



Recognizing Challenges and Opportunities to Support
**Adoption of Advanced
Manufacturing Technologies
for Medical Products**





ISSUE

Advanced manufacturing technologies (AMTs) for medical products, such as pharmaceutical continuous manufacturing (PCM), additive (3D printing) manufacturing, direct perfusion, and decentralized manufacturing (for example, distributed manufacturing and point of care manufacturing), have the potential to improve manufacturing efficiency, reduce production costs, reduce environmental footprints, and support supply chain resilience. Advanced manufacturing may also be applied to batch manufacturing to utilize innovative and emerging approaches to enhance the quality and performance of solid dosage form products.

Despite interest and efforts by policymakers and stakeholders to bolster adoption of AMT, manufacturers continue to encounter various practical, operational, and regulatory challenges to developing, piloting, and implementing AMTs. These challenges can include lack of clarity about the return on investment given the costs of change, facilities, capital investments, and organizational expertise. They are exacerbated by limited knowledge of the areas where AMT could be the most impactful, how and when to best implement it, workforce capacity or capability challenges with an industry-wide shortage of AMT expertise, and ongoing uncertainties or potential risks regarding regulatory review or approvals of medicines made with AMT, especially in global markets.

Engagement with a broad group of stakeholders, including academic research centers, federal and global regulatory agencies, and manufacturers, is necessary to identify gaps in technical knowledge and workforce development, develop standards and practices, and disseminate knowledge to a broader group of stakeholders that will help to make advanced manufacturing more accessible and achievable for industry uptake.

POSITION

U.S. Pharmacopeia (USP) supports policies that aim to enable increased adoption and implementation of AMTs that support an agile, resilient pharmaceutical supply chain to address current challenges and that are well-situated to adapt to future challenges. These public policy and regulatory proposals include:

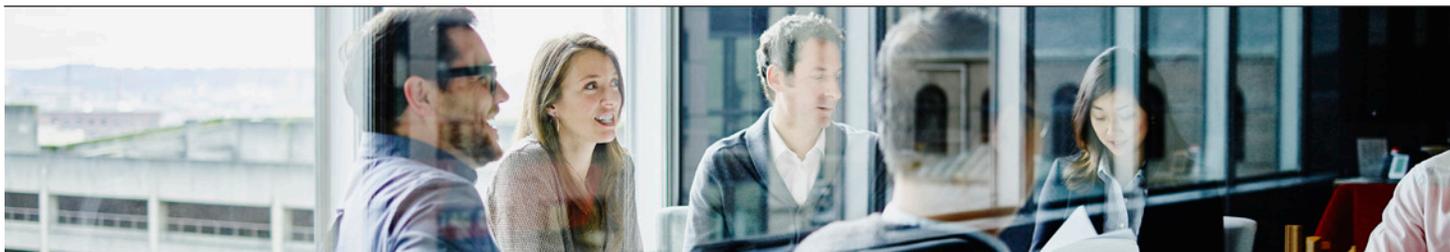
1. **A multifaceted approach to support a diversity of products, technologies, and processes**

USP recognizes the technical, scientific, and regulatory complexities associated with AMT and urges a multifaceted approach to promoting the development, adoption, and implementation of AMT within the global pharmaceutical industry. As such, USP supports policy reforms with the greatest potential for strengthening pharmaceutical supply chain resiliency, addressing underutilization of existing manufacturing infrastructure, promoting global geographic diversity in pharmaceutical production where viable, or advancement of technologies with potential for significant public health impact.

2. **Near- and long-term incentives to enable adoption of AMT**

USP supports near- and long-term financial incentives and public investments that will bolster and enable greater adoption of AMT, including in scientific and technical research such as:

- Financial incentives to provide manufacturers with the necessary support to invest in AMTs for increased production capabilities.
- Direct or indirect market-based subsidies or incentives to support new manufacturing capabilities or to encourage utilization of existing excess and dormant drug manufacturing facilities.



