

For pharmaceutical companies, private wireless networks power advanced manufacturing technologies



### Why read this paper?

As the US Food and Drug Administration (FDA) continues development of its Advanced Manufacturing Technology (AMT) Designation Program, pharmaceutical manufacturers are intensifying their evaluation and implementation of innovative technologies. This paper examines the critical role that private cellular networks will play in enabling the successful implementation of AMT in the pharmaceutical industry.

From "computer vision" used to enhance quality assurance to "smart factory" applications that streamline production and minimize supply chain disruptions, the manufacturing sector has for some time been bursting at the seams with innovation; with the FDA's AMT initiative, the availability and adoption of next-generation manufacturing capabilities will only accelerate. Robotics, automation, IoT, Artificial Intelligence and new approaches to data security also promise to help pharmaceutical companies and other manufacturers compete more efficiently and effectively.

While advanced manufacturing technologies come in many varieties, they all have one thing in common: the need for robust, agile and reliable wireless network connectivity.

#### AMT on the horizon

In June of 2023, the FDA co-sponsored and participated in a public workshop—Advancing the Utilization and Supporting the Implementation of Innovative Manufacturing Approaches"—at the Duke-Margolis Center for Health Policy. Inspired by the discussions at this event, and based on subsequent public input, the FDA in September 2024 published a draft Strategy Document on Innovative Manufacturing Technologies, which outlines the specific activities the FDA intends to "undertake to facilitate the use of innovative manufacturing technologies.

Specifically, under the draft strategic plan, the FDA intends to implement its "Advanced Manufacturing Technology (AMT) Designation Program." The FDA issued a final program guidance on December 29, 2024.

According to the FDA's website: "'Advanced manufacturing' is a term for an innovative pharmaceutical manufacturing technology or approach that has the potential to improve the reliability and robustness of the manufacturing process and supply chain and increase timely access to quality medicines for the American public.



The agency further writes: "Advanced manufacturing can integrate novel technological approaches, use established techniques in an innovative way, or apply production methods in a new domain where there are no defined best practices or experience. Advanced manufacturing can potentially be used for new or currently marketed small molecule drugs or biological products."

As the FDA finalizes its framework and vendors begin to compete to attain "designated AMT" status for their solutions, pharmaceutical industry leaders and decision-makers will no doubt face an onslaught of marketing about newly-available AMTs—even as some manufacturers seek to develop their own designated AMTs.

"Use of designated AMTs," the FDA advises, "can provide greater assurance of quality, shorten drug development time, assist stakeholders in more efficiently meeting regulatory requirements for commercial manufacturing and strengthen regulatory predictability for products that use a designated AMT."

However, before a pharmaceutical manufacturer can adopt AMTs, they will first have to determine if their current connectivity infrastructure can scale with the promise and demands of advanced manufacturing technologies.

### Connectivity is business-critical

As designated AMTs emerge in 2025 and beyond, advanced connectivity solutions like private LTE and private 5G networks will become business-critical. This is because legacy connectivity solutions have inherent limitations:



Wi-Fi is most effective for indoor office environments but typically encounters performance issues in dynamic industrial/manufacturing enterprises. Poor coverage, unreliable quality of service, mobility hand-off issues between access points and the total cost of ownership of the network are just some of Wi-Fi's limitations. The greater the need for more Wi-Fi access points, the higher the cost and complexity of installing, securing and managing those access points.



Public wireless often has spotty or no reception within the confines of a dynamic industrial manufacturing facility. This can sever connectivity to cloud-based platforms used and shared by developers, researchers and operational partners, leading to possibly significant business interruptions.



Wired networks can be costly to expand and maintain, and the risk of devastating business interruption due to an accidental cable cut is real. Wired networks limit equipment mobility and agility on the manufacturing floor, and the extensive use of copper-based cabled can negatively offset environmental sustainability initiatives.



A **private wireless network** can overcome these challenges, helping pharmaceutical manufacturers achieve their current objectives while allowing them to imagine and evaluate future operational enhancements. A private wireless network is a customized solution, right-sized for each facility and its unique operational requirements and use cases. It provides consistent, predictable and highly-secure coverage and bandwidth for business-critical applications.

Deploying private LTE or private 5G however, does not require an end-to-end replacement of a company's network infrastructure. A private wireless network can be seamlessly integrated into an existing network infrastructure; many companies use a mix of private 5G, Wi-Fi and fiber technologies to optimize operations across different facilities, such as offices, manufacturing plants, research facilities and distribution centers.

Legacy Wi-Fi and other wireless networks still serve some needs effectively, but private 5G can be used for specific, innovative and business-critical use cases, like "smart factories" or autonomous robotic process devices.

## With powerful connectivity comes powerful capabilities

Today, manufacturers are leveraging private wireless networks to enable game-changing capabilities, including:



Industrial Internet of Things: Also called IIoT, this capability involves placing sensors on specific factory equipment to perform tasks such as measuring, monitoring and managing performance, running proactive maintenance analytics and scanning for problems like temperature extremes, leaks or other environmental hazards. Data generated by IIoT devices can be used for "predictive maintenance." This capability allows manufacturers to monitor, maintain and prevent a machine from breaking down, which avoids costly downtime and improves productivity by keeping production running. Data collected from IIoT devices and harvested in near real-time using a high-speed, low-latency wireless connection can also inform a company's efforts to leverage Artificial Intelligence for process optimization.



Advanced and intelligent robotics: These include mechanized arms that have computer vision capabilities or mobile robots, such as automated guided vehicles and autonomous mobile robots, which can complete material handling tasks that help to replace manual carts on a factory line. By having the right materials provided to factory workers at the right time, downtime can be avoided instead of having to wait for workers to manually deliver critical materials to a production location.



