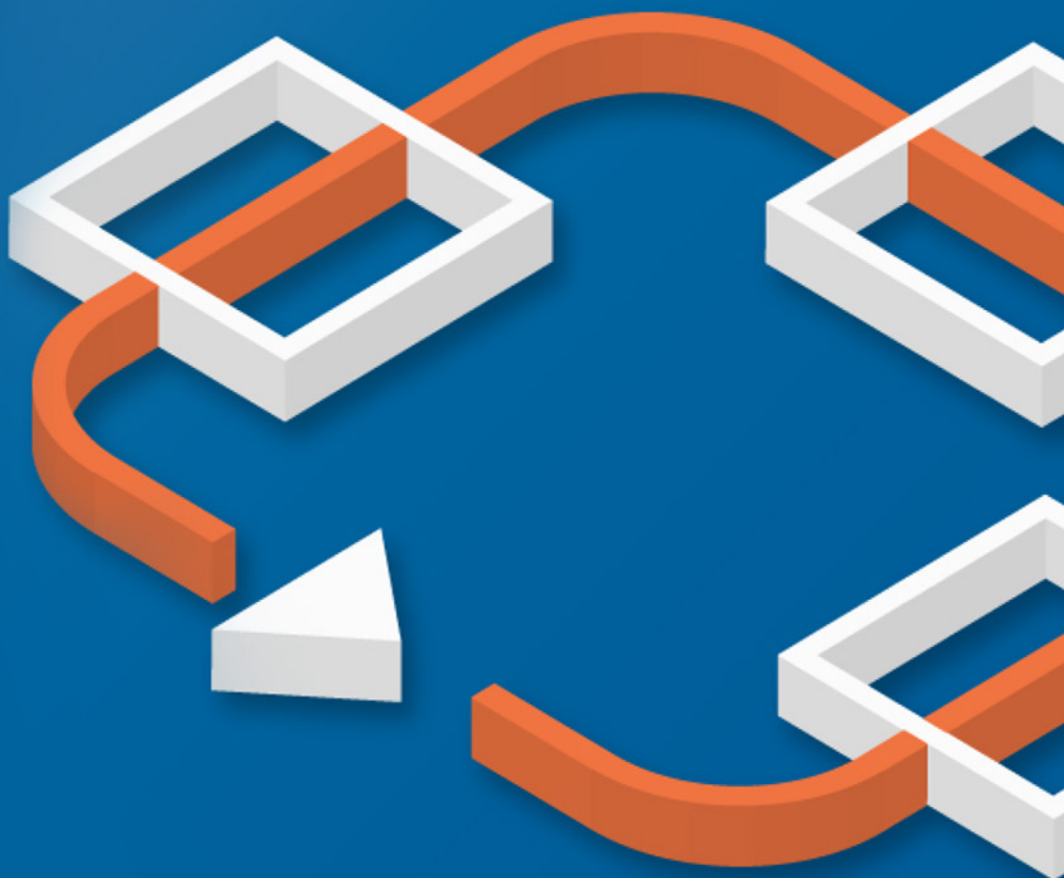


USP Convention Exchange

Ensuring a Resilient Supply Chain

A Shared Imperative



February 2023



The U.S. Pharmacopeia (USP) supports resiliency in almost every stage of the medicines supply chain.^{1,2} Through our public quality standards and related programs, USP helps governments, manufacturers, and healthcare practitioners increase the availability of safe, quality medicines that support public trust in medicines throughout the world.

USP standards help promote a strong, resilient medicine supply chain – crucial for patients to receive the medicines they need when they need them. Science-backed standards enable quality throughout the development and manufacturing process, fostering confidence that the medicines we use are safe and effective. Broad and diverse stakeholders are found along the supply chain, beginning with idea generation, and ultimately extending to patients

and consumers. Therefore, the responsibility for ensuring a strong and resilient global supply chain for medical products is shared by a wide range of stakeholders.

