



December 12, 2025

By Electronic Submission to [www.regulations.gov](http://www.regulations.gov)

Michael Kratsios  
Assistant to the President and Director  
White House Office of Science and Technology Policy

**Re: RFI: National Strategic Plan for Advanced Manufacturing (Docket No. [NIST-2025-0004](#))**

Dear Mr. Kratsios:

The Advanced Medical Technology Association (“AdvaMed”) appreciates this opportunity to submit comments in response to the Office of Science and Technology Policy (“OSTP”) Request for Information on National Strategic Plan for Advanced Manufacturing (“OSTP RFI”), published at 90 Fed. Reg. 26,335 (Jun. 20, 2025).

AdvaMed is a trade association that represents the world’s leading innovators and manufacturers of medical devices, diagnostic products, digital health technologies, and health information systems (“medtech”). Together, our members invent, develop, distribute, and manufacture much of the lifesaving and life-enhancing healthcare technology transforming healthcare through earlier disease detection, less invasive procedures, and more effective treatments. Medtech manufacturing is a critical pillar of U.S. economic competitiveness, national security, and public health.

Our members, which range from the largest to the smallest medtech innovators and companies, help patients stay healthier longer, recover more quickly after treatment, and improve clinicians’ ability to detect disease (including chronic diseases) earlier and treat more patients more effectively and efficiently. At the same time, the innovation and advancements in medtech driven by our members result in dramatically reduced healthcare costs. The role of medtech in improving patient health is well-known. In the United States (“U.S.”) there exists an innovation ecosystem for medtech that improves both patient health and access to care. Indeed, the U.S. medtech industry is responsible for a highly disproportionate share of medical advances globally.<sup>1</sup>

AdvaMed supports OSTP’s efforts to advance U.S. manufacturing competitiveness, grow the economy

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<sup>1</sup> The U.S. is ranked first in various measures of healthcare innovation. See, e.g., 2020 FREOPP World Index of Healthcare Innovation, ranking the U.S. first in Science & Technology Healthcare Innovation with a score of 75.14, well above second-place ranked Netherlands (49.97). Available at <https://freopp.org/wihi2020-505b1b60bce6>.



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across multiple industrial sectors, strengthen national security, and improve healthcare, and is pleased to provide input to inform the development of the 2026 National Strategic Plan for Advanced Manufacturing (the “Plan”). Further, AdvaMed and its members are committed to ensuring the U.S. remains the unrivaled world leader in medtech, including through strong research and development and domestic manufacturing. To this end, AdvaMed offers the following responses to OSTP RFI questions in support of this commitment and OSTP’s efforts to advance the U.S. manufacturing competitiveness.

## I. Emerging Science and Technology Areas (Question 1)

### A. *Which emerging science and technology areas (e.g., artificial intelligence) will be key to the next generation of innovative advanced manufacturing technologies, and how will they impact advanced manufacturing?*

We believe the following emerging science and technology areas will be key to innovative advanced manufacturing technologies:

- **Artificial Intelligence/Machine Learning and Digital Twins.** Combined with automation and manufacturing systems, artificial intelligence/machine learning (“AI”) and Digital Twins could improve production efficiency and impact planning, scheduling, quality control, and root cause anomaly detection with respect to advanced manufacturing. For example, enhanced AI could be used to enable more accurate and faster reading from PET scans while utilizing less advanced pixel technology. Generative AI could also be applied to equipment for real-time feedback and analytics. Digital twins could reduce product development time to market through the ability to rapidly iterate on product designs, and could also lead to individualized personal medicine through the creation of human digital twins.
- **Additive Manufacturing.** Additive manufacturing, also known as 3D printing, enables the rapid prototyping and iteration of complex components, as well as the manufacturing of materials, tools, jigs, fixtures, and products, including those not possible with conventional means. This could also enable bespoke, on-demand, patient-specific solutions, including individualized device design for patients or adjustable post-implantation customizations.
- **Advanced Materials & Nanotechnology.** Advanced materials (natural and synthetic) and nanotechnology offer the potential for new and superior materials and properties, and could be combined with AI and additive manufacturing for rapid ideation of new material systems and property evaluations. Examples include implantable sensors, microchips, micro energy/power sources, and consumable materials to support manufacturing processes. Additionally, technology that enables the growth of synthetic tissue in various structures, from flat sheets to actual organs, can serve as an alternative to using porcine and bovine tissue. Synthetic tissue offers more consistency in material properties and supply chain availability than material taken from livestock.
- **Robotics and Automation.** Robotic solutions could be utilized for complex and tedious manufacturing processes, and could also increase production speeds/efficiency and reduce operator-dependent



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variation.

