

Manufacturing Matters: Why Rapid Biologics Production Must Become a Cornerstone of Global Pandemic Preparedness

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Mark Emalfarb, CEO of Dyadic Applied Biosolutions, argues that rapid, scalable monoclonal antibody production must become a cornerstone of global preparedness as the world braces for future threats ranging from H5N1 and Ebola to Disease X.

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MANUFACTURING MATTERS: THE MISSING LINK IN GLOBAL PANDEMIC PREPAREDNESS

Why rapid, affordable monoclonal antibody production must be as important as vaccine development in preparing for future outbreaks.

MARK EMALFARB
CEO
Dyadic Applied Biosolutions

- SPEED**
CI platform goes from frozen vial to upstream fermentation in as little as 5 days vs. up to 50 days in mammalian systems.
- HIGHER PRODUCTIVITY**
Delivers higher grams-per-liter-per-day and up to ~3 batches in the time of one CHO batch.
- LOWER COST**
Lower-cost media, no viral clearance requirements and compatible with existing infrastructure.
- EQUIVALENT PERFORMANCE**
mAbs produced in CI bind and neutralize virtually identically to those made in CHO cells.
- GLOBAL IMPACT**
Collaborations with CEPI, Gates Foundation, NIAID and leading academic institutions to strengthen outbreak preparedness.

“The next pandemic may not be limited by our ability to discover solutions—it may be limited by our ability to manufacture and deliver them quickly enough to save lives.”

The COVID-19 pandemic demonstrated that scientific discovery can move at extraordinary speed, but it also exposed the limitations of global manufacturing infrastructure. As the world prepares for future threats ranging from avian influenza and Ebola to the next Disease X, the ability to rapidly produce and distribute life-saving biologics is emerging as a critical component of preparedness. **In an exclusive conversation with BioSpectrum Asia during BIO 2026, Mark Emalfarb, CEO of Dyadic Applied Biosolutions,** discusses the role of next-generation manufacturing technologies, monoclonal antibodies, and scalable biologics production in strengthening global outbreak response

Why do you believe monoclonal antibody manufacturing remains an underrepresented topic in global pandemic preparedness discussions?

Much of the pandemic preparedness discussion focuses on prevention through vaccines, which are critically important. However, for individuals who are already infected, vaccines are often too late. Monoclonal antibodies (mAbs) can serve as an important first line of defense by neutralizing a virus in the body and reducing severe disease or death.

While significant attention has been devoted to discovering new antibodies, far less attention has been paid to how they can be manufactured rapidly, affordably, and at scale during an outbreak. Most mAbs today are produced in mammalian cell systems such as CHO cells, which typically require more than 20 hours to double, lengthy cell line development timelines, long scale-up activities, expensive media, and additional viral clearance steps before release. These factors can significantly delay patient access during a rapidly evolving outbreak.

COVID-19 had an approximate 1% lethality rate, yet it caused millions of deaths worldwide. If a future airborne virus spreads as efficiently as Omicron but has the lethality of Ebola, Hantavirus, or avian influenza, the potential death toll could increase dramatically. Rising vaccine hesitancy further compounds this risk, making rapid access to therapeutic antibodies even more important. The world does not just have a discovery problem—it also has a manufacturing problem.

What are the biggest barriers preventing rapid deployment of monoclonal antibody therapies during outbreaks such as Ebola, H5N1, and other emerging infectious diseases?

The primary barriers are manufacturing speed, production capacity, cost, and global access. Traditional monoclonal antibodies are generally produced in mammalian cell systems that can take months to establish and scale. Mammalian cells typically require more than 20 hours to double, resulting in lengthy development timelines, extended scale-up periods, and bioreactor production cycles that can take up to 50 days from a frozen vial to completion of upstream fermentation.

Additional viral clearance requirements, complex downstream processing, and high media costs further increase manufacturing timelines and expenses.

COVID-19 highlighted these limitations. As the virus rapidly evolved, manufacturers often struggled to develop and produce updated monoclonal antibodies quickly enough to keep pace with emerging variants. By the time some therapies were developed and manufactured, the virus had already changed.

Future outbreaks involving highly lethal pathogens such as Ebola, H5N1, Hantavirus, or Disease X could expose these same bottlenecks on an even larger scale. If a virus combines Omicron-like transmissibility with Ebola-, Hantavirus-, or avian influenza-like lethality, delays in producing and deploying mAbs could translate into dramatically higher mortality.

How does Dyadic's C1 protein production platform differ from conventional biologics manufacturing approaches in terms of speed, scalability, and cost?

Dyadic's C1 platform utilizes a filamentous fungal production organism that doubles approximately every 2.5 hours, compared with more than 20 hours for typical mammalian cells. This enables significantly faster strain development, scale-up, and manufacturing timelines.

