Advancing the **quality of medicine**

2022 USP Annual Report

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USP Reimagined

For over 200 years, USP has repeatedly reimagined and reinvented the impact we deliver in response to the evolving global healthcare landscape. Our mission—to build trust in the quality of medicines that patients rely on—continues to drive the work across our global enterprise. Transitioning to a post-pandemic environment ensured that FY22 was no exception.

Despite a global environment with geopolitical tensions and economic challenges, USP met each of our goals while increasing our mission impact and sustaining operations. We expanded our support for the global supply of quality medicines through our coordinated standards, advocacy, and capability-building activities.

USP continues to serve as a strategic leader in global pharmaceutical quality. We oriented our science ("quality paradigms") on areas of innovation and emerging technologies. Our progress on digital initiatives was accelerated by a more iterative and agile way of working. We advanced the development of priority standards to address emerging health challenges and align with analytical, manufacturing, and technological advances. In response to guidances from the Centers for Disease Control and Prevention (CDC) and World Health Organization (WHO) we revised our COVID-19-related content.

This year, USP's Dietary Supplement Verification Program hit an exciting milestone—20 years of protecting global consumer health through quality and trust. Since the program's inception, the USP Verified Mark has appeared on more than 880 million labels and packages of dietary supplements.

USP Convention Sectors and Regional Chapters convened on shared priorities. Engagement of the Convention Membership enabled USP to deepen its role in the broader conversation around medicine safety and quality.

FY22 is a year that everyone at USP is proud of. We look towards the future with optimism about the important impact USP will have upon the supply of quality medicines around the world. Please, take a moment and join us in revisiting some of the milestones and accomplishments of FY22 highlighted in this annual report.

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

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

USP by the numbers

23,258

people
attended USP Education courses and workshops

753

experts
in science, industry, healthcare, academia, and government liaisons from 40 countries

448

convention members

258

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

409

new or revised documentary standards
bringing the total to 7,575

53

new reference standards
bringing the total to 4,063

470+

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

174

countries, principalities and territories
received shipments of USP standards

1,196

staff members globally

> The Expert Panel Members contributed to the development of a world class tool kit which is helping millions of vaccine providers. It was a pride and joy to work with the other Expert Panel Members. Most importantly, our teamwork made a big difference to deliver safe administration of vaccines, resulting in avoidance of patients suffering from serious sequelae of the COVID disease."
>
> — Roy Guharoy, PharmD, MBA
> Vice President, Chief Pharmacy Officer, Baptist Health

USP's continuing response to the global COVID-19 health crisis

While the devastation wrought by the COVID-19 pandemic cannot be overstated, it united the world like no other event in recent memory. Political and economic differences were set aside (at least temporarily). Industry, academia, regulatory bodies, governments, non-governmental organizations, and other entities joined forces and pooled efforts to defeat a common threat.

USP's COVID-19 response continued to expand and evolve in FY22 to address global, regional and local public health challenges. USP continued its work supporting access to and building trust in the quality of COVID-19 vaccines, treatments and preventatives. Additional guides and toolkits supported the public health response to the coronavirus and helped healthcare professionals quickly and safely vaccinate more people, maximizing every dose available, without compromising quality and safety.

USP's International COVID-19 Vaccine Handling Guide

USP's International COVID-19 Vaccine Handling Guide brought operational strategies to address potential efficiency gaps to the front lines of vaccination efforts. It helped accelerate the pace of vaccinations around the world while maintaining quality, preventing vaccine waste, and avoiding mix-ups with other vaccines.

Quality Assessment Toolkits

USP's Quality Assessment Toolkits are resources to help national control laboratories develop and validate test methods for regulators overseeing the reception and distribution of vaccines in their countries. The toolkits have been used by governments worldwide to ensure the quality of authorized COVID-19 vaccines, build capacity, and increase access to COVID-19 vaccines. As of June 2022, 280 unique organizations had accessed the resource.