- **Augmented & Virtual Reality.** Augmented and virtual reality technology can be utilized for engineering collaboration, operator training, and the potential for remote problem-solving.
- **Sterilization Technologies.** Development of alternative sterilization methodologies will be important for medical technologies.
- **Lasers.** While there are technical improvements in laser capabilities in the research and development (“R&D”) space, these are slow to translate into the industrial space. Green femtosecond laser technology, for example, is effective in an R&D setting but lacks the robustness required to be incorporated into a manufacturing or industrial environment at scale.
- **Inspection Capabilities.** Inspection methods that can examine a fully assembled part and measure internal features, such as CT Scanning, exist, but are not robust enough to handle 24/7 operations, thereby limiting the ability to effectively implement such technology.

***B. What are the primary challenges and barriers that need to be addressed to ensure the successful integration and widespread adoption of emerging technology in manufacturing?***

We believe the following challenges and barriers need to be addressed to ensure the successful integration and adoption of emerging technology:

- **Regulatory Misalignment.** High-level, blanket regulations that are implemented without sufficient consideration of the impact on emerging technology in manufacturing serve as a barrier to advancement and should be addressed, as should regulatory bottlenecks and misalignment with quality and regulatory bodies.
- **Workforce Constraints.** Access to a skilled workforce is crucial for the adoption of emerging technologies in manufacturing and must be addressed. One way to address this challenge may be to upskill existing employees.
- **Capital Intensity.** Initial investment and capital costs are a primary barrier that must be addressed to ensure the successful integration and adoption of emerging technology.
- **Integration Complexity.** Integrating emerging technology into current designs and manufacturing facilities will be a challenge that must be addressed.
- **Knowledge Gaps.** A lack of necessary knowledge, data, and information repositories will serve as a barrier to the successful integration and adoption of emerging technology in manufacturing.
- **Critical Materials Access.** Access to key critical minerals, including rare earths, is a challenge that must be addressed to produce best-in-class medical imaging equipment. In addition, the high price of development and the time to market, compared to manufacturers that may be able to obtain the rare



earth portion faster and at a significantly lower cost, will be a barrier to success.

## II. Disruptive Manufacturing Technologies (Question 2)

### ***A. Which disruptive manufacturing technologies (e.g., additive, nanotechnology, biotechnology) hold the potential to eliminate reliance on foreign sources for critical minerals and materials, and how will they do that?***

All disruptive manufacturing technologies have the potential to reduce reliance on foreign sources of critical materials and minerals. This includes, for example, microsensors, power sources, and invasive imaging technology, as well as the development of alternate materials to simulate biological structures, and a combination of both additive and subtractive technologies to meet complex functional needs.

In the short term, domestic identification, processing, and production of critical materials would reduce foreign dependence on imports, although regulatory and environmental considerations would need to be assessed in conjunction with these short-term actions. In the long term, innovation through rapid prototyping and accelerated development times could potentially lead to the discovery of replacement or alternative materials that can be domestically sourced.

Notwithstanding the foregoing, currently, there is no developing technology that will eliminate our need for foreign sources. Although the U.S. has deposits of precious metals and rare earths, they are not actively being mined due to access restrictions and regulations that make it cost-prohibitive.

### ***B. What are the technical challenges and barriers associated with implementing these technologies at an industrial scale, and how can they be addressed?***

There are multiple challenges and barriers associated with implementing disruptive manufacturing technologies, including high startup costs and a shortage of skilled labor. In addition, the issue of scaling, i.e., achieving a volume/scale of production for emerging technologies that yields returns sufficient to be competitive, is a challenge.

With respect to additive manufacturing, there are currently limited material options, large-scale manufacturing is highly capital and space-intensive, and manufactured parts often require subsequent post-processing and quality control. Advanced materials development through cross-industrial and government collaborative efforts could help advance additive manufacturing.