USP engages with diverse stakeholders to help shape the supply chain resiliency dialogue and supports a collective, multifaceted approach to support a globally diverse supply chain, help avoid disruptions, and foster resiliency in the face of crises. To champion this multifaceted approach, in early 2022, USP launched a three-part virtual event series, the **“Convention Exchange – Ensuring a Resilient Supply Chain: A Shared Imperative”** (the Exchange Series). The Exchange Series brought together Members of the USP Convention from various segments of the supply chain to share their diverse perspectives, expertise, and insights on a resilient supply chain, including barriers and potential solutions to global pharmaceutical supply chain vulnerabilities.³ This report details learnings from the three Exchange Series convenings.

Exchange Series objectives



Increase stakeholder understanding of USP’s ongoing work and approaches to bolstering supply chain resiliency.



Provide an opportunity for Convention Members to inform USP policy recommendations related to global medicines supply chain resilience.



Increase understanding of the value of partnerships to supply chain resiliency.



Explore existing and emerging solutions to identify vulnerabilities and disruptions in the global pharmaceutical supply chain and consider collaborative solutions.

The three Exchange Series convenings included experts from Convention Member organizations as well as external stakeholders who represent government and regulators, patient advocates, healthcare practitioners, pharmaceutical manufacturers, academia, and other public health sectors.

The first meeting of the Exchange Series focused on reducing barriers to the adoption of advanced manufacturing technologies (AMT), the second meeting explored establishing a continuous cycle of supply chain preparedness, and meeting three addressed the impact of and potential solutions to address antimicrobial resistance (AMR). Each meeting is detailed on the following pages. ▲

Series Highlights

Convention Exchange 1

Reducing barriers to adoption of advanced manufacturing technologies

Advanced Manufacturing Technologies (AMT) are emerging to help facilitate efficiency, shorten and scale production, and enhance preparedness for global healthcare emergencies. AMT, such as pharmaceutical continuous manufacturing (PCM) and 3D printing, requires new thinking to establish appropriate guidelines, best practices, and standards to help ensure that safe, quality medicines are the result of these new technologies. Multiple barriers remain in the adoption of AMT, and USP is developing tools and resources to help mitigate some of these challenges for manufacturers to incorporate AMT into their production.

Exchange Meeting 1:

Reducing Barriers to Adoption of Advanced Manufacturing Technologies explored approaches such as investments and policy reforms, and ways that standards can foster efficient production of critical medicines using innovative manufacturing methods while meeting expectations for quality.

Panel Discussion: Exploring solutions to reduce barriers to the adoption of AMT

We convened a panel with representation from multiple stages along the supply chain. The panelists were:

- **Jenny Luray**, MPA, Vice President of Strategy and Communications, Research!America⁴
- **Kelley Rogers**, PhD, Technical Program Director for Biosciences/Material Measurements Laboratory at National Institute of Standards and Technology⁵
- **Lisa Parks**, RPh, Vice President, Sciences and Regulatory Affairs, Association for Accessible Medicines⁶
- **Moderated by: Michael Levy**, MSc, MBA, Senior Vice President of Digital & Innovation, USP

The panel explored the benefits of public-private partnerships (PPP) for scalable innovations, and strategies to prepare a workforce to support AMT. Following the panel, attendees continued the discussion in small groups.

Highlights from the discussion

- The challenges to AMT adoption for generic pharmaceutical manufacturers include the lack of regulatory guidance regarding new product development and approval or when converting from batch to a continuous process. Other challenges include how to navigate the product lifecycle, and the lack of clarity around patents and exclusivity parameters.
- Significant preparation and training are necessary for the future workforce to help ensure quality in an innovative infrastructure. The dialogue emphasized that legislation is critical to address higher education and workforce development measures related to not only STEM but also manufacturing, facilitating entrance of workers into new advanced manufacturing jobs.
- The COVID-19 pandemic accelerated the development of PPPs by the federal government to test the viability of using real-world data and evidence for expediting products to the market. The use of these PPPs suggests that while senior career staff in federal agencies as well as Congress value these partnerships, there needs to be additional capacity and increased workforce training built into future partnerships.

Next steps for USP

USP continues to explore and recommend solutions to reduce the barriers to the development and implementation of AMT for critical drugs and active pharmaceutical ingredients (API) in domestic and foreign manufacturing facilities, one solution for strengthening the global supply chain. USP seeks to expand collaborations with stakeholders to address knowledge gaps and identify where new standards may be needed. USP is also working with partners to certify and validate related manufacturing processes and plans to develop and disseminate pharmaceutical continuous manufacturing (PCM) technical guides.

