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The growing use of AI within the medtech production environment is providing numerous benefits

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Incorporating Intelligence into Manufacturing

A Q&A regarding the advantages that can be realized and considerations to keep in mind when leveraging an artificial intelligence solution in medical device manufacturing.

SEAN FENSKE | EDITOR-IN-CHIEF

As artificial intelligence (AI) permeates every industry, from healthcare to manufacturing, there remain many questions as to how it should be best implemented, what factors should be determined, and what challenges await. As such, gaining valuable insights from experts regarding its emergence and handling are critical for its successful application.

Recognizing the potential benefits, medical device manufacturers are curious as to how to best involve AI in their production workflows. With this in mind, MPO reached out to a provider of AI solutions for the industry. In the following Q&A, QAD responded to a series of questions that dig deeper into the use of AI in medtech development, the advantages that can be realized, and what users need to keep in mind.

Sean Fenske: Thank you for taking the time to address this important topic. I know many readers are curious about us-

ing AI and how it can help improve their production methods.

QAD: It is a pleasure to address these questions for MPO. We know our customers have already moved from the initial "AI hype" phase into a period of asking hard questions about AI investments, such as:

- What do I really want or need AI solutions to accomplish?
- What's the real value of AI for my manufacturing process?
- If I invest in this, how and where will it have the most impact?

They are also taking care to ensure pragmatic, high-impact executions. With the myriad solutions pitched to them, there's the "Do we do this ourselves or do we buy a pre-packaged application?" question. In this environment, where hype is culled and real-world use cases are starting to emerge, there is a sense of wanting to ensure you "get it right" and not over-

invest. There is also concern regarding regulatory compliance around the implementation of AI solutions in manufacturing environments.

Fenske: When it comes to leveraging artificial intelligence in the medical device manufacturing environment, what are we talking about? What is being supported by AI?

QAD: Many manufacturing processes—ranging from predictive analyses for demand planning and compliance support to a growing set of AI-driven use cases—are being transformed by intelligent automation.

- **Procurement and Sourcing:** Automating the request for quotation (RFQ) cycle and managing supplier coordination.
- **Sales Operations:** Extracting order details from customer emails and validating them against complex contracts.
- **Shop Floor Intelligence:** Monitoring real-time signals to identify quality risks—such as recurring stoppages—before they lead to non-conformance reports (NCRs) or corrective actions (CAPAs).

Fenske: How is AI being incorporated into the environment? Through what systems/software is it being used?

QAD: At QAD, AI is incorporated as a “smart layer” of the manufacturing software ecosystem. We deliver this through three core pillars:

1. **Adaptive ERP:** The intelligent backbone that manages the central business data.
2. **ChampionAI:** Our agentic engine that performs specialized tasks like inventory optimization or procurement management using Adaptive ERP as a solid foundation for daily operations with regulatory guidance.
3. **Redzone Connected Workforce:** A frontline-shop floor worker-focused system that puts AI-driven insights into the hands of operators on the production floor via mobile devices.

These systems are built on a high-security cloud infrastructure, specifically AWS, ensuring sensitive industry and customer data, and proprietary research are protected and not used to train public AI models. A plus for medical device manufacturers is that the environment in which QAD Adaptive ERP operates is an FDA-qualified environment.

Fenske: What advantages are realized from using AI in the medical device manufacturing environment? What efficiencies are achieved?

QAD: When leveraging QAD ChampionAI, medical device manufacturers have a product that has been trained on over 40 years of medical device manufacturing data collected as a start. There's no need to “build from scratch.” The primary advantage is that ChampionAI, the agentic layer on top of QAD Adaptive ERP, helps medical device manufacturers transition from a “System of Record”—which merely documents history—to a “System of Action” that predicts and acts proactively while keeping humans in the loop. Some advantages include:

- **Support for Human Capacity:** AI agents supporting procurement processes can free up 50% to 80% of a buyer's

or planner's workday by eliminating manual administrative tasks. One QAD customer using QAD ERP reduced service order entry time from 7 minutes to under 30 seconds. Another medical device manufacturer

noted how surprised she was at the time savings and volume handled by the ChampionAI procurement agent. These are just two of many examples of the benefits achieved by medical device manufacturers using a modern ERP system.