> I was awed and honored to work with the dedicated and knowledgeable team that volunteered their efforts to respond in such a timely manner to support the front-line workers and volunteers who mobilized to confront the COVID crisis. I also was impressed by the quality and urgency of the USP staff in assuring the expertise of the working group got translated into actionable resources."
>
> — Ginette A. Pepper PhD RN FAAN FGSA
> Professor Emerita, University of Utah
> Professor, University of Colorado Anschutz Medical Campus

With funding from the United States Agency for International Development (USAID), USP's Promoting the Quality of Medicines Plus (PQM+) program continued working with regulators in Africa and Asia to further support safe deployment of COVID-19 vaccines and strengthen COVID-19 prevention and response efforts. Examples include:

Practical guidance documents on emergency use authorizations for vaccines and in vitro diagnostics were finalized and disseminated.

PQM+ assisted Burkina Faso, Ethiopia, Ghana, Kazakhstan, Pakistan, and Uzbekistan in developing pharmacovigilance procedures and reporting systems to strengthen monitoring for adverse events following immunization.

In Bangladesh, PQM+ collaborated with the National Control Laboratory to develop guidelines for vaccine lot release.

USP continued working with stakeholders to develop and provide operational strategies that enable compounders to respond more effectively to COVID-19 and potential future pandemics. USP updated its **Operational Considerations for Sterile Compounding During the COVID-19 Pandemic** to ensure consistency with recent changes made to the packaging of conventionally manufactured COVID-19 treatments with emergency use authorization, including recommendations for minimizing waste.

700+

monographs were listed on the dashboard

Ten international pharmacopeias—including USP—collaborated to publish an interactive dashboard of active pharmaceutical ingredients and monographs for existing generic drugs being investigated as COVID-19 treatments.

Committed to access to quality-assured medicines

Thankfully, the acute phase of the pandemic has passed in many parts of the world, but work remains to achieve equitable access to treatments and preventatives around the globe. The same is true for medicines to treat a myriad of other conditions not related to the pandemic.

Disparity in global access to quality medicines existed long before COVID-19. Since its inception, USP has been committed to helping patients around the world have access to quality-assured medicines that they can trust, so they can live longer, healthier lives. USP has a long history of helping develop competencies and skills that advance this goal.

From education opportunities that develop individuals' technical competencies, to programs for verifying quality on an organizational level, to support for stronger healthcare system infrastructures, we continue to expand our capability building work to strengthen individual and organizational capacity to address local, regional, and global health issues.

Reducing barriers to advanced manufacturing innovation

Scientific, medical and technical advances bring with them the potential for innovations in therapeutic modalities and increased manufacturing efficiencies, which can accelerate wider access to better treatments for more patients. In FY22, USP made great strides in expanding its portfolio of solutions to further support new manufacturing paradigms and novel therapeutics in an evolving biopharmaceutical landscape.

USP collaborated with the Indian Pharmaceutical Alliance on a PCM conference in India for global stakeholders in the field. It featured speakers from industry, academia, and regulatory authorities including the U.S. FDA and European Directorate for the Quality of Medicines & HealthCare.

260+

participants attended the event

Pharmaceutical Continuous Manufacturing

Within the next decade, pharmaceutical continuous manufacturing (PCM) is poised to become an industry staple, alongside traditional batch manufacturing, to produce both innovative and generic pharmaceuticals and biologic products. PCM technology can help increase output and efficiency, lower costs, cut environmental footprints, accelerate production and scale-up in response to emergencies, and reduce dependence on foreign suppliers.

As with any innovation, PCM brings opportunities and challenges. USP is collaborating with stakeholders to explore how to further support innovation and adoption of PCM. USP has continued its work through **a collaborative agreement** to develop analytical methods for PCM manufacturing processes for use by manufacturers, and to set up a new lab for developing PCM methods and processes.

In April 2022, USP also announced a collaboration with the National Institute for Pharmaceutical Technology and Education to create a central and comprehensive repository of PCM information accessible by all stakeholders, funded by FDA. The resulting **USP CM Knowledge Center** aims to capture, contextualize, organize and update rapidly expanding knowledge about PCM to help accelerate the adoption of PCM, increase supply chain resilience and benefit patients.