On December 12th, 2022, USP opened the **USP Advanced Manufacturing Technology Lab** in Richmond, Virginia as part of its launch of a suite of R&D analytical solutions. These analytical lab services will support the efforts of drug manufacturers seeking to adopt AMT PCM, as one way to help increase geographic diversity in pharmaceutical manufacturing and support medicines supply chain resilience. ▲



Michael Levy, M.Sc., M.B.A.
USP Senior Vice President,
Digital & Innovation

Exchange 1: Q&A with Michael Levy

During the Member Exchange last year, you mentioned that Pharmaceutical Continuous Manufacturing (PCM) was a proof-of-concept idea initiated at USP around 6-7 years ago. It has now since 'graduated' out of the program. What are examples of other emerging technologies to 'graduate' similar to PCM's graduation?

USP is transitioning to new platforms for our clinical and chemical information, as determined by our technology assessment activities. As well, we are converting some of our physical reference standards into digital references that, in some circumstances, will enable stakeholders to quickly identify and quantify specific molecules in a mixture without needing to run High Performance Liquid Chromatography (HPLC) and without needing to use physical reference materials.

Similarly, we are digitizing some of our documentary content and we will release a product enabling customers and laboratory software vendors to ingest some of our content directly into their digital systems without the need for human intervention. The [USP Medicine Supply Map](#) is another example of an early user program that is showing customer interest in better characterizing, identifying, and quantifying vulnerabilities in the upstream pharmaceutical supply chain.



Dennis Hall, M.A., MBA
USP Vice President,
Advanced Manufacturing
Technologies

Exchange 1: Q&A with Dennis Hall

Please provide an update on the USP partnership with the National Institute for Pharmaceutical Technology & Education (NIPTE) to launch the digital knowledge management resource for continuous manufacturing. What are the objectives of this partnership?

The USP Continuous Manufacturing Knowledge Center (working title) is still under development. We have revised our estimated launch date to the Summer of 2023. Once launched, this will be a USP site supported by leading technical experts across NIPTE. NIPTE is performing the initial content aggregation, curation, and evaluation. USP is building the technical infrastructure and the community engagement plans. On an ongoing basis, USP will operate and update the site with technical support from NIPTE and others. This site will be a one-stop resource for manufacturers to capture, contextualize, organize, and update rapidly expanding knowledge about PCM with the goal of facilitating innovation in PCM and lowering barriers to its adoption to help strengthen the medicines supply chain.

Now that the USP Advanced Manufacturing Technology (AMT) Lab has opened, as part of the launch of a suite of R&D analytical solutions, how will USP gauge progress and capture learnings?

- **Gauge progress.** USP has a set of milestones and objectives for the AMT Lab based on metrics such as the number of APIs in which USP has developed qualified analytical methods, successful technology transfers to manufacturing, and the fit-for-purpose quality of those methods. As other work comes online, specific metrics will be developed for those as well. Lastly, the laboratory does operate under good management practices such as looking at staff utilization, equipment utilization, budget tracking, etc.
- **Capture learnings.** USP's analytical lab services will support manufacturers to further drive innovation, contain production costs, and optimize efficiencies in staffing and resources while facilitating market access to quality medicines made with PCM. In this regard, we have three processes in place to capture learnings.
 - **Project level translational science.** We have a formal scientific learning and translational action plan process at the conclusion of each project the USP AMT Lab performs, no matter the size or complexity. This process looks at the totality of the scientific learnings and determines what can and should be included into standards from that specific project. Additional work may be required once a determination is made.
 - **Aggregate level translational science.** On an annual basis, USP will conduct a review of all project learnings to determine if there are broader, cross-product aspects to incorporate into best practice guidelines, process standards, or other solutions.
 - **Continuous improvement.** USP will conduct a "lessons learned" session for non-scientific aspects – laboratory operations, improvements for collaborations, facilities, or administrative process improvements, etc. These sessions are conducted as a matter of course at the end of each project.