- Establishment of AMT-specific innovation and incubation centers that are focused on translating AMT into new, innovative companies and to help established companies understand and implement new technologies.

3. Public-private partnerships and cooperation to address knowledge gaps

USP supports accelerating scientific and technical knowledge of advanced manufacturing and workforce development through coordination of efforts and public-private partnerships between government bodies, academia, industry, and other allied stakeholders. This may include, but is not limited to:

- Establishment or expansion of consortia.
- Development of technical guides, educational tools, standards, and training opportunities that help to address workforce, regulatory science, and technical feasibility concerns that hinder the adoption and implementation of AMT.
- Establishment of facilities that provide training and hands-on experience for industry in a precompetitive space and for regulators to build understanding and cross-functional collaboration domestically and internationally.

4. Informed regulatory expectations and greater alignment among authorities

USP urges government authorities to revise, and clarify as needed, regulatory expectations and pathways that are reflective of new programs and opportunities that help to further promote the development, adoption, and implementation of AMT. Additionally, USP recommends further movement toward regulatory convergence and to clarify regulatory expectations and support broader adoption of AMT.

DISCUSSION

What are AMTs?

Advanced manufacturing technologies (AMTs) hold the potential to speed the production of drug products, improve the quality of medicines, mitigate drug shortages, and improve the reliability of the pharmaceutical supply chain. AMT has been identified as a key aspect of the overall strategy to strengthen domestic pharmaceutical manufacturing and support geographic diversification and AMTs such as pharmaceutical continuous manufacturing (PCM) can increase flexibility and efficiency, lower production costs, reduce the environmental footprint.¹ Advanced manufacturing is generally characterized as, “a collective term for new medical product manufacturing technologies that can improve drug quality, address shortages of medicines, and speed time-to-market.”² The National Academies of Sciences, Engineering, and Medicine (NASEM, or the National Academies) further identifies AMT as, “manufacturing developments in which innovative technologies are used to upgrade or replace existing manufacturing systems to improve product quality and process performance.”³ In addition to PCM, examples of AMTs include, additive (3D printing) manufacturing, distributed manufacturing, point-of-care manufacturing, and artificial intelligence. All areas of AMT are enhanced by the development and deployment of advanced enabling technologies such as process analytical technologies (PAT), digital control systems, and automation, among others.

The globalization and specialization of supply chains have led to geographic concentration of manufacturers that produce key starting materials (KSMs), active pharmaceutical ingredients (APIs), finished dosage form (FDF) products, and other medical products in locations where labor and raw material costs may be lower, environmental regulations are more permissive, and where there are greater infrastructure



AMT Regulatory Landscape

U.S. Regulatory Landscape and Government AMT Initiatives

The FDA has implemented numerous programs and initiatives over the past two decades to address scientific or technical concerns and reduce regulatory uncertainties around AMT. In 2014, FDA's Center for Drug Evaluation and Research's (CDER) Office of Pharmaceutical Quality established the Emerging Technologies Program (ETP), and the Center for Biologics Evaluation and Research (CBER) established the Advanced Technologies Team, to "offer pre-submission support for applicants looking to adopt advanced manufacturing technologies for the development of human drugs." Participants in ETP can meet with regulatory review staff to answer technical or regulatory questions during the development and adoption of a proposed technology, among other activities. CDER's Framework for Regulatory Advanced Manufacturing Evaluation (FRAME) initiative, implemented in 2021, aims to prepare a regulatory framework for AMT and identifies certain technologies for prioritization based on a report commissioned by CDER from the National Academies.⁵ CBER has a similar program to the ETP, the CBER Advanced Technologies Team (CATT) to "promote dialogue, education, and input among CBER staff and between CBER and prospective innovators/developers of advanced manufacturing technologies."⁶ The omnibus spending bill approved by Congress and signed into law in late 2022 authorized FDA to designate five National Centers of Excellence in Advanced and Continuous Manufacturing, as well as required FDA to initiate an advanced manufacturing designation program within one year of enactment, or by the end of 2023.