Advanced material development and nanotechnology materials are similar to additive manufacturing in that current methods require expensive processes and equipment. The developing quality of these advanced materials will hinder their wide-scale adoption, especially in life-sustaining applications. Additionally, the handling and processing of nanomaterials and small-scale materials could pose risks

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associated with industrial hazards. Scaling advanced biomaterials is also challenging and complex due to various issues, including inconsistent yields and contaminants.

Another challenge and barrier that needs to be addressed is the separation technology and the desire to get beyond magnet metals. To address this challenge, there must be an understanding within the market that this material is needed and that a market exists for it. Advancement in the ability to separate the material is also necessary.

**III. Technology R&D Priorities (Question 3)**

**A. What should be the near-term and long-term technology R&D priorities for advanced manufacturing, reasons for those priorities, key objectives based on those priorities, the timeframe for achieving objectives, and the metrics for assessing progress toward the objectives?**

Technology R&D priorities for advanced manufacturing should include the following, for the reasons and objections noted, as well as the additional digital priorities detailed on [Exhibit A](#).

Priority	Reasons & Objectives
3D/4D Printing (Polymers & Metals)	Custom tools, patient-specific parts
Bioresorbable Materials	Implantables with no retrieval need
AI Visual Inspection	Quality control in cleanrooms
Digital Twins	Simulate product & factory performance
Edge-AI	Quality inspection or connected manufacturing
Smart IoT Sensors	Real-time process/device monitoring
Collaborative Robotics	Safe automation for medtech lines
Lights-Out Cleanrooms	Fully automated sterile production
Green Manufacturing	Sustainable materials & energy use
Materials	Shape-memory alloys or nanocoatings
Rare earth mining	There is no known replacement for Lutetium to achieve the best PET images. Any change would be a step backward (e.g., returning to BGO-based detectors) and would still require rare earth materials. It would take a scientific breakthrough. Mining for rare earths should occur outside of China (USA, Canada), as large deposits do exist.



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In addition to the specific reasons and key objectives for those priorities identified above, focusing on these priorities to advance technology will disrupt the higher U.S. cost profile and allow the U.S. to compete more effectively with lower-cost countries for manufacturing.

***B. What are the major technical challenges to achieving the priorities identified [above] and how can they be mitigated to ensure timely progress?***

Major technical challenges to achieving the technology R&D priorities identified above include the following:

- **Design Complexity & Integration.** There is difficulty in aligning design tolerances across different processes (e.g., machining + additive). There are also challenges in ensuring compatibility between parts made with different technologies.
- **Process Coordination Between Suppliers.** Increased lead times due to sequential or interdependent processes create technical challenges in achieving the above priorities. There are also logistical complexities in managing multiple vendors or internal departments.
- **Cost & Resource Management.** Higher costs due to tooling, setup, and process-specific requirements, as well as inefficient resource utilization when processes are not optimized holistically, create technical challenges in achieving the above priorities.
- **Prototyping & Iteration Delays.** Longer development cycles when changes affect multiple processes create technical challenges, as do limited agility in manufacturing and testing design iterations quickly.
- **Post-Processing & Assembly Challenges.** The need for extensive post-processing to meet final specifications, as well as tolerance stack-up issues during final assembly create technical challenges in achieving the priorities identified above.
- **Rare Earth Mining.** Regarding rare earth mining, government action is necessary to support the mining/separation processes required to produce usable rare earths.

**IV. Public-Private Partnerships (Questions 4 and 10)**

***A. [Question 4.a] What are examples of U.S. manufacturing-related technological, market, or business challenges that may best be addressed by public-private partnerships and are likely to attract both participation and primary funding from industry?***

We offer the following two examples of U.S. manufacturing-related challenges that may best be addressed by public-private partnerships:

- Appropriate regulation setting for critical materials to perform device function with no suitable alternative (e.g., PFAS, EtO); and



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- Mining and separation projects, i.e., how to handle all material separated beyond magnet metals, such as Thorium and other radioactive materials.