> “The Ethiopian Food and Drug Authority and PQM+ have been working together for a number of years. With the technical support from USP PQM+ we achieved a number of milestones - accreditation of our medicine laboratory with ISO 17025 is one of them. In addition, we worked together in strengthening all medicine regulatory functions and our branch laboratories. We strongly believe that PQM+ has contributed a lot to reach the stage where we are now. Our vision is great: to become a regulatory center of excellence! Working together we can achieve it. Thank you for all of your support.”
>
> — Mr. Seyoum Wolde
> Deputy Director General, EFDA

It takes a village to manage the supply of quality medicines

The complexity of the global supply chain means that no single government, organization, or company has all the solutions or capacity to remedy the weaknesses exposed during the COVID-19 pandemic. Perspectives, input, expertise, and resources from many sectors are needed.

USP’s commitment to building a more resilient medicines supply chain was stronger than ever in FY22. Our standards, advocacy and capability building work enabled us to identify and make progress towards resolving some of the most pressing global pharmaceutical supply chain challenges.

USP continued to work with FDA, the Administration for Strategic Preparedness and Response, the Biomedical Advanced Research and Development Authority, and the Federal Emergency Management Agency on supply chain-related issues. This included sharing data and data-derived insights generated from USP’s Medicine Supply Map to inform policy decisions in support of increasing supply chain resilience.

USP worked to ensure that key recommendations to improve medicines supply chain resilience, including those developed in collaboration with other stakeholders, were shared with U.S. legislators for inclusion in legislative proposals developed during the year, including the PREVENTS Act and COMPETES Act.

As part of a multi-faceted approach to inform and shape the ongoing dialogue on supply chain-related issues, USP remained an active participant with various public-private partnerships and continued to build and strengthen relationships with key committees and offices on Capitol Hill. During the year, USP made over a dozen submissions, including statements for the record, comments to proposed legislation, and letters of support for key supply chain resilience policies.

Building stronger relationships with international partners

Recognizing that strengthening the global pharmaceutical supply chain requires a global commitment and concerted effort, USP is engaging with governments and regulatory bodies around the world to chart a path towards the shared goal of global access to quality medicines. The following are some of the notable events and accomplishments of FY22.

Building relationships with key stakeholders

USP signed a **memorandum of understanding** with the South African Health Products Regulatory Authority to advance risk-based inspections and post-marketing surveillance; strengthen quality control laboratories for medicines, biologics, and medical devices; and advance regional harmonization.

PQM+ is supporting a multifaceted approach to developing Uzbekistan's pharmaceutical sector that includes economic incentives, strengthening regulatory systems, and building workforce capabilities. During the year, USP hosted the inaugural U.S.-Uzbek Pharmaceutical Summit, supported by PQM+, which sought to catalyze partnership, collaboration, and investment opportunities.

Helping control the risk of impurities in medicines

USP initiated a pilot project on testing for nitrosamine impurities with the Vietnam National Institute of Drug Quality Control (NIDQC). The collaborative project assisted the country in strengthening post-marketing surveillance (PMS) to detect nitrosamine impurities in angiotensin receptor antagonists (sartans).

USP facilitated testing for nitrosamines in finished products by the National Control Lab of the Turkish Medicine and Medical Devices Authority. USP provided the lab with nitrosamine impurities Reference Standards as well as training on nitrosamine testing in line with USP standards.

> "This is also an opportunity to strengthen NIDQC's PMS activities as well as quality testing capability to ensure quality medicine in our legal supply chain.... This pilot research project has the potential to be further extended to other product groups to ascertain the overall quality of the medicine in the supply chain."
>
> — Do Thi Bich Thuan
> Vietnam National Institute of Drug Quality Control (NIDQC)

USP is working with regulators in Europe, Brazil, Saudi Arabia, and elsewhere to **improve detection and mitigation of nitrosamine impurities** through workshops, preferential access to nitrosamine reference standards and access to the USP Nitrosamines Exchange online community.