FDA has also issued guidances and discussion papers on these emerging technologies, including draft guidance entitled *Quality Considerations for Continuous Manufacturing*⁷, a discussion paper *Distributed Manufacturing and Point-of-Care Manufacturing of Drugs*⁸, and the recent discussion paper *Proposed Regulatory Framework for Modifications to Artificial Intelligence/Machine Learning Based Software as a Medical Device*⁹. Additionally, in 2021,

subsidies. The United States relies on many foreign sources for raw materials, KSMs, APIs and FDFs. In fact, domestic manufacturing in the United States supplies less than 30 percent of APIs for branded and generic drugs.⁴ Drugs with a greater concentration of API or FDF manufacturing are more susceptible to shortages and may have greater vulnerability in their supply chains.

PCM has gained attention as a method to help expand domestic manufacturing capabilities for essential medicines and other critical medicines often in short supply. PCM involves a continuous flow of materials, from inputs to process outputs, without intermediate interruption in the manufacturing process. PCM can include full, end-to-end flow of materials or continuous processes at discrete steps in a manufacturing process. In traditional batch manufacturing, the raw materials that are eventually transformed into the final product are processed in different machines at different times and potentially different locations. PCM allows each element of the manufacturing process to take place in a single facility, which can accelerate production and scale-up in response to emergencies, reduce potential quality issues through continuous process monitoring, and require a smaller production facility area.



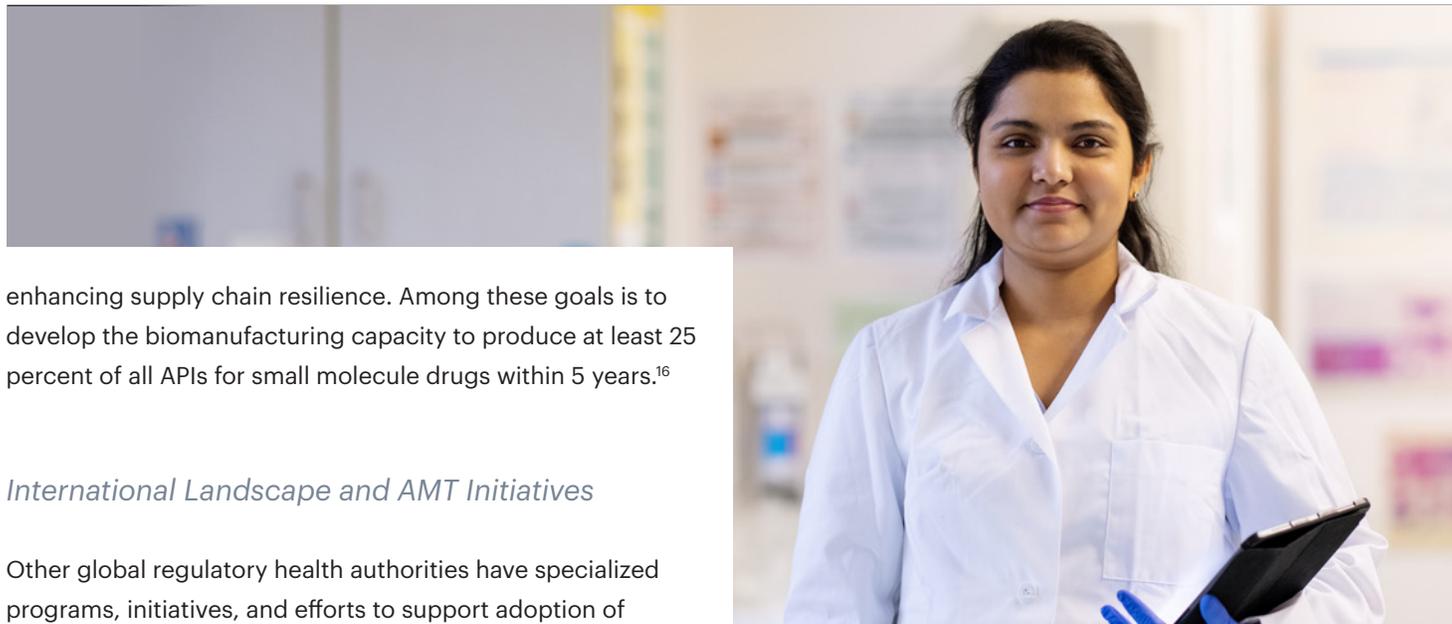
FDA announced a Center for Excellence for Advanced Manufacturing, a collaboration between CDER and CBER intended to generate knowledge, provide training for staff, and support standard, policy, and guidance development¹⁰ as well as an internal Center for Advancement of Manufacturing Pharmaceutical and Biopharmaceuticals¹¹. Also in 2021, FDA entered into a Memorandum of Understanding (MOU) with the National Institute of Standards and Technology (NIST) to advance domestic pharmaceutical manufacturing and mitigate risk of supply chain disruptions through the adoption of 21st century technologies, including AMT.¹²