***B. [Question 4.b] How can public-private partnerships be structured to overcome potential hurdles and foster successful collaboration?***

Structuring public-private partnerships as joint research and innovation hubs with a focus on collaborative manufacturing R&D, with university and/or government research groups to support industry needs, will help overcome potential hurdles and foster successful collaboration. In addition, in the context of advanced materials development, there is often a significant amount of rigor associated with up-front R&D and development of new materials for medical device applications. One primary concern for participants in these types of R&D efforts is the ownership and sharing of intellectual property (“IP”) and subsequent revenue generated from these efforts. In order to overcome this potential hurdle and foster successful collaboration, there should be an equitable structure to address IP before engaging in these efforts.

***C. [Question 10] What are examples of public-private partnership models (at the international, national, state, and/or local level) that could be expanded to facilitate manufacturing technology development, technology transition to market, and workforce development?***

Governments in international locations have designed and implemented highly effective industrial development policies through a combination of support grants and loans, as well as tax incentives for qualifying projects and economic activities. The Federal government could likewise incentivize targeted domestic hubs or advanced manufacturing. Any Federal policy reforms involving tax relief should consider the current and future state of the OECD/G20 Global Minimum Tax project under Pillar 2 of the Base Erosion and Profit Shifting (BEPS) initiative to ensure that federal policy is not undone by the Global Minimum Tax.

Another example of a *model that could be expanded here* is the public/private partnership model adopted and implemented in Singapore. Through the Economic Development Board (“EDB”), the Singapore government has a model that allows private industry to invest with confidence, with support, incentives, and advocacy (including through global diplomatic ties). Singapore also has a governmental entity called the EDBI, which is dedicated to government co-investment in private models.

**V. Commercialization of Research Findings (Question 5)**

***A. How can Federal agencies and federally-funded R&D centers supporting advanced manufacturing R&D facilitate the transfer of research results, intellectual property, and technology scale-up into commercialization and manufacturing to benefit all Americans and ensure economic and national security?***

Federal agencies and federally funded R&D centers can facilitate the transfer of research results, IP, and



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technology scale-up into commercialization and manufacturing through the following:

- Funding and Incentives. Accelerating funding and incentives by offering attractive tax incentives and grants for domestic production of federally funded innovations.
- Public-Private Partnerships. Establishing public-private partnerships to foster collaboration between research and industry. These partnerships connect federal R&D with private sector needs and co-fund projects to scale targeted technologies, allowing for the sharing of risks and capital resources, rather than individual companies being forced to bear all the burden.
- Pilot and Demonstration Projects. Offering or supporting grants, loans, or tax incentives for pilot-scale and demonstration projects to assist with the scaling of technology from laboratory research and commercial production. There could be regional development organizations or hubs where technology is co-located.
- Workforce Training. Co-developing programs and partnerships with universities for workforce training, which could lead to industry-wide and recognized standards. In addition, government policies and incentives to prevent the offshoring of skills once the technology is developed would be beneficial to retaining technology and talent.
- FDA. Standardizing and streamlining FDA pathways.
- Manufacturers outside of the US. Reviewing entry plans, cost, and patent approvals for manufacturers outside of the US.
- Government Support. Offering government support for IP, assets, and talent transfers.
- Base Erosion and Anti-Abuse Tax. Fixing the Base Erosion and Anti-Abuse Tax, as further discussed in Section IX.B below, as it creates a barrier to entry for companies that are looking to onshore IP to the US.
- Rare Earths. Reviewing the uses for rare earths, which are byproducts beyond the magnet metals, and examining the U.S. contracts already in existence with minor and separators around the world to determine if they can advance the technology beyond its current capabilities to include medical imaging applications using rare earths.

***B. What are the key challenges in translating research findings into commercially viable manufacturing processes and products, and how can they be overcome?***

Key challenges in translating research findings into commercially viable manufacturing processes and products include regulations and the availability/suitability of existing infrastructure to support production at scale. In addition, with respect to rare earths, key challenges include the fact that the market is primarily based in the medical imaging field, with little to no market for rare earth byproducts during the separation process, and the process itself is complicated.



