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Goal: Stimulate Discussion on “Where does the community go from here?”

I: Although different stakeholders have different perspectives, there is a common purpose across the ecosystem, including by the regulated industry and the FDA:

~To ensure patient access to a [safe, efficacious, reliable] supply of medicines to enhance our health and well-being.



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Company Mission Statements taken from their websites (10/27/21)

At **Pfizer**, we innovate every day to make the world a healthier place.

What is the mission of **Merck**? We aspire to improve the health and wellness of people and animals worldwide and to expand access to our medicines and vaccines. All of our actions must be measured against our responsibility to those who use or need our products.

Amgen strives to serve patients by transforming the promise of science and biotechnology into therapies that have the power to restore health or save lives.

Bristol Myers Squibb is a global biopharmaceutical company whose mission is to discover, develop and deliver innovative medicines that help patients prevail over serious diseases.

GSK: We aim to bring differentiated, high-quality and needed healthcare products to as many people as possible, preventing and treating disease and keeping people well with our scientific and technical know-how and talented people.

Company Mission Statements taken from their websites (10/27/21)

even suppliers are aligned

At **Sartorius**, we empower scientists and engineers to simplify and accelerate progress in life science and bioprocessing, enabling the development of new and better therapies and more affordable medicine.

At **MilliporeSigma**, our mission is to help our customers improve human health and life worldwide.

FDA Mission (from their website 10/27/2021)

The Food and Drug Administration is responsible for protecting the public health by ensuring the safety, efficacy, and security of human and veterinary drugs, biological products, and medical devices; and by ensuring the safety of our nation's food supply, cosmetics, and products that emit radiation.

FDA also has responsibility for regulating the manufacturing, marketing, and distribution of tobacco products to protect the public health and to reduce tobacco use by minors.

FDA is responsible for advancing the public health by helping to speed innovations that make medical products more effective, safer, and more affordable and by helping the public get the accurate, science-based information they need to use medical products and foods to maintain and improve their health.

FDA also plays a significant role in the Nation's counterterrorism capability. FDA fulfills this responsibility by ensuring the security of the food supply and by fostering development of medical products to respond to deliberate and naturally emerging public health threats.

The Center for Drug Evaluation and Research (CDER) ensures that safe and effective drugs are available to improve the health of the people in the United States



Goal: Stimulate Discussion on “Where does the community go from here?”

II. Current situation: “Advanced manufacturing” approaches are typically not limited by technology. They are limited by business risk.

- Speed to market is key.
- Adoption of a new technology increases risk of speed to market.
- Little (or no) business incentive for new technology in today’s climate.
- Fragmented global regulatory environment raises the bar even higher.

FDA: Advanced manufacturing is a collective term for new medical product manufacturing technologies that can improve drug quality, address shortages of medicines, and speed time-to-market.

- <https://www.fda.gov/emergency-preparedness-and-response/mcm-issues/advanced-manufacturing>

FDA is responsible for advancing the public health by helping to speed innovations that make medical products more effective, safer, and more affordable

What is **working well** based on my understanding/experience:

- Positive messaging from the podium.
- A genuine willingness to partner.
- Engaging PPPs to advance understanding and build relationships.
 - Active listening to understand industry perspective on barriers to technology adoption.
 - Project participation for scientific research.
 - CRADA.
 - ETT.
 - Opportunities to engage in shared testbeds, and ETT by consortia.



snapcomms.com

What are some **challenges** based on my understanding:

- While there is a willingness to partner, there is a lack of resources and bandwidth.
- Not always an easy organization to partner with.
- While mechanisms are in place, experience with those mechanisms sometimes falls short.
 - Application Reviews
 - BAA Reviews
- Reviewers may be dissuaded to support innovation – the reviewer has everything to lose.



tiempodev.com

A need for community action!

Organizations and individuals must actively engage in a sustained effort to help realize change!

It's not good enough to say: hey, we know there's a hurdle there, let's talk about it.

Let's all be partners for change.

Our industry matters.

Our access to advanced manufacturing capability matters.

U.S. leadership and competitiveness matters.

worldbankgroup.org



The opportunity to address everyone's **mission** is too great.... it isn't even the technology!

~To ensure patient access to a [safe, efficacious, reliable] supply of medicines to enhance our health and well-being.

What Can Be Done Moving Forward?



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III. Policy Action Opportunities

- 1) Increase appropriations to facilitate the headcount necessary to more actively engage the community on advanced manufacturing adoption.
- 2) Consider a tax incentive for products / processes that adopt *advanced manufacturing** approaches (to help various types of companies).
- 3) Consider extended period of exclusivity for products that are first to adopt *advanced manufacturing** approaches (to encourage innovators to debate the business benefit of new technology relative to risk to timeline).

**defining advanced manufacturing is nontrivial from a public policy perspective*

What can I do?

- NIIMBL can commit to hosting follow-up workshops to continue the discussion. We need organizations to be willing to engage. (How often, what do we want to accomplish and over what time?).
- I am willing to help advance thinking around relevant Policy Actions.
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