Members are welcome to reach out to me with any questions: DH@usp.org

Convention Exchange 2

Preparedness: Bolstering key points along the medicines supply chain

The COVID-19 pandemic exacerbated worldwide pharmaceutical supply chain disruptions leading to shortages, concerns about medicines quality, and price volatility. Nearly three years into the pandemic, it is critical to implement measures to prepare for the next pandemic, natural disaster, or other disruptive crisis. Preparedness is a continuous cycle that includes planning, evaluating, and taking corrective action in an effort to ensure effective coordination and response during an emergency.⁷ The cycle of medicines supply chain preparedness is one element of a broad preparedness system to prevent, protect, mitigate, and respond to public health emergencies, natural disasters, acts of terrorism, geopolitical conflicts, and other disasters.⁸ Building a supply chain eco-system that can still respond, or quickly be re-established, under stress is critical to establishing resiliency.

Exchange Meeting 2:

Preparedness: Bolstering Key Points along the Medicines Supply Chain provided attendees, presenters, and USP staff with the opportunity to discuss the need, challenges, and potential approaches to establishing a continuous cycle of preparedness before a crisis (e.g., funding, training, staffing, outdated data systems and collection, and equity).

Panel Discussion: Establishing preparedness measures to mitigate future supply chain disruptions

The National Academies recently published a supply chain resilience framework that includes recommended measures for awareness, mitigation, preparedness, and response to help provide protection against supply chain disruptions.⁹ Expert panelists from various sectors of healthcare and from along the supply chain contributed to a robust discussion of these preparedness measures, as well as essential considerations for success. The panelists were:

- **Nicolette Louissaint**, PhD, Senior Vice President, Policy and Strategic Planning, Healthcare Distribution Alliance¹⁰
- **Barbara Solow**, PhD, Vice President, Business Development & Government Contracting, Curia¹¹
- **Brian Tse**, PhD, Vice President, The Conafay Group¹²
- **Moderated by:** Carrie Harney, JD, Vice President, U.S. Regulatory and Government Affairs, USP

The panel explored what preparedness entails and imperatives for success, emphasizing that working to ensure a resilient pharmaceutical supply chain is complex and that preparedness before a crisis happens is crucial.

Highlights from the discussion

- Elements of preparedness within the medicines supply chain were in place before COVID-19, such as additional buffers to absorb disruptions to the supply chain. However, evaluation is needed to determine how these buffers performed during a crisis and how they can be strengthened. Additionally, vulnerabilities demonstrated during the COVID-19 public health emergency underscored the need for a six-month roadmap of capabilities necessary to navigate through the next public health crisis.
- Interdisciplinary collaboration and Public- Private Partnerships (PPPs) are crucial to supply chain preparedness. In response to the recent public health emergency, U.S. government agencies such as the Biomedical Advanced Research and Development Authority (BARDA) were able to rapidly reward and mobilize over 150 PPPs by leveraging existing relationships. These collaborations highlight that ongoing attention and investment in PPPs can significantly aid the rapid and efficient formation of partnerships in times of crisis.
- Investments needed to bolster supply chain resiliency and enable preparedness for the next crisis include flexible infrastructure for warm-base manufacturing that can quickly ramp up domestic production of essential medicines; additional resources within government response agencies which focus on supply chain management, consolidate industrial base engagement activities, and strengthen the strategic national stockpile; and targeted and sustained approaches to the adoption of advanced manufacturing.

Next steps for USP

USP continues to explore innovative solutions and resources to improve supply chain vulnerabilities and improve visibility into the upstream medicines supply chain to predict and address vulnerabilities before potential disruptions occur. One of these resources is the USP Medicine Supply Map, an information system that identifies, characterizes, and quantifies risk in the upstream pharmaceutical supply chain and may help stakeholders prioritize supply chain investments that reduce drug shortages.¹³ This work is essential to bolster preparedness and facilitate improved situational awareness, which in turn allows for better identification of vulnerabilities in the supply chain and proactive mitigation of disruptions.

Several of these key priorities were recently passed in the 2022 end of year omnibus bill. This mammoth \$1.7 trillion, bipartisan bill appropriated funds to increase supply chain visibility, support advanced drug manufacturing technologies, and bolster federal health agencies for the benefit of patients and public health. These investments will help create a more resilient medicines supply chain and prepare for future public health emergencies.