## VI. Skilled Workforce (Question 6)

### ***A. What are the main challenges in attracting, training, and retaining a skilled workforce for advanced manufacturing, and how can they be addressed?***

The primary challenge in attracting, training, and retaining a skilled workforce for advanced manufacturing is the high cost of entry, as well as ensuring that the workforce possesses the actual knowledge and expertise required for advanced manufacturing. The process and technology are out there, but there is a limited knowledge base. For example, access to skilled hourly maintenance technicians to maintain and support automated manufacturing equipment is lacking. Many technicians need to be trained on the job and do not come out of technical schools able to support heavily automated equipment. There is also a need for dual-skilled workers (combining robotics and regulatory compliance) and a shortage of automation engineers in the medical technology (medtech) manufacturing sector. The global distribution of supply chain talent presents another challenge. Regarding rare earths, there is a need for both skilled workers and adequate space. Separation is a skilled labor process involving chemicals and multiple-step processing.

These challenges can be addressed by creating incentives for universities to recruit students in these fields and by strengthening university research centers through grants to reinforce this effort. In addition, more technical schools training hourly maintenance technicians in the maintenance of robots, programming, PLC, and PC controlled systems are needed.

### ***B. How can Federal agencies and federally-funded R&D centers develop, align, and strengthen all levels of advanced manufacturing training, certification, registered apprenticeships, and credentialing programs?***

Federal agencies and federally funded R&D centers can assist by positioning national labs and Manufacturing USA institutes as regional training hubs offering hands-on experience with emerging technologies. In addition, government support for training, as well as the streamlining of workforce mobility programs, would strengthen all levels of advanced manufacturing training, certification, registered apprenticeships, and credentialing programs. Finally, work must be focused not just on R&D, but also on how to make the R&D solutions robust enough to be deployed in a 24/7 production environment. Making something once or twice is not the challenge; we need to be able to make thousands or millions of units rapidly, with minimized labor costs. To achieve this, the R&D technology needs to be industrialized, and there is a lack of focus on transitioning technologies from R&D to Industrialization. Funding companies that are doing this work would facilitate the adoption of those technologies into manufacturing.

## VII. Advanced Manufacturing Clusters and Technology Hubs (Question 7)

### ***A. In what ways can the Federal government assist in the development of advanced manufacturing clusters and technology hubs nationwide, beyond funding needs?***



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Beyond funding, the Federal government can assist in the development of advanced manufacturing clusters and technology hubs nationwide in the following ways:

- Bringing local research institutions and corporations together for exploration of joint needs or opportunities in these areas, and by facilitating the big problem statements to be addressed.
- Implementing regulations and policy support for US-based companies.
- Facilitating coordination, seed funding, and support for local hubs where common technologies are needed and present (e.g., electronics and semiconductors in Phoenix, AZ), as well as providing infrastructure support to support these hubs.
- Supporting training programs to train technicians and engineers in those regions where technology hubs are located. Technology hubs already exist in many locations across the country (e.g., the Mid-Atlantic/New England region is a hub for injection molding). This results in many companies centralizing production, utilizing that technology in the region, and facilitating educational and training programs to improve talent in that region. However, as additional companies rely on those hub areas, it puts a strain on finding top talent. Associated training programs need to be conducted in the relevant region to ensure a skilled workforce.
- With respect to rare earths, funding the effort to mine for rare earths and removing the regulatory barriers while pulling companies together in the effort (e.g., like the recent Apple announcement at the White House in supporting MP Minerals for magnet production).

***B. Is there a need for new or expanded advanced manufacturing clusters or technology hubs for the competitiveness of U.S. manufacturers, and if so, in what sectors or technologies?***

Yes, there is a need for new or expanded advanced manufacturing clusters or technology hubs for the competitiveness of U.S. manufacturers with respect to light and heavy rare earth materials, such as magnets and lutetium. Lutetium is the final separation with preceding rare earths, benefiting many other industries. It requires a joint effort to make this affordable.

***C. Should Federal incentives prioritize industry-specific advanced manufacturing clusters or instead focus on technology hubs centered on advanced technologies, critical components, and materials? If so, why?***

The government should lead an effort with industry to determine whether Federal incentives should prioritize industry-specific advanced manufacturing clusters or focus on technology hubs centered on advanced technologies, critical components, and materials. We offer the following suggestions with respect to tax incentives:

- Tax incentives toward prioritized manufacturing could include an increase in the Foreign-Derived Deduction Eligible Income deduction percentage (Internal Revenue Code Section 250) or an expansion



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or targeting of eligible income to include more domestic manufacturing.