In practical terms, C1 can progress from a frozen vial to completion of upstream fermentation in as little as 9 days, compared with up to 50 days for conventional mammalian systems. Because C1 is a non-mammalian production platform, it does not require the same viral clearance processes associated with mammalian cell manufacturing, potentially reducing both manufacturing time and cost. In addition, C1 utilizes lower-cost chemically defined media and is compatible with existing microbial fermentation infrastructure.

Importantly, studies conducted by multiple independent groups have demonstrated that monoclonal antibodies produced using C1 can bind and neutralize their targets in a manner virtually identical to antibodies produced in mammalian systems such as CHO cells. At the same time, C1 has demonstrated higher grams-per-liter-per-day productivity and can potentially produce approximately three upstream manufacturing batches in the time required to complete a single CHO production batch.

The result is a platform designed to help accelerate production of monoclonal antibodies, vaccine antigens, and other biologics while improving manufacturing flexibility, scalability, affordability, and response speed during outbreak situations.

What lessons from the COVID-19 pandemic should governments and public health organisations apply when preparing for the next Disease X scenario?

COVID-19 demonstrated that scientific discovery can move at unprecedented speed when resources are aligned. However, it also exposed significant weaknesses in manufacturing readiness and supply chains.

One important lesson is that discovering an effective antibody or vaccine is only part of the solution. Manufacturing platforms must be capable of rapidly producing sufficient quantities at affordable costs. During COVID-19, viral evolution often outpaced the ability of traditional manufacturing systems to develop, scale, manufacture, and distribute updated monoclonal antibodies. By the time some therapies were fully developed and produced, the virus had already evolved.

Governments should invest not only in discovery but also in next-generation manufacturing technologies capable of shortening development timelines, increasing productivity, reducing costs, and rapidly responding to emerging variants.

COVID-19 had an approximate 1% lethality rate, yet it overwhelmed healthcare systems and caused millions of deaths. A future airborne pathogen with Omicron-like transmissibility and the lethality of Ebola, Hantavirus, or avian influenza could be far more devastating. With vaccine hesitancy increasing in many parts of the world, preparedness strategies should include both vaccines and rapidly deployable therapeutic options such as monoclonal antibodies.

How is Dyadic collaborating with organisations such as CEPI, Gates Foundation, NIH/NIAID, and academic institutions to strengthen global outbreak preparedness?

Dyadic is collaborating with a broad network of global health organizations, government agencies, and academic institutions to evaluate and apply its C1 platform for vaccines, monoclonal antibodies, and other biologics.

These collaborations include projects supported by the Gates Foundation, CEPI, NIH/NIAID, the European Vaccines Hub/Fondazione Biotechnopolo di Siena, Oxford University, Scripps Research, Johns Hopkins University, Wits University, and the Israel Institute for Biological Research, among others.

A common objective across many of these programs is to address manufacturing bottlenecks by evaluating technologies that may enable faster strain development, shorter production timelines, higher productivity, and lower manufacturing costs compared with conventional approaches. Several collaborations are evaluating C1's ability to rapidly produce monoclonal antibodies and complex antigens while maintaining functional performance comparable to products manufactured in traditional mammalian systems.

The ultimate goal is to help move more rapidly from scientific discovery to deployable vaccines, antibodies, and other biologics that can be used to respond to future outbreaks.

Looking ahead, what policy, investment, or manufacturing changes are most urgently needed to ensure life-saving biologics reach patients faster during future outbreaks?

The most urgent need is greater investment in manufacturing innovation. Advances in artificial intelligence, genomics, and antibody discovery are accelerating the identification of promising vaccines and therapeutics, but manufacturing capacity remains a critical bottleneck.

Governments and global health organizations should support technologies that can reduce development timelines, shorten bioreactor cycle times, lower media and production costs, increase productivity, and simplify manufacturing workflows. Investments in distributed regional manufacturing networks and rapid-response production platforms are also essential.

Preparedness strategies should recognize that speed matters. If a manufacturing platform can produce antibodies that bind and neutralize comparably to CHO-produced antibodies, while delivering higher productivity, lower costs, eliminating viral clearance requirements, and potentially producing three batches in the time required for one conventional mammalian batch, that can have a meaningful impact on global access during a crisis.

The next pandemic may not be limited by our ability to discover solutions—it may be limited by our ability to manufacture and deliver them quickly enough to save lives. This is especially urgent if a future airborne virus combines Omicron-like transmissibility with the lethality of Ebola, Hantavirus, or avian influenza. Rising vaccine hesitancy only increases the need for rapidly available therapeutic options, including monoclonal antibodies.

Ensuring rapid, affordable, and scalable access to biologics must become a core objective of global health preparedness efforts. Manufacturing matters, because breakthroughs only save lives when they can reach patients in need.