Advancing efforts to prevent, detect, and eliminate substandard and falsified medicines

In collaboration with the Asia-Pacific Economic Cooperation (APEC) forum, the USP-APEC Supply Chain Center of Excellence hosted an event on "Confronting Substandard and Falsified COVID-19 Vaccines and Treatments" in partnership with the Pharmaceutical Security Institute, Moderna, and Sanofi. The workshop was attended by 75+ regulators and other key stakeholders across Asia and the Americas. USP also led the APEC Task Force on Post-Market Surveillance and contributed to the APEC Task Force on Internet Pharmacies led by the Alliance for Safe Online Pharmacies to help support access to quality-assured medicines across the region.

USP partnered with the Association of Southeast Asian Nations in an initiative led by Cambodia to combat substandard and falsified medicines in the region.

USP supported the Philippine FDA's National Consciousness Week on Anti-Counterfeiting campaign to increase awareness of the issue.

Strengthening public procurement in Asia and Africa

In collaboration with the WHO's Southeast Asia regional office, USP provided technical support for self-assessments by public procurement agencies—including in the Indian states of Tamilnadu and Gujarat, and 10 other countries in Southeast Asia—to help strengthen public procurement practices in the region.

PQM+ helped Rwanda and Nepal develop and implement procurement guidelines that incorporate medical product quality considerations.

Medicine Supply Map Insights

The USP Medicine Supply Vulnerability **Insights Series** looked at the geographic concentration of pharmaceutical manufacturing and related risks of shortages for critical medicines, from broadly used classes such as antimicrobials and statins to those that are critically needed in small populations, such as pediatric oncology medications.

USP shared related insights with stakeholders to facilitate decision-making to guard against over-concentrated sources of API, reduce disruptions, and inform public investment and policy reforms that build supply resilience.

> **The USP Medicine Supply Map is helping us identify upstream vulnerabilities in the supply chain for various essential medicines and determine those where Phlow's capabilities in advanced manufacturing can have the biggest impact."**
>
> — Dave Levin, M.D.
> Chief Medical and Information Officer, Phlow Corp

Physician survey

The pandemic revealed both longstanding vulnerabilities and acute, pandemic-driven resiliency gaps in the global medicines supply chain. In February 2022, USP shared the findings of an extensive **survey** of U.S. physicians which explored their perspectives on the strengths and weaknesses in the medicines supply chain and the risks associated with inaction.

A large majority believe the responsibility for solutions falls on multiple stakeholders – a view shared by USP. "The challenges today are bigger than any one group can solve, so it is important for us to work together," USP's CEO, Ron Piervincenzi said. "Together with stakeholders across the healthcare ecosystem, USP works to support supply chain resilience and trust in medicines through public quality standards, which are an essential part of the solution."