- Tax incentive reform should contemplate the interaction of Corporate Alternative Minimum Tax (Internal Revenue Code Section 55), which can significantly reduce or eliminate the benefit of tax incentives in some fact patterns. An important example is the clawback of the tax benefit of deductibility of U.S.-performed R&D expense provided for in the recent reconciliation bill.
- Refundable grant incentives provided in upfront, negotiated agreements with the Federal government may be preferred over tax credits to be administered by the Internal Revenue Service and subject to disallowance many years after the economic activity occurs.

## VIII. Domestic Supply Chains (Question 8)

### ***A. What are the primary vulnerabilities and weaknesses within the current domestic supply chains?***

The primary vulnerabilities and weaknesses within the current domestic supply chains include the following:

- Some sub-sectors of the supplier base have either a limited or small presence in the U.S. market, forcing reliance on supplies from other markets (e.g., chips, sensors, metals, raw materials). For example, many rare earths are not mined domestically, and it is challenging to do so under current regulations and the high investment hurdle. There is heavy dependence on Asia for raw materials.
- Single-sourcing risk for specialty raw materials and semiconductors.
- Getting parts from one “hub” region to another for further operations can be cost-prohibitive and challenging because of, for example, the trucking industry, roads, traffic, infrastructure, power grids, and increasing demand for power due to AI.
- Chronic labor shortages in transportation, warehousing, and manufacturing sectors slow production and delivery capabilities.
- Increasing climate-related and geopolitical events.

### ***B. What programs and policies need to be implemented to develop and re-shore a resilient domestic advanced manufacturing supply chain and industrial base?***

To develop and re-shore a resilient domestic advanced manufacturing supply chain and industrial base, government incentives are needed to encourage companies to onshore the manufacture of critical parts or technologies and to invest domestically. For example, there should be Federal incentives to localize the production of medical-grade resin and magnets.



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Programs and policies that support workforce capability and participation are also critical to develop and re-shore domestic manufacturing, as are strategic partnerships to onshore specialty component suppliers.

In addition, the Base Erosion and Anti-Abuse Tax should be adjusted. Currently, the Base Erosion and Anti-Abuse Tax imposes a barrier for companies that would move their IP to the US, as it effectively leads to double taxation via the denial of tax deductions related to any IP that is on-shored in the US. Until this provision is amended, companies will be challenged to justify the economic burden of relocating IP, including that related to advanced manufacturing, to the US.

Finally, programs and policies that focus on mining, separation, and refining need to be implemented to develop and re-shore a resilient domestic advanced manufacturing supply chain and industrial base.

## **IX. Small and Medium-Sized Manufacturing Companies (Question 9)**

### ***A. What are the biggest obstacles faced by small and medium-sized manufacturing companies in adopting advanced technologies to increase efficiency and productivity?***

The same barriers and challenges discussed above in Sections II.B and III.B are also obstacles faced by small and medium-sized manufacturing companies in adopting advanced technologies. In particular, small and medium-sized manufacturing companies face obstacles in the form of cost barriers to entry, upfront investment, talent availability, and the ability to upskill existing talent.

### ***B. How can Federal agencies assist these companies in adopting advanced technologies and participating in the establishment of robust and resilient domestic manufacturing supply chains?***

Federal agencies can help small and medium-sized manufacturing companies adopt advanced technologies and establish robust, resilient domestic manufacturing supply chains by providing technical assistance and consulting services. Many small companies lack the necessary relationships to connect with the right service providers or to navigate the initial regulatory barriers.

## **X. National Strategy for Advanced Manufacturing Top-Level Goals (Question 11)**

### ***A. The current 2022–2026 National Strategy for Advanced Manufacturing has three top-level goals, each with objectives and priorities: (1) Develop and implement advanced manufacturing technologies; (2) Grow the advanced manufacturing workforce; and (3) Build resilience into manufacturing supply chains and ecosystems. Are these goals appropriate for the next 4–5 years? Why or why not?***

In general, we believe the current goals of the 2022–2026 National Strategy for Advanced Manufacturing



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are appropriate. They address urgent and evolving needs related to advancing technology to stay globally competitive, building a skilled workforce to close talent gaps, and strengthening supply chains to ensure resilience against disruptions, aligning well with current trends and challenges in manufacturing. They are also likely to position the U.S. for sustainable growth over the next four to five years, allowing the U.S. to remain economically competitive on a global basis in the future and to prepare for the next generation of economic transition.