In addition to government efforts for the development and adoption of pharmaceutical AMT generally, the FDA Office of Counterterrorism and Emerging Threats (OCET) established a dedicated advanced manufacturing program for cross-cutting (two or more FDA regulated product areas) platform technologies and processes. The program included the U.S. Department of Health and Human Services (HHS) Advanced Manufacturing Innovation Hub (I-TEAM Hub), the Smart Design and Manufacturing Pilot, and various other intramural and extramural projects and efforts to support adoption of AMT, such as a 2021 analysis of the advantages of and barriers to adoption of smart manufacturing for medical products.¹³ The Biomedical Advanced Research and Development Authority (BARDA) is also making investments in manufacturing capacity as part of its mission to improve preparedness and response through public-private partnerships, such as a 2020 partnership with Phlow Corporation to utilize advanced manufacturing technologies to produce critical medicines during public health emergencies. These efforts underscore the recognition of the potential benefits of AMT across a variety of government agencies.

The Government Accountability Office (GAO) released a report in March 2023 examining FDA's existing pharmaceutical AMT-related activities which found that there is limited information on whether their policy, regulatory, and engagement efforts have resulted in greater adoption of AMT and recommended that FDA "document and finalize performance goals and measures related to its advanced manufacturing program efforts and regularly assess progress."¹⁴ HHS concurred with GAO's recommendation.

U.S. Legislative and Administrative Initiatives

AMT continues to be of interest to federal policymakers, particularly its potential to contribute to bolstered domestic manufacturing capabilities and to help in mitigating drug shortages. In 2022, the Committee on Technology within the National Science and Technology Council released an update to the 2018 *Strategy for American Leadership in Advanced Manufacturing*, which identified needed investments in advanced manufacturing to support the U.S. position as a manufacturing leader globally.¹⁵ The omnibus spending bill signed into law in December 2022 included several investments and authorizations intended to strengthen the resilience of the U.S. supply chain, including the creation of National Centers of Excellence in Advanced and Continuous Manufacturing, health agency funding, and research into current and future efforts to support a strong and sustainable supply chain. Additionally, in March 2023, the White House Office of Science and Technology Policy released a report, *Bold Goals for U.S. Biotechnology and Biomanufacturing*, which recognized the potential for harnessing biomanufacturing advancements for API production and



enhancing supply chain resilience. Among these goals is to develop the biomanufacturing capacity to produce at least 25 percent of all APIs for small molecule drugs within 5 years.¹⁶

International Landscape and AMT Initiatives

Other global regulatory health authorities have specialized programs, initiatives, and efforts to support adoption of AMT, including PCM. For example, the European Medicines Agency (EMA) expanded its existing Process Analytical Technology (PAT) team to include PCM as well as a Quality Innovation Group. The Japanese regulatory authority, the Pharmaceuticals and Medical Devices Agency (PMDA), has formed the Innovative Manufacturing Technology Working Group which interfaces with industry to “discuss regulatory issues related to quality assessment and good manufacturing practice inspection to facilitate the introduction of innovative manufacturing technologies while ensuring appropriate quality.” PCM is the primary target for the working group.¹⁷ PMDA has approved at least six drug products produced using PCM, including at least one product that has also been approved by FDA. Applications for PCM-produced solid oral dosage forms have also been approved in Canada, Australia, Switzerland, and New Zealand.¹⁸