Nine out of 10
physicians surveyed

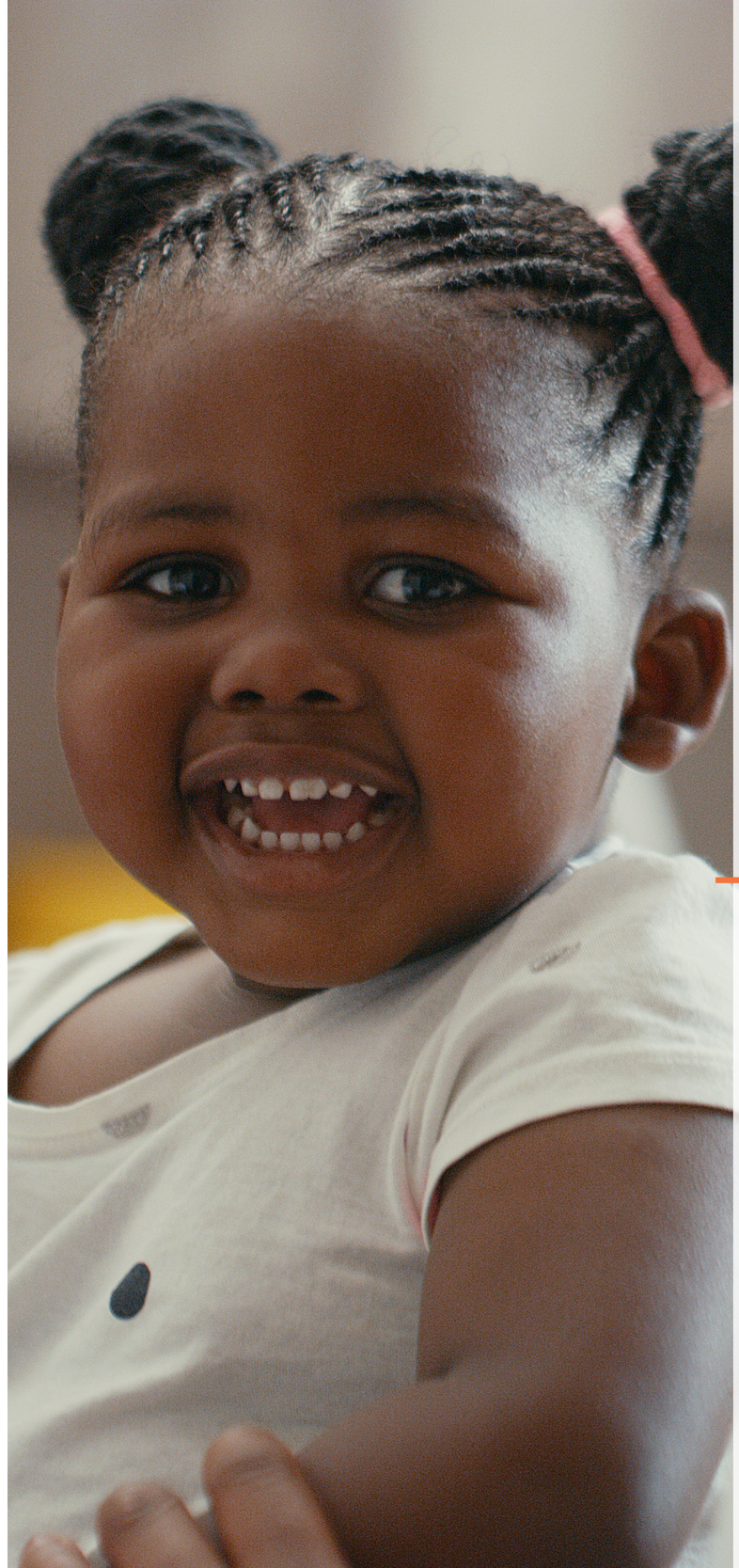
90%

said they are conerned that the global supply chain may not be reliable in a time of crisis

83%

of U.S. physicians surveyed

believe drug shortages have become a bigger problem in recent years – a topic touched on in a **2019 FDA report** that found 62% of drug shortages occur because of quality issues in manufacturing.



Angels for Change — pediatric drug shortages

Drug shortages are often caused by a combination of factors, such as quality issues, incomplete or inaccurate data and other weaknesses in the medicines supply chain. Nowhere is this a more urgent or heartbreaking challenge than with pediatric oncology drugs. USP collaborated with Vizient, a group purchasing organization, and Angels for Change, a non-profit patient advocacy group, to characterize and quantify supply chain risks to improve pediatric oncology patient access to quality medicines.

For **this study**, the supply chain resilience of a specific drug was compared to the supply chain resilience of the average generic drug. The various validated factors were captured in a scorecard and include quality, geographic concentration, price, market competitiveness, and manufacturing complexity.

USP's graph-based data capability, the **Medicine Supply Map**, served as the foundation for the analysis. Collecting and analyzing multiple datasets from a variety of sources helps build a more complete picture of upstream supply chain risk. These insights can be used by governments and manufacturers to prioritize investments in improving the resiliency of the supply chain.