To learn more about this legislation see the related [USP Quality Matters](#) blog. ▲



Vimala Raghavendran,
MBA
Senior Director, Informatics
Product Development

Exchange 2: Q&A with Vimala Raghavendran

Please provide examples of how the Medicines Supply Map has been utilized as a practical resource for end users to identify and de-risk their supply chain operations?

The Medicine Supply Map was utilized by Angels for Change, a patient advocacy organization with a mission to end drug shortages, to identify a set of vulnerable drugs in the U.S. Angels for Change selected two drugs from the list for their [Project Protect](#) pilot. Project Protect funded a 503B compounding, STAQ Pharma, to supply the market in the event of a shortage. When these drugs went into shortage, STAQ Pharma was able to make 500,000 doses available to hospitals that would otherwise have not been available.

Series Highlights

Convention Exchange 3

Preserving a quality supply of antimicrobials and combatting antimicrobial resistance

In the United States, more than 2.8 million antibiotic-resistant infections occur each year, resulting in more than 35,000 deaths.¹⁴ The World Health Organization (WHO) has declared antimicrobial resistance (AMR) one of the top ten global public health threats facing humanity. A recent study estimated that 1.27 million people died worldwide in 2019 due to AMR.¹⁵ Without an immediate, collaborative global response, AMR could lead to ten million deaths a year by 2050.¹⁶ Sustaining a resilient supply of antimicrobials that continues to remain effective against disease is a global health imperative. Strategies to combat AMR will require global partnerships and alliances and must include the conservation of existing antimicrobial medicines along with concurrent therapeutic innovation.

Exchange Meeting 3:

Preserving a Quality Supply of Antimicrobials and Combatting Antimicrobial Resistance focused on strategies for addressing AMR, including ensuring broad access to affordable medicines, proper stewardship of existing antimicrobial treatments, and investments in the development of new treatments.

Panel Discussion: A multifaceted approach to address AMR

According to WHO reports, one in ten medicines in low- and middle-income countries is substandard, and nearly half of those are antimicrobial medicines. [USP Quality Institute](#) Fellow, Carly Ching, PhD, opened the meeting with an overview of her research showing that AMR can arise when pathogens are exposed to substandard antimicrobials that contain only subtherapeutic levels of their API.¹⁷⁻²³ A panel of experts continued with a discussion of strategies for addressing antimicrobial resistance that include ensuring broad access to affordable medicines, proper stewardship of existing antimicrobial treatments, and investments in the development of new treatments. The panelists were:

- **Kristen Hayes**, MS, RN, CPHQ, Director Clinical Quality, AHA Center for Health innovation, American Hospital Association²⁴
- **David Hyun**, MD, Project Director, Antibiotic Resistance Project, The Pew Charitable Trusts²⁵
- **Amanda Jezek**, Senior Vice President, Public Policy and Government Relations, Infectious Diseases Society of America²⁶
- **Emily Wheeler**, Director of Infectious Disease Policy, Biotechnology Innovation Organization (BIO)²⁷
- **Moderated by: Anthony Lakavage**, JD, Secretary, USP Convention and Board of Trustees and Senior Vice President, Global External Affairs, USP

The panel noted adoption of strong stewardship as essential to fight antimicrobial resistance and championed investments in a robust pipeline of innovative antibiotics and antifungals as well as legislative proposals to authorize the U.S. federal government to create market incentives for the development of lifesaving, novel antimicrobials.

Highlights from the discussion

- AMR is not just a problem in low- and middle-income countries; COVID-19 has underscored that the developed world is not insulated from AMR. AMR contributes to nearly five million deaths globally, including in the U.S. Yet, USP research found that, during the 2019 World Health Assembly, only 30 to 40 percent of National Action Plans mentioned the link between poor medicine quality and AMR.²⁸ Furthermore, the increasingly common shortage of antimicrobials is an additional mitigating factor to the emergence of AMR in the developed world. While the threat of such drug shortages is most acutely experienced in low- and middle-income settings, consequences can impact the quality and effectiveness of antimicrobials worldwide.
- Conservation and stewardship of antimicrobials are the responsibility of many public health stakeholders. Practitioner prescribing guidelines have seen success, but they are only one approach to combatting AMR. The panel also noted that transparency in clinical data can be a helpful tool to inform and reduce overprescribing amongst healthcare providers. According to 2020 research conducted by The Pew Charitable Trusts and the American Medical Association, 70 to 80 percent of antibiotics are prescribed in an outpatient setting, where there is very limited expansion and adoption of stewardship programs.^{29,30}
- Investments in manufacturing innovation are critical to ensuring a quality supply of antimicrobials. The mass hospitalizations caused by COVID-19 infection underscored the need for investments in a robust pipeline for antibiotics