Harmonization of guidance documents and regulatory expectations across the globe is frequently mentioned by stakeholders as an area that should be prioritized to encourage adoption of AMT. The International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use (ICH) guidance *Q13 Continuous Manufacturing of Drug Substances and Drug Products* (Q13) is one step toward harmonization and regulatory convergence.¹⁹ Q13 builds on existing ICH quality guidelines and highlights certain considerations and concepts unique to PCM. FDA engages in international harmonization activities via ICH and plans to work to harmonize international guidelines through the FRAME Initiative.

A ROBUST ENVIRONMENT FOR INCREASED ADOPTION AND IMPLEMENTATION OF AMT

Policy approaches to progress the development and adoption of AMTs should be flexible enough to recognize and support a diversity of products, technologies, and processes.

In 2004, FDA’s “Pharmaceutical Quality for the 21st Century” Initiative expressed the goal of “an agile, flexible pharmaceutical manufacturing sector that reliably produces high quality drugs without extensive regulatory oversight.”²⁰ Without new incentives and more predictable regulatory environments, the potential of AMT is likely to remain underrealized. AMTs have been cited as key components to ensuring a resilient, sustainable pharmaceutical supply chain by promoting efficiencies, increasing diversity in medicines manufacturing, and helping to mitigate over-reliance on over-concentrated sources and the related potential for supply chain disruptions. Expanded utilization of AMT, such as PCM, can help enable a more nimble, domestic production of essential medicines and APIs while helping to strengthen the overall supply chain.

AMTs are typically defined and viewed through a broad lens; however, it should be noted that general purpose discussions of AMTs do not necessarily reflect the complexities underlying a globalized pharmaceutical supply chain with

multiple actors and differing processes and capabilities. The challenges or opportunities for manufacturers producing APIs are different than those producing FDFs, and possible process improvement solutions applicable to those products may be vastly different. Similarly, while utilization of AMT in the production of drug products or drug substances may be appropriate in some instances, it may not be the most efficient or appropriate mechanism for all products. Traditional batch manufacturing will remain an essential pillar of global medicine manufacturing capacity, and any discussion related to bolstering domestic manufacturing capabilities must also consider upgrades and updates to existing capacity for batch manufacturing. Hybrid models of pharmaceutical manufacturing which utilize batch and continuous manufacturing processes may also be an efficient and effective utilization of AMT. Additionally, some AMT initiatives at the academic, research and development, and pilot scale level do not consider certain factors, such as commercial viability, as heavily as they do technical feasibility or efficiency, for example.

Distinguishing these nuances is vital to any policy discussions or proposals aimed at supporting AMT development and adoption. **USP recognizes the financial, scientific, and regulatory complexities associated with AMT and urges use of a multifaceted approach to promoting the development, adoption, and implementation of AMT within the global pharmaceutical industry. As such, USP supports policy reforms that prioritize approaches with the potential for greatest effect on strengthening pharmaceutical supply chain resiliency, addressing underutilization of existing manufacturing infrastructure, promoting global geographic diversity in pharmaceutical production, or advancement of technologies with potential for significant public health impact.**

Financial and other incentives are necessary to overcome barriers and encourage adoption of AMT.

The business case for AMT differs depending on several factors such as size of the company, portfolio of products (innovator versus generic), type of product, and existing infrastructure, among others. The degree to which cost-effectiveness or lifecycle management factor into the business case for AMT adoption varies by company, and assessing two manufacturing processes, such as batch versus continuous, is unlikely to provide a direct comparison.