> I visited the [Nitrosamines Exchange] community daily and read all the threads at least once. And I posted in the thread many times to understand [nitrosamine] NA issues correctly and communicate with many scientists.... I also shared the knowledge I gained in this community in my presentation. I am thrilled to participate in this Nitrosamines Exchange. I believe it is the best tool to get information related to nitrosamines."
>
> — Yosuke Mino
> Impurity Expert, Takatsuki, Japan

The science of medicine quality

For over 200 years, USP has been grounded in science. It's at the foundation of everything we do. Facilitated by robust scientific dialogue and cutting-edge approaches, USP is evolving and expanding our standards and solutions that help to assure the quality of medical products.

USP staff, scientists, and Expert Bodies shaped a bold strategic direction for USP science, exploring standards and solutions in strategic topic areas: evolving and expanding standards, product and substance performance, emerging modalities, technologies, and the quality environment. The FY22 Annual Council of Experts Report details key activities and accomplishments of FY22 and the foundations put in place for FY23 and beyond.

Impurities

USP standards continue to be integral to enabling global access to quality medicines and supporting a more resilient medicines supply chain. In addition to an important contribution in the fight against impurities in medicines, USP advanced revisions and development of several standards, guidelines, and best practices in response to public health issues, scientific and technical advances in pharmaceutical development and manufacturing.

Nitrosamines

As new nitrosamine impurities continue to be found in medicines, the importance of the most up-to-date information for scientists and manufacturers continues to grow. Since its launch in 2021, the **Nitrosamines Exchange** has more than doubled its user base to 1,600 from 60+ countries and 22 languages. This robust online community is a hub for stakeholders and experts to share the latest information and facilitates real-time conversations on nitrosamine impurities. The Nitrosamines Exchange has fostered deeper engagement of community members through activities including user-driven collaborative projects and publications, such as co-development of specific nitrosamine impurity analytical methods leveraging external resources, and a peer-reviewed article on the complex nitrosamines landscape.

> I was one of the first to sign up for the Nitrosamines Exchange, and have seen it grow into a valuable forum for discussion and learning – one of the first places I turn either to ask questions or share my nitrosamine research."
>
> — David Ponting
> Research Principal Scientist at Lhasa Limited

Impurity reporting thresholds

Chromatography is a useful analytical procedure used by researchers to quantify formulations and detect impurities in the components of a drug formulation. Proposed new *USP* General Chapter <477> *User-Determined Reporting Thresholds*, published in the *Pharmacopeial Forum* (*PF*), helps users determine the value to report for chromatographic test procedures when a monograph specifies a user-determined reporting threshold.

> “USP-ID removes so much of the expertise required to do benchtop qNMR analysis, and helping to automate this process further increases the accessibility of NMR.”
>
> — Matt Leclerc
> Manager of Application Development, Nanalysis

qNMR

In the last two decades, quantitative nuclear magnetic resonance (qNMR) has become increasingly important for quality control testing and analysis in the pharmaceutical industry. USP revised and published *USP* General Chapters <761> *Nuclear Magnetic Resonance Spectroscopy* and <1761> *Applications of Nuclear Magnetic Resonance Spectroscopy* to support the use of qNMR technology to help ensure quality, including the control of impurities.

USP developed a software application that allows qNMR data to function as a digital reference to help ensure quality. By characterizing a physical reference standard using high field qNMR, the resulting data can be compared with experimental qNMR data through this process. Beta testing of the USP–ID software, which uses smart algorithms to automate identity and purity analysis of molecules in complex mixtures, was completed with academic and industry partners. USP also formed a Council of Experts subgroup to examine potential compendial applications for digital reference standards.

> “These guidelines are an important step towards establishing best practices for accessing mRNA vaccine quality for all.”
>
> — Dr. Mark Van Ooij, Scientific Director
> Janssen Pharmaceutical Companies of Johnson & Johnson

Compounding

Compounding medicines is essential for treatment of patients with unique needs that cannot be met with commercially available products. USP continued to develop monographs to ensure the quality of products on FDA’s lists of bulk drug substances that can be used in compounding drug products. During the year, USP published five draft compounded preparation monographs (CPMs) in *PF* for public comment and added six new CPMs in *USP–NF*.