However, we recommend setting an additional goal related to AI, recognizing that this may be a more long-term objective. The significant focus and emergence of AI in both personal and corporate environments could significantly disrupt the development of both the technology and the workforce, making it essential to establish a specific goal for managing these tools. For example, with respect to rare earth elements, AI may help reduce the need for large quantities of these materials. However, domestic rare earth technologies are likely several years away, as no one in the U.S. is currently separating rare earths, and the production process and training would likely extend beyond five years.

***B. What emerging needs or opportunities might require the addition of new top-level goals, and why?***

As noted above, AI may require the addition of a new top-level goal. In addition, new top-level goals related to the following issues would help future-proof U.S. manufacturing against evolving risks and opportunities:

- Sustainability. Address climate change through green manufacturing and circular economy practices.
- Cybersecurity. Protect increasingly digital manufacturing systems from cyber threats.
- Global Competitiveness. Strengthen trade resilience and international collaboration to stay competitive.

**XI. Additional Information**

***A. Is there any additional information related to advanced manufacturing in the United States, not requested above, that you believe should be considered? If so, describe.***

Like any other industry, medtech utilizes high-end electronic components, assemblies, and advanced computing methods for research and development (R&D) and manufacturing. Computing infrastructure, imaging, and robotic fields within our industry require the latest and high-performance technologies and equipment. Very often, these types of high-end technologies and items are strictly controlled for export control and may require several export control measures to ensure compliance with applicable export control laws. These restrictions may pose challenges to the transfer of items and the exchange of ideas that are essential for improving and utilizing advanced manufacturing techniques in the production of



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medical equipment. Policy and procedures that simplify and facilitate the transfer of advanced manufacturing technologies and items, such as agnostic AI modules, GPUs, servers, and software to the medtech industry from other industries, and within the medtech industry from one location to another, may help in bringing rapid growth of advanced manufacturing technologies within the medtech industry.

## **XII. Conclusion**

AdvaMed thanks the OSTP for soliciting input on these critical issues and stands ready to work with the OSTP and other relevant federal agencies to implement these recommendations and comments. Thank you for your consideration of these comments. Please contact Terry Chang (tchang@advamed.org) for further information or collaboration.

Sincerely,

/s/

Christopher L. White

General Counsel & Chief Policy Officer

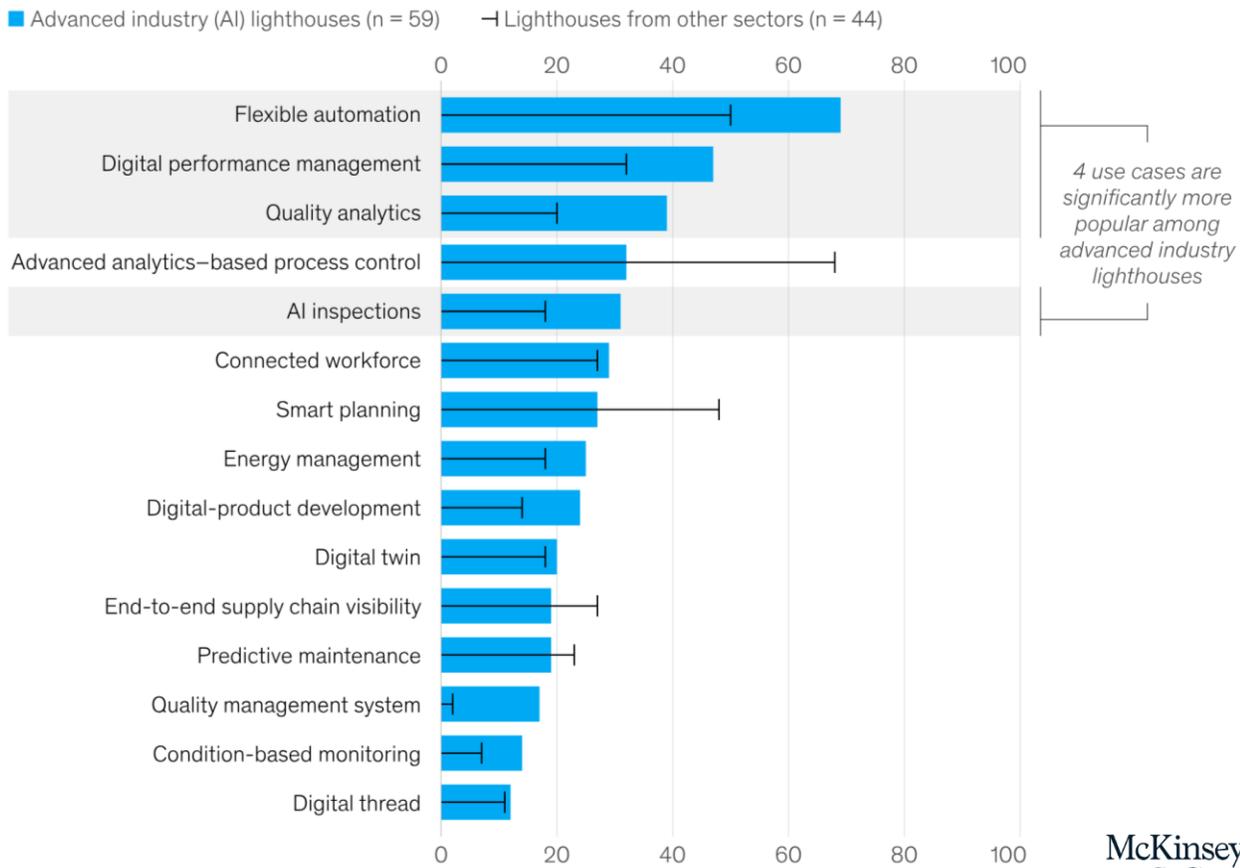
Advanced Medical Technology Association (AdvaMed)