The financial risks and return on investment are generally understood with technologies such as batch manufacturing, but the same is not true for AMT. However, some data are now available demonstrating the potential commercial benefits of AMT, particularly PCM. An audit of PCM regulatory submissions and outcomes in the United States found annual sales of drug products made with PCM processes to be over \$3 billion in 2020, and that PCM applicants had shorter times to approval compared to similar batch applicants resulting in an estimated \$171 to \$537 million in early revenue benefit.²¹ Furthermore, an analysis of investments of batch versus PCM technologies found that new construction of PCM manufacturing facilities yielded a factor net present value higher than that of batch manufacturing.²²

Geographic concentration of pharmaceutical manufacturing can create vulnerabilities in the global upstream medicines supply chain. AMT is one potential solution to bolster supply chain resilience by helping to return manufacturing to the United States and allowing economies new to pharmaceutical manufacturing to establish manufacturing capacity. Nearly half of the generic pharmaceutical manufacturing capacity in





the United States is idle; a survey by the Center for Analytics and Business Insights at the Olin School of Business at Washington University shows many of these sites could be brought up to full production capacity within two years.²³ Repurposing existing production lines where possible could speed production of critical medicines, and market-based incentives could encourage utilization of this excess domestic capacity.

U.S. policymakers and other government leaders could help to overcome barriers to AMT adoption, in part, through a combination of public financing and incentives for private investments, particularly for those medicines identified as vulnerable or essential. Significant up-front capital investment is often required for technologies such as PCM, which becomes an even greater challenge for low margin, low priced products such as generics with multiple competitors. Furthermore, smaller manufacturing companies may not have the resources or capabilities to test the technological feasibility of AMTs for their specific products. More favorable economic environments abroad, including corporate tax rates, labor and manufacturing costs, regulatory and environmental costs, and other expenses, may also factor into whether companies are willing to make investments in domestic production capabilities.²² Any incentives or benefits should recognize and reflect the variability in potential solutions and should be flexible enough to encourage and support the adoption of AMT by different stakeholders. Early efforts to align incentives for manufacturers with their development of PCM may result in more impactful outcomes.

Industry stakeholders have expressed support for proposals to encourage onshoring production, such as grants from HHS to support construction, alteration, or renovation of facilities

for U.S.-based manufacture of medicines included on the list of essential medicines²⁴ as well as tax credits and reduced tax rates on income from domestically produced drug products and drug substances. The U.S. Department of Commerce’s Economic Development Administration also has initiatives such as the Regional Technology and Innovation Hubs program which aims to bring together consortia to focus on regional technological and innovative growth, including manufacturing. These kinds of investments are needed to enable modern manufacturing approaches.

USP supports near- and long-term financial incentives and public investments that will bolster and enable greater adoption of AMT including in scientific and technical research such as:

- **Financial incentives to provide manufacturers with the necessary support to build facilities supporting AMTs for increased production capabilities.**
- **Direct or indirect market-based subsidies or incentives to support new manufacturing capabilities or to encourage utilization of existing excess and dormant drug manufacturing facilities.**
- **Establishment of AMT-specific innovation and incubation centers that are focused on translating AMT technology into new, innovative companies and helping established companies understand and implement new technologies.**



To bridge knowledge gaps related to technical or scientific obstacles or regulatory uncertainties, stakeholders should leverage partnerships, learning opportunities, and development of resources.

From industry line workers and upper management to regulatory inspectors and FDA reviewers, lack of familiarity with advanced manufacturing drives risk-averse decisions that can slow the adoption of AMT.

Along with the necessary development of scientific methods, the capabilities and expertise of scientific or technical personnel and enterprise decision makers also require further development. Both industry and regulators lack practical experience with AMT, including PCM, because the application of some technologies to pharmaceutical manufacturing may be relatively new. Knowledge gaps must be addressed, and scientific and technical knowledge should be improved through training and educational programs, leveraging the expertise and experience of those who have more extensive knowledge of AMT, and the development of standards for materials, characterization, models, and digital methodologies essential for successful implementation of AMT.