and novel antifungals; the current manufacturing pipeline is inadequate for addressing the threat of AMR. Over 80 percent of research in this area is conducted by small biotech companies due to the unwelcoming and unstable marketplace for antibiotics; CARB-X and the AMR Action Fund are examples of successful public-private investments to incentivize novel antibiotic development.^{31,32} In the U.S., the Pioneering Antimicrobial Subscriptions to End Upsurging Resistance or PASTEUR Act has been introduced, which authorizes the federal government to create market incentives for the development of lifesaving, novel antimicrobial drugs.^{33,34}

Next Steps for USP

COVID-19 underscored that pathogens are not restricted by geographic borders and can rapidly travel around the world and as they do, they can cause drug resistance. Recent findings of the USP Medicine Supply Map show antimicrobials are at an especially high risk of shortage, 42% more likely to be in shortage than the average drug product. Moreover, API manufacturing is highly concentrated in a few geographies, and antibiotic API quality concerns have been both a source of supply chain vulnerability and an underlying cause of AMR.³⁵ Global cooperation is vital in combating AMR, and will necessitate working collaboratively on antimicrobial supply challenges, antibiotic shortages, and drug quality concerns. USP will help facilitate this effort by harnessing the expertise and networks of national and global stakeholders, as well as through continued USP Quality Institute research, to evaluate the link between poor-quality medicines and AMR and helping to identify solutions to this pressing global health problem. ▲



Carly Ching, Ph.D.
USP Quality Institute Fellow

Exchange 3: Q&A with Carly Ching

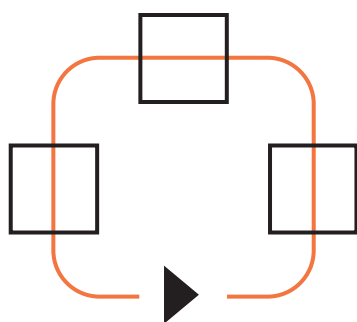
During the Member Exchange meeting, you cited research that the dangerous cycle of falsified and substandard medicines led to increased rates of antimicrobial resistance (AMR), especially in low- and middle-income countries. However, as you noted, AMR is a global issue and affects US patients in great numbers as well. How can US stakeholders collaborate to have a multiplier effect on combatting AMR globally? Is this possible?

AMR does not stop at specific borders, and the U.S. is not insulated from the impact of resistance. The COVID-19 pandemic has demonstrated that infectious diseases are not isolated and can spread worldwide rapidly, especially given the increase in international travel. Specifically, because antibiotic API manufacturing is highly concentrated in other countries, the US is vulnerable to supply chain disruptions, or any issues with quality that arise during manufacturing or distribution. This is compounded by a stagnant antibiotic pipeline. The U.S. can strengthen investment in research and development of new antibiotics, as well as partner with other countries to help diversify and strengthen manufacturing both domestically and globally to ensure access to quality antibiotics.



Looking ahead together

USP's 2022 Convention Exchange Series on fostering pharmaceutical supply chain resiliency was a valuable source of stakeholder dialogue and knowledge sharing. The USP Convention Membership represents the span of the global supply chain, and these informative discussions have and will shape discourse and advance meaningful solutions.



As we look to the future, USP will continue to lead discussions with relevant stakeholders, including Member organizations, that explore the development of guidelines, best practices, and standards to support quality, regulatory predictability, and manufacturing capability for established medicines and emerging modalities. It will be critical to apply lessons learned from the COVID-19 pandemic, stakeholder partnerships, and from diverse dialogues, including the Exchange Series, to bolster resilience in the medicine supply chain, prepare for future public health crises, and help ensure the quality and benefit of emerging innovations.

The current challenges facing the medicines supply chain are bigger than any one group can solve, making collaboration and cooperation imperative. Together with stakeholders across the health care ecosystem, USP can coordinate and support efforts to improve global supply chain resilience and trust in medicines. ▲

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