity groups bring together staff members with shared interests and experiences to advance understanding, promote a culture of respect and inclusion, provide support, and help contribute to personal and professional development in the work environment to help USP deliver on our global public health mission.

Equity office achievements during the year included formation of more than a half dozen affinity groups and in-depth DEIB training for the executive team and entire USP staff, to help advance DEIB goals.



“Our mantra in advancing diversity, equity, inclusion, and belonging programs and initiatives at USP is that equity equals excellence. It's about leveraging our diversity and embracing our authentic selves. It's about culture building, and how best to approach complex problems from different viewpoints and foster the best workplace for our people.”

Debra Joy Pérez, Ph.D., chief equity officer and senior advisor to the CEO



As a nonprofit scientific organization committed to improving global health, USP prioritizes responsible stewardship of our resources to advance our mission. In fiscal 2021—the first fiscal year of our new five-year cycle—USP was resilient in meeting our goals and sustaining our operations and mission-critical activities while continuing to respond to the global health crisis caused by COVID-19. We sustained our operating margin and increased productivity in a very challenging environment.

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. This summary of financial information has been extracted from the USP audited consolidated financial statements for the fiscal year that ended June 30, 2021.

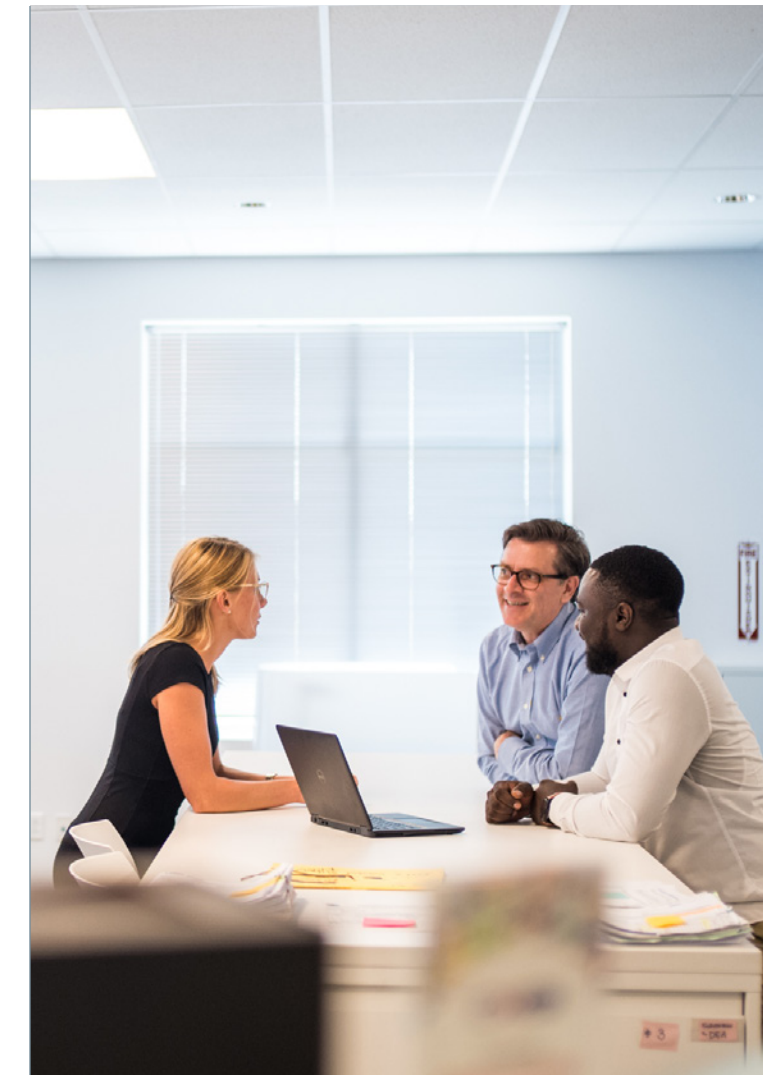
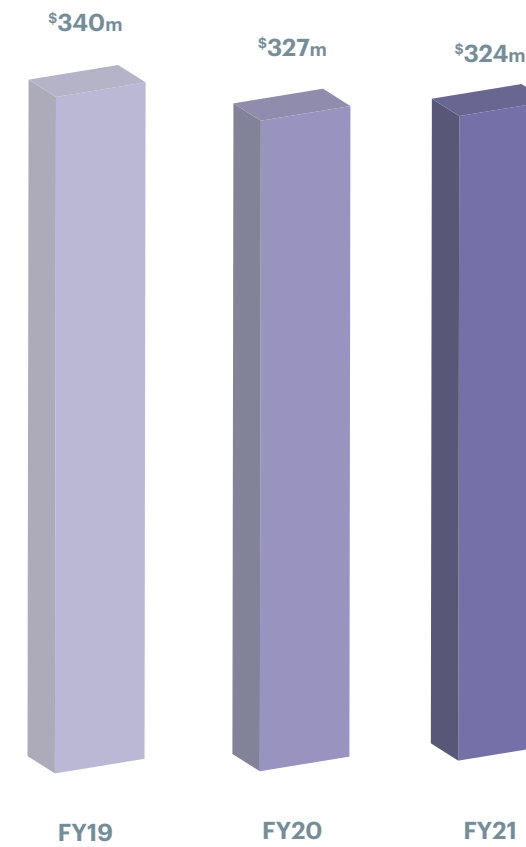
The full 2021 audited consolidated financial statements are available [here](#).



Revenues contribute to USP's mission-driven programs

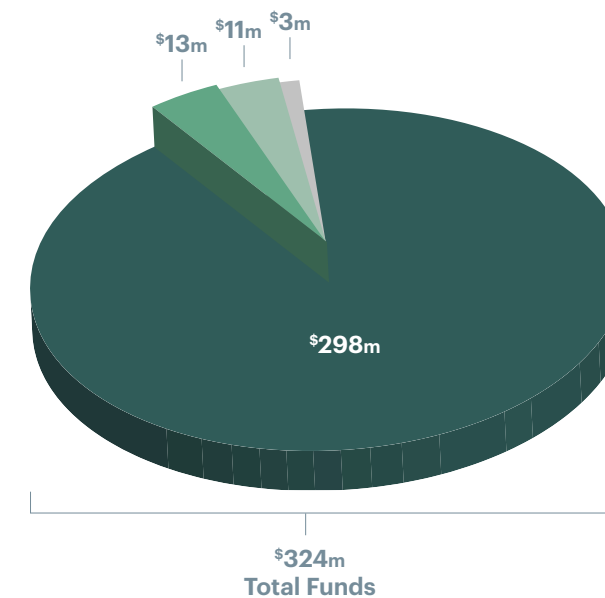
USP invests approximately 95 percent of every dollar the organization receives in the development of public quality standards and programs that advocate for quality throughout the medicines supply chain, build stronger regulatory systems, and educate healthcare practitioners and pharmaceutical industry stakeholders. The remaining 5 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.

Revenue



FY21 Sources of funds

- Sales of reference standards and publications
- Contributed reference standards and services
- Grants and other donor funding
- Quality verification and other programs



Assets

- Net assets
- Total assets