AMT represents a paradigm shift in pharmaceutical production, requiring different skills and knowledge to design, implement, and operate production lines. Manufacturers need more staff with technical knowledge of the processes, capabilities, and constraints of AMT to enable them to develop new process analytical technologies, models, and statistical tools. This technical knowledge factors into decisions about hiring and re-training the workforce.

Those most experienced with AMT may be concentrated among certain companies or in certain areas and may not be easily accessible for information sharing.

There is a need to identify avenues for knowledge sharing in a pre-competitive space for those who want to develop and adopt these technologies as well as for regulators. Educational courses and workshops, expanded access to information, interactive discussions, and other educational materials can help to bridge these gaps and develop a broader workforce knowledgeable about the technical and regulatory environment for AMT. For example, the Continuous Manufacturing Knowledge Center (CMKC), an online, open access collaborative forum established by USP and the National Institute for Pharmaceutical Technology and Education (NIPTE), provides a space for discussion, information sharing, and learning. The CMKC aggregates information organized by USP and NIPTE including research publications, industry practices, presentations at technical forums, and non-peer-reviewed materials, as well as facilitates discussion among stakeholders.²⁵ Additionally, USP has developed a technical guide on control strategies for continuous manufacturing of solid oral dosage form drug products which serves as a detailed conceptual and practical illustration of the process of developing these products. The technical guide is another resource that helps to share knowledge and best practices for those involved in the development of AMT and in this case, for the development of continuous manufacturing platforms.

Public-private partnerships including U.S. government agencies, academia, research institutes, and industry also aim to proactively address challenges presented by advanced

and continuous manufacturing technologies. One public-private partnership, the National Institute for Innovation in Manufacturing Biopharmaceuticals (NIIMBL), works to enable collaboration on the establishment of reference standards and measurement technologies to enhance efficiencies and cultivate the biopharmaceutical workforce through training and education, among other objectives.²⁶ These types of public-private partnerships can facilitate cooperative research and development agreements that allow the parties to share resources in a precompetitive environment and produce meaningful outcomes that are broadly beneficial.

USP supports accelerating scientific and technical knowledge of advanced and continuous manufacturing through coordination of efforts and public-private partnerships among government bodies, academia, industry, and other allied stakeholders. This may include, but is not limited to, the establishment or expansion of consortia and the development of technical guides, educational tools, standards, and workforce training opportunities that help to address workforce, regulatory science, and technical feasibility concerns that hinder the adoption and implementation of AMT. Such programs should include the establishment of facilities that provide training and hands on experience for industry and regulators in a precompetitive space.

Addressing regulatory challenges and increasing harmonization and regulatory expectations of global health authorities is essential to increasing adoption of AMT.

Although various factors impact decisions to invest in AMT—commercial viability, buy-in from company decision-makers, the financial position of the company, and the availability of a skilled workforce to successfully implement the technology—those that facilitate progress toward implementation may encounter challenges within regulatory frameworks. AMT solutions will only progress as fast as the regulatory structure permits.

There are also various regulatory obstacles for manufacturers and developers to navigate, such as working within existing regulatory frameworks for current good manufacturing practices, inexperience with PCM among application reviewers, post-approval issues, and lifecycle management issues that stakeholders may encounter, as well as perceptions of increased regulatory risk or uncertainty. Another significant source of uncertainty comes from organizations seeking approval in multiple markets; there can be key differences between the FDA's approach and the approach of other regulators around the world. Consideration of more fluid and targeted guidance, a greater focus on underlying technology as opposed to individual product approvals, and a pilot program for incorporation of industry





input and collaboration have been identified as potential solutions to these challenges.¹⁴

Within the United States, policymakers and stakeholders have responded to the needs of industry, such as through the issuance of guidance and the establishment of programs to increase communications between FDA and stakeholders. Within the United States, policymakers and stakeholders have responded to the needs of industry, such as through the issuance of guidance and the establishment of programs to increase communications between FDA and stakeholders. Recent Congressional authorization for the establishment of an advanced manufacturing technologies designation program and support for five academic institutions to be designated as National Centers of Excellence in Advanced and Continuous Manufacturing will further aid in identifying and overcoming technical, scientific, and regulatory challenges.