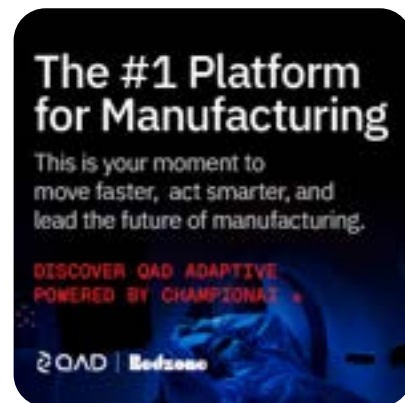
- **Reduction in Material Spend:** When valuable planners and buyers are freed from the repetitive and mundane—yet necessary—tasks, they can focus on more strategic cost containment and reduction initiatives.
- **Geopolitical Risk Management:** ChampionAI's “Procurement Champion” includes geopolitical risk mapping action.
- **Release Working Capital:** ChampionAI's “Inventory Optimization Champion” automatically identifies opportunities to right-size stock, freeing up critical cash flow.
- **Production Velocity and Quality Assurance Support on the Production Floor:** AI can help front-line production employees achieve “five days of product in just four days” through better equipment effectiveness and reduced downtime.

Companies don't have to achieve these benefits by building their own AI agents or agentic layer to embed in their manufacturing processes; instead, they can reap these benefits from a company with decades of manufacturing domain expertise.

Fenske: What is the FDA's view of the use of AI in the manufacturing environment?

QAD: The FDA has long advocated for the use of technology that would improve manufacturers' ability to deliver needed, effective, and safe devices to the market efficiently. To encourage manufacturers, over the past few years, the FDA has released various guidance documents on how to reduce validation effort for software used in the production of medical devices and medicines, by using a less burdensome “risk-based approach.” Even the Quality Management System Regulations (QMSR) that became effective on February 2, 2026, with its incorporation of ISO 13485:2016 by reference, also emphasizes a risk-based approach.

Many medical device manufacturers are familiar with the Computer Software Assurance methodology from previous FDA guidance, and on February 3, 2026, the FDA released the document entitled “Computer Software Assurance for Production and Quality Management System Software—Guidance for Industry and Food and Drug Administration Staff.” In the FDA's own words, it describes the intent of the guidance: “The FDA



QAD PRO TIP:

Reduce validation effort using the Computer Software Assurance approach. This risk-based focus is emphasized in the QMSR. Also, see the FDA's Computer Software Assurance for Production and Quality Management System Software Guidance for Industry and Food and Drug Administration Staff.

envision a future state where the medical device ecosystem is inherently focused on device features and manufacturing practices that promote product quality and patient safety. FDA has sought to identify and promote successful manufacturing practices and help device manufacturers raise their manufacturing quality level." On page 30 of this document is guidance specifically related to "Business Intelligence Applications."

The FDA is also leading by example through ELSA, its internal AI tool used to analyze massive safety and regulatory datasets. This means FDA is now using AI to identify high-priority inspection targets by detecting patterns in adverse events or manufacturing deviations faster than human investigators ever could.

Fenske: How can companies ensure they are in compliance with FDA's requirements/guidelines for the use of AI in the manufacturing environment?

QAD: There are many organizations with expertise in this subject that are available for hire if your organization does not have CSA experts in house. Interestingly enough, the new QMSR emphasizes risk-based approaches to validation of computerized systems used in the production of medical devices, and AI used for GMP-related processes is covered by the QMSR regulation.

In addition, international standards such as ISO 42001 provide an excellent framework for establishing governance and monitoring of AI systems.

The good news is that with regard to AI systems that do not have a GMP impact, such as sales agents, medical device manufacturers do not have to validate them. For example, the sales and contract management agents don't have an impact on device production, so they are outside of the scope of required validation. Medical device manufacturers can reap the productivity benefits of their sales order management agents without need for validation.

Fenske: What's misunderstood about AI in the manufacturing environment that people expect it to do or handle? What are the unrealistic expectations?

QAD: AI applications don't replace the expertise of manufacturing staff. Humans should and are expected to guide and monitor the output of AI agents. Furthermore, be sure to select AI solution providers that can clearly explain how their AI agents work and the intended use so you can evaluate the key performance indicators you'd most like to impact to ensure your AI application selection will target the outcomes you want to achieve. Ask questions, ensure the Agentic AI security protocols are clearly explained by the vendor, and your organization understands them.