Vaccine quality

Since the successful application of mRNA technology for therapeutics is relatively new, regulatory guidelines and industry standards are still evolving. Researchers, manufacturers, regulatory agencies, and national control laboratories worldwide need a common set of methods to help determine vaccine quality and build public trust and confidence in innovative vaccine products. USP staff and vaccine experts from USP’s Expert Committees released a series of draft guidelines, including “**Analytical Procedures for mRNA Vaccines Quality**” in February 2022 and “**Analytical Procedures for Viral Vectored Vaccine Quality**” in April 2022. USP received public comments from a broad set of global stakeholders, including vaccine manufacturers, biopharma companies, regulators, and vendors that help ensure their real-world relevance and applicability.

> “The USP Verified Mark on our bottle is truly a trust mark. It instills confidence and credibility in our brand among both consumers and healthcare professionals. I believe the more people that are aware of USP and the more brands that become USP Verified, the safer and healthier we will all be.”
>
> — Bill Donovan
> Senior Vice President, Valensa International

Evolving approaches to ensuring medicine quality

USP has always taken an iterative approach to developing standards, evolving them in response to stakeholder input and advances in technology and regulatory science. As the pace of innovation continues to accelerate, evolving approaches become ever-more important.

A ***Stimuli*** article titled “USP’s Iterative Approach to Standards Development and the Emerging Standards Concept” outlines USP’s iterative approach.

“Emerging standards”—standards under development that are made available for earlier stakeholder input and contributions—are intended to improve collaboration and accelerate standards development by increasing transparency and allowing for broader stakeholder participation prior to formal notice and comment in the *Pharmacopeial Forum*. The first two examples of emerging standards (for acetaminophen injection and palbociclib) were published along with the article.

USP Verified 20th anniversary

This year, **USP’s Dietary Supplement Verification Program** hit an exciting milestone—20 years of protecting consumer health through quality. This voluntary program is open to manufacturers of dietary supplement finished products from around the world. Through a rigorous testing and auditing process, USP evaluates voluntarily submitted products against science-based quality standards – including federally recognized *USP–NF* standards of quality, purity, potency, performance, and consistency – and FDA current good manufacturing practices.

Many consumers and healthcare practitioners look for independent oversight from a “third party” not associated with the manufacturer and with the necessary expertise to assess quality.

Since the program’s inception, the USP Verified Mark has appeared on more than 880 million labels/packages of dietary supplements.

“We are also honoured to participate and co-host engagements with our regulatory colleagues through the annual APAC Regional Convention Meetings, a platform to build trust and transparency among regulators. It is through trust and collaboration that we can solve issues, improve supply chain resiliency and the quality of medical products. In doing so, we jointly promote health and well-being and help this region prepare to better respond to future public health threats.”

— Professor John Lim
Regional Chapter Chair for APAC

Leveraging our strengths

USP Convention engagement. Convening the USP Convention’s Members from across the health and science community brings together stakeholders with diverse perspectives and generates dialogue to inform policymakers’ understanding of supply chain vulnerabilities, their potential impact on the availability of quality medicines, and USP solutions to bolster supply chain resilience.

- USP’s six **Convention Sectors** bring together member representatives around common areas of focus to share insights, learn from each other, provide input to USP and collaborate on priority topics.

- **Regional Chapters** engage member representatives from a geographic region to discuss important issues, share knowledge and experience, and collaborate to advance common priorities.

Convention Exchange Series

Beginning in February 2022, USP hosted a **three-part series of conversations** that brought together USP Convention Members representing patient, provider, scientific, regulatory, and industry perspectives to examine key points along the pharmaceutical supply chain. Topics included lowering barriers to the adoption of advanced manufacturing technologies, the requirements for establishing a cycle of preparedness to help withstand disruptions to the supply chain and reducing antimicrobial resistance through a resilient supply of quality antimicrobials.

“I’m pleased to serve as Chair of the Biologics Sector of the USP Convention. Over the last two years we’ve convened for robust dialogues on topics such as vaccines quality and clinical assessments on genomic data. I’m especially proud of the contributions that Members made to an infographic that supports conversations between practitioners and patients about biosimilars quality. What started as a Member dialogue about biosimilars identified a challenge that then resulted in a resource that can help patients trust the quality of the medicines they need. That kind of impact is ultimately what the USP Convention Sectors and Regional Chapters are really about.”