## EXHIBIT A

### Four use cases account for significantly more impact in advanced industry lighthouses than in other lighthouses.

Prevalence of high-impact<sup>1</sup> use cases by industry, % of lighthouses

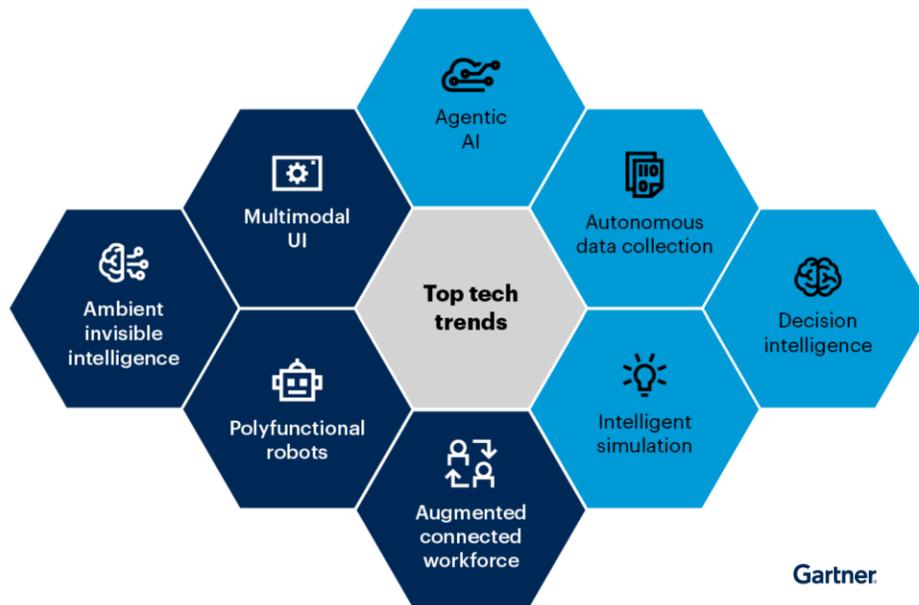


<sup>1</sup>Use case cited by lighthouse as one of the four highest-impact use cases implemented.

<https://www.mckinsey.com/capabilities/operations/our-insights/transforming-advanced-manufacturing-through-industry-4-0>

### Top Trends in Supply Chain Technology for 2025

■ Connectivity    ■ Intelligence



<https://www.gartner.com/en/newsroom/press-releases/2025-03-18-gartner-identifies-top-supply-chain-technology-trends-for-2025>