For instance, QAD's ChampionAI takes data security seriously. All data is protected with TLS 1.2 and 1.3 during transit and AES-256 encryption while at rest. Encryption keys are securely

managed and regularly rotated. For AI queries, your data stays within your environment, and Retrieval-Augmented Generation (RAG) is used to limit access to only relevant information. Data is secured using robust encryption, strict access controls, and data sanitization to protect it from unauthorized access. Access is tightly restricted, logged, and continuously monitored.

Moreover, the system's architecture ensures that QAD customer data is never written directly into the AI model; instead, it remains in the QAD customer's environment, with secure access managed through AWS's infrastructure.

This offers peace of mind for those interested in implementing QAD ChampionAI from a data security standpoint and further, makes it more compelling to leverage QAD's business outcome-focused Agentic AI versus trying to build one's own Agentic AI solution stack—at least initially.

Fenske: What is QAD's role in this process? What do you bring to the table with regard to AI in medical device manufacturing?

QAD: Related to the last sentence of the previous response, data security guardrails and knowledge of what is needed to secure the data. ChampionAI is pre-built for supporting medical device manufacturers in achieving specific business outcomes. QAD ChampionAI is purpose-built, and each agent has a specific intent or focus. Monitoring for intended use is a regulatory requirement, and each of the ChampionAI agents aims to support a specific process and deliver against specific business goals. Many CMOs are focused on delivering high-quality and compliant devices for their customers. Large investments in AI pilots are not typically a top priority, so if they can work with an organization with manufacturing domain expertise that has developed AI solutions targeting key performance metrics a CMO would like to achieve cost efficiently, that's a huge win for the CMO. Bottom line, they receive the benefits of domain expertise in their AI solution without significant upfront cost or project failure risk.

Fenske: Anything additional you'd like to share with readers on this topic that wasn't covered?

QAD: QAD's role is a visionary organization to usher in the new era of manufacturing. The QMSR regulations are embedded directly into the QAD Adaptive ERP workflow mapping, and ChampionAI is the agentic layer that spans across the QAD solution set. This means our medical device manufacturing customers don't have to "bolt on" AI or regulatory guidance; QAD Adaptive ERP supports the environment they work in every day.

We bring a "System of Action" to the table, specifically scaled for the mid-market. A traditional ERP solution is only a system of record that tells a manufacturer what happened in the past but doesn't help them proactively analyze trends that may impact their business currently or in the future, so they can take mitigation or opportunistic actions. Our "Champion" agents are purpose-built with deep manufacturing expertise to handle inventory, sourcing, and procurement out of the box.

In addition, I would encourage your readers to consider that regulators are moving toward an expectation of data integrity and verifiable data output across the entire lifecycle—from design to post-market surveillance. Manufacturers still relying on paper or disconnected spreadsheets are facing an existential risk as FDA's AI-driven oversight grows over the years. It's no secret AI is rapidly changing every industry sector and ways of working.



Photo: Alamy/stockadobe.com

The Future Is Here:

Redefining Automation and Manufacturing Excellence

The capabilities of advanced robotics, AI, smart data systems, and lean thinking are opening new doors.

KYLE RAGAN | DIRECTOR OF MANUFACTURING EXCELLENCE, CORDICA MEDICA

In today's global medtech manufacturing landscape, competition is relentless, customer expectations are rising, and margins are tighter than ever. In this transformative age, artificial intelligence (AI), engineering innovation, manufacturing excellence, and automation aren't just buzzwords; they are the backbone of sustained growth and operational agility.

The capabilities of advanced robotics, AI, smart data systems, and lean thinking are opening new doors—streamlining processes while empowering people to amplify their impact and build resilient, scalable systems that outperform yesterday's limits.

Robotics & Automation: The Productivity Game-Changer

Imagine a facility where robotic arms tirelessly execute repetitive, high-precision tasks with 99.9% accuracy, 24/7. This isn't tomorrow; it's happening now. With the integration of robotics into production lines, companies are achieving unprecedented uptime, improving product quality, and redeploying skilled labor into higher-value roles.

While the term automation brings to mind speed and efficiency, it offers much more. Automation means consistency, safety, scalability, reduced scrap, and improved workplace ergonomics.