— Susan Cantrell
CEO of Academy of Managed Care Pharmacy

Equity and empowerment drive excellence

USP aspires to be a diverse, inclusive, innovative, and engaging organization that empowers and engages staff and volunteers to contribute to its mission to improve global health. We are committed to creating a culture where every employee feels fully empowered and valued. We strive to build a vibrant global community where our collective team, with our many and varied talents, come together to fulfill our mission.

> “The inclusive work environment establishes a sense of belonging among team members. When employees feel more connected at work, they tend to work harder and smarter, producing higher quality work.”
>
> — Senior Scientist, USP-India

Two interactive training sessions, Choosing Respect and Unconscious Bias created opportunities for staff to explore these concepts and learn from one another. USP’s 21-Day Racial Equity Challenge featured daily activities in which nearly 600 participants explored equity issues from diverse perspectives, shared personal experiences, and felt the impact of small changes in behavior. In a post-program survey, participants indicated that the program increased their awareness and understanding of equity issues in the workplace, helped them feel more comfortable discussing equity issues and prompted them to change at least one behavior.

Based on survey data

85%

of staff feel that Diversity, Equity, Inclusion, and Belonging (DEIB) will help USP to fullfill its mission

82%

believe USP is taking the right steps
to create a diverse and inclusive environment

> “We (as an organization and as individuals) need to understand the individual in front of us and work on their specific and personal situation that can be affected by many overlapping oppressions.”
>
> — Senior Scientist, USP–US

Diversity among USP Volunteers

Recognizing opportunities for more diversity and inclusivity not only among USP staff, but also with our Expert Volunteers, USP sought new ways to leverage the diverse backgrounds, experiences and talents of the collective volunteer community.

The Council of Experts unanimously voted to form a DEIB Expert Panel to help implement the DEIB strategy for Expert Volunteers. This included development of the Health Equity Guiding Principles by the Health Equity Advisory Group and monitoring progress in DEIB to inform future Expert Volunteer recruitment. Changes to the Call for Candidates application system have already resulted in a shift in the composition of USP volunteers. Numbers of female, non-white and non-U.S. volunteers have increased compared to the 2015-2020 cycle. The greatest change has been to the leadership of Expert Committees, with 9% and 12% increases in the number of female and non-white Committee Chairs, respectively.

> “Changing the hearts and minds of people... can be achieved through education, reading, and continued dialogue.”
>
> — Associate Director, USP–India

USP’s Affinity Network

USP’s Affinity Network recognizes the diverse backgrounds and experiences of USP staff, affirming the value each group’s perspectives contribute to our collective organizational culture. USP’s ten affinity groups create opportunities for staff to connect, share and celebrate the breadth and depth of our global work family. The welcoming, inclusive work environment fostered by USP’s Affinity Network has fostered a sense of inclusion and belonging, increasing employee engagement and meaningful contributions towards our global mission.

Financial highlights

As a nonprofit scientific organization committed to improving global health, USP prioritizes responsible stewardship of our resources to advance our mission. In fiscal year 2022, USP met our goals and sustained operations and mission-critical activities. 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, 2022.

→ **The full 2022 audited consolidated financial statements are available.**

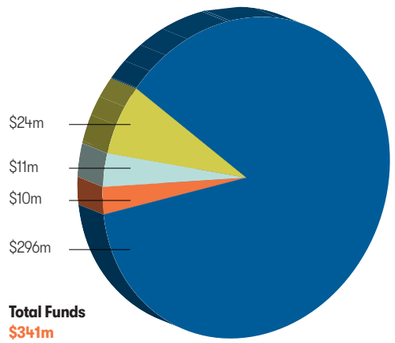
Revenues contribute to USP's mission-driven programs

USP invests approximately 95 percent of every dollar the organization receives in the development of public quality standards, products, 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

FY22 Sources of funds

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



Assets