Augmented and virtual reality systems: Also known as AR/VR, can be used to provide product demonstrations for workers as well as for training front-line workers to better handle equipment and avoid hazardous materials to help prevent or reduce workplace injuries.



Real-time inventory management: Put simply, real-time inventory management is the continuous monitoring and updating of inventory levels; it gives companies comprehensive insight into their stock levels, including information on component availability and location. Achieving real-time inventory tracking demands a reliable network connectivity that works across a facility, indoors and outdoors, sometimes over tens or even hundreds of thousands of square feet.



Digital twins: This technology creates virtual environments for running simulations. Many of these simulations can also provide predictive maintenance capabilities, identifying potential parts that could break down soon and prompting teams to replace them before they break. Leveraging 5G and mobile edge computing (MEC)-powered digital twin solutions could boost manufacturing productivity through continuous performance adjustments based on real-world data streams.

# Manufacturers already prioritizing private wireless investment and mobile edge computing

### Two powerful acronyms: MEC and NHN

- + Mobile edge computing (MEC) puts processing power and storage where it's most needed: at the edge of the network, close to where data is generated. As part of a cloud computing solution, MEC helps manufacturing enterprises reduce latency and particularly when coupled with Private 5G makes access to remote servers vastly more efficient. Learn more here.
- + Many organizations require reliable coverage from multiple mobile network operators to support their operations, tenants, customers, visitors and staff. Neutral Host Network (NHN) allows public subscribers from multiple mobile network operators (e.g., Verizon, AT&T, T-Mobile, etc.) to connect to a common Radio Access Network (RAN). Learn more <a href="https://example.com/here/be/here/b

A recent Verizon-commissioned research paper from the Enterprise Strategy Group (ESG) highlights how MEC initiatives have become a top ten priority for almost every organization (94%) surveyed—and why private wireless networks are so critical.



The ESG report—"Going Beyond Digital Transformation<sup>2</sup>—surveyed a large sample size of business and IT leaders in the manufacturing and health care industries, among others, and finds: "As organizations deploy massive numbers of IoT devices, IP cameras, autonomous vehicles and artificial-intelligence-driven applications, they will likely find it challenging to collect, analyze and act on the huge amount of data these devices yield. What's becoming evident as organizations strive to be even more 'data-driven' is the need for a network design that provides the high speed, low latency and edge computing power needed for real and near-real time decision-making and action."

### "

Research shows that building an effective edge computing capability has already become a top priority for many companies, and that 5G will have a critical or significant impact on edge computing."

Going Beyond Digital Transformation, ESG, August, 2023.

Additional research bears out the importance of private wireless in manufacturing – today, and tomorrow.

According to a recent study by ABI Research,<sup>3</sup> private 5G networks can significantly improve operational efficiency and productivity in manufacturing processes—and enhance worker safety and cybersecurity, too. The ABI white paper, "Private 5G Drivers & Use Cases in Manufacturing," describes how and why manufacturers are re-evaluating their commitment to traditional wired and Wi-fi connectivity, calling private 5G "a compelling alternative."

Sharing data from a May 2024 survey of more than 100 manufacturers, the Verizon Business-sponsored ABI paper reveals that four specific desired business outcomes are the main drivers for investment in both Information Technology (IT) and Operational Technology (OT):

Improved security IT - 54% OT - 47%	Increased capacity OT – 42%
Increasing flexibility	Quality goals
IT – 46%	IT – 38%
	OT-39%

Private 5G networks, the ABI paper contends, can support the attainment of these goals.

#### **Conclusion: Partnership will make it possible**



IT transformation that is, deploying advanced manufacturing technologies—is only the first step in true business transformation. True business transformation demands a strategic, end-to-end approach that turns data into insights that solve real-world business problems. While turning data into action requires technology like private 5G networks, edge computing and more and more connected devices, it also requires business leaders who have a vision for a more agile and competitive future.

Given the promises and challenges of AMT, it makes sense that telecommunications providers would play a significant role in helping pharmaceutical companies create both the proper strategy and network to enable advanced manufacturing techniques.

The ESG research cited earlier in this paper confirms this: "Almost two-thirds of survey respondents (stated) want to take advantage of telecommunications providers for either their connectivity and distributed environments to host edge, or to leverage their skills and expertise to deploy and manage 4G or 5G networks in their environments."

And the ABI research paper cited earlier in this paper reinforces this need for a trusted partner, saying: "Private 5G networks offer significant opportunities for manufacturers to digitize operations and enhance communication infrastructure as part of a broader digital transformation strategy. However, with ongoing advancements in cellular technology, manufacturers should partner with experts linked to the telecoms industry to ensure their network remains upgradable and future-proof, facilitating the transition from wired to wireless connectivity in factory settings."



### Verizon recognized as a Leader in Private Wireless<sup>4</sup>

Verizon has been recognized as a Leader in the first-ever Gartner® Magic Quadrant™ for 4G and 5G Private Mobile Network Services, the only U.S.-based provider to be placed in the Leaders' Quadrant. Vendors are recognized for a combined assessment of Ability to Execute and Completeness of Vision related to their activity in the private mobile network services market.

Learn more here: <u>verizon.com/about/news/verizon-named-leader-gartner-magic-guadrant</u>

Learn how Verizon helps power enterprises with a broad portfolio of secure connectivity solutions that are built to support scale and growth. Visit: <a href="https://www.verizon.com/business/products/networks/connectivity/private-5g-network/">werizon.com/business/products/networks/connectivity/private-5g-network/</a>

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- $2.\ \underline{verizon.com/business/content/dam/resources/e-book/2023/businesses-going-beyond-digital-transformation.pdf}$
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  4. Gartner, Magic Quadrant for 4G and 5G Private Mobile Network Services, Sylvain Fabre, Peter Liu, et al., 6 January 2025

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