BEFORE AUTOMATION	AFTER AUTOMATION
92 Operators	93% Reduction in Operators
Four Shifts	75% Reduction in Number of Shifts
2,190 Parts per Hour	179% Increase in Number of Parts per Hour

Table 1: A look at the results of automation implementation.

In some cases, cycle times can be reduced by up to 35%. Just as importantly, automation can lead to a meaningful reduction of ergonomic injuries and process rework/scrap rates.

Case in Point #1

One automation project is saving millions and reshaping operations for a company. At Cordica Medical's North American facilities, an investment in automation is delivering significant returns, both in performance and profitability. The initiative targets the full automation of a previously labor-intensive assembly process for a high-volume, Class II medical device. The results have been transformational (Table 1).

This represents a 180% increase in throughput with a 93% reduction in labor. Beyond productivity, the company gained in process reliability, product consistency, and overall quality assurance, all of which equated to significant savings.

Strategic Gains and Long-Term Value

- Cost Savings:** With fewer labor hours and increased throughput, the cost-per-unit dropped significantly.
- Price Stability:** A three-year price hold was secured with the customer—extending a two-year freeze—reinforcing long-term cost control.
- Investment Security:** The company and customer worked collaboratively to develop an arrangement that ensured consistent demand throughout the payback period and beyond. This collaborative approach helped to justify the capital investment and reduce risk.

Why It Matters

In a global environment where cost, quality, and speed must be carefully balanced, this project illustrates how intelligent automation can deliver all three. It's not just about accomplishing more with less; it's about doing it better, faster, and smarter.

By eliminating unnecessary manual processes, standardizing output, and aligning commercial agreements with operational performance, the location has become a benchmark for scalable, sustainable manufacturing.

AI-Powered Systems: Transforming Quality Control

The integration of AI in quality inspection is changing how the industry can ensure consistency in the process. AI systems can quickly analyze data, detect defects, and predict equipment failures, leading to better quality, higher efficiency, and less waste. For service provider customers, this results in lower costs and more flexible operations.

Case in Point #2

To enhance quality control on many manufacturing lines across the company, vision systems equipped with AI-based inspection tools are being incorporated. The system uses deep learning to identify subtle defects and variations that traditional rule-based methods often miss, particularly on complex surfaces. By automating tasks like scratch detection, character recognition, and part verification, the AI-driven camera significantly reduced false rejects and inspection time. It also minimized manual setup by automatically optimizing lighting, focus, and inspection parameters, allowing the company to deploy quickly and adapt to changes in production with minimal operator input. This upgrade led to improved consistency, faster line throughput, and a more robust quality assurance process.

By investing in automation, embracing data-driven decision-making, and building smart, lean operations, companies won't just keep pace, they'll set the pace.

Data Analytics: Turning Information into Action

Where decisions were once based on yesterday's reports, real-time analytics now provide a live view of a company's operations—from overall equipment effectiveness trends and downtime reasons to scrap rates and bottlenecks.

By leveraging machine-level sensors, Internet of Things (i.e., connected) devices, and advanced analytics platforms, a company can shift from reactive decision-making to predictive. The power of data lies not just in its collection but in how it drives informed action.

Lean Manufacturing: The Foundation of Excellence

Lean isn't a project, it's a mindset—one rooted in continuous

improvement, respect for people, and the relentless elimination of waste. Through Kaizen events, value stream mapping, and frontline engagement, changeover times can be reduced and non-value-added activities eliminated on the production floor and beyond.

Case in Point #3

At a U.S.-based site, margins on a production line running for less than a year needed to be improved. The manufacturing excellence team applied the Theory of Constraints to identify and address key bottlenecks while systematically eliminating waste across the process. These targeted efforts delivered a 34% increase in throughput and cut labor in half, resulting in direct savings of \$408,000. More importantly, the initiative created a cultural shift from operator training and labor dependency to long-term process stability and continuous improvement.

Smart Manufacturing: The Connected Enterprise

The era of siloed departments and disconnected systems is over. Smart manufacturing links machines, people, and data into one cohesive ecosystem. From automated quality alerts to digital work instructions, factories that think, learn, and evolve are being developed and constructed.

This digital infrastructure supports faster decision-making, fewer manual errors, and better cross-functional collaboration. It's not about being high-tech for the sake of it; it's about enabling agility in a world that demands speed.

Cost Reduction & Inventory