As more is learned from industry experience, experiences within these programs, and other avenues for information sharing, **USP urges** the relevant agencies and stakeholders **to revise, and clarify as needed, regulatory expectations and pathways that are reflective of new programs and opportunities that help to further promote the development, adoption, and implementation of AMT.** For example, FDA could consider whether technologies that receive an AMT designation should be eligible for an expedited approval pathway or whether to create a new pathway to support innovative technologies. As stakeholders look ahead to other innovative technologies and how those technologies interact with each other, ongoing discussions on how to improve and build upon the current framework will be necessary.

Lack of consistency in regulatory guidance or expectations among international health authorities can have an impact upon stakeholders’ willingness to adopt AMT. Variation in the international regulatory environment continues to be one of the larger regulatory hurdles to AMT adoption. The United States and other health authorities with more experience with innovative technologies continue to work to identify opportunities for alignment, but this may not be the case for other less experienced health authorities that do not have the same resources or capabilities to support these efforts. Additionally, not all health authorities participate in ICH, and for those that do, each regulatory jurisdiction has their own legal structures and timelines for implementation. This may result in inconsistencies even among those who have adopted ICH guidance, such as Q13, making implementation a challenge and causing delays to convergence of regulatory practices. **USP recommends further movement toward regulatory convergence and to clarify regulatory expectations and support broader adoption of AMT by industry.** This may be achieved, in part, through ongoing collaborative participation in ICH and robust stakeholder and regulator engagement to identify and understand the primary barriers to AMT adoption. Currently, there does not exist a repository or database that clearly identifies and compares the regulatory approaches among the major market regulators (USA, Europe, Brazil, Mexico, Japan, etc.). Such a comparison is instrumental to understanding which gaps to harmonize and could be valuable to companies seeking to enter multiple markets for a product produced using an AMT.

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ABOUT USP

USP is an independent, scientific, global non-profit organization founded in 1820 when eleven physicians took action to protect patients from poor-quality medicines. Convening in the old U.S. Senate Chamber, they published a national, uniform set of guidelines for medicines called the U.S. Pharmacopeia. A core pillar of USP's work is to help strengthen the global supply chain so that the medicines, dietary supplements, and foods that people rely on for their health are available when needed and meet quality standards as expected and required.

USP is active in supporting stakeholders as they consider adoption of advanced manufacturing technologies and works to identify gaps, challenges, and solutions to emerging needs. Information about USP's work in this area, as well as additional resources can be found on [USP's advanced manufacturing technologies website](#).

The Federal Food, Drug, and Cosmetic Act of 1938 created the statutory requirement that medicines sold in the United States generally must adhere to USP's public quality standards to help ensure the quality of medicines and the safety of patients. USP standards are developed by nearly 800 scientific and healthcare experts who volunteer their time on USP's standard-setting committees, which also include over 200 U.S. Food and Drug Administration (FDA) government liaisons. In these and other ways, USP works closely with the FDA, other government agencies, and across health and science communities to develop USP standards (over 6,000 today) that are enforced by the FDA. Recognizing the need for public quality standards and appropriate testing methods to help ensure the quality of medicines made utilizing innovative technologies, USP has convened its Expert Bodies, including volunteer experts and Government Liaisons, and developed analytical laboratory infrastructure staff expertise as well as training for workforce development.

In addition to our work on standards, USP is an active participant in many public-private partnerships on supply chain-related issues. This includes work with the FDA, ASPR, and the Biomedical Advanced Research and Development Authority (BARDA). USP also engages with the World Health Organization and the Pan American Health Organization as an officially recognized non-state actor and hosts the USP-APEC (Asia-Pacific Economic Cooperation) Center of Excellence for Securing Medical Product Quality through the Supply Chain, under the sponsorship of the FDA.

USP is governed by more than 500 organizations, including scientific, healthcare practitioner, consumer, and industry organizations, as well as dozens of government agencies, who together comprise the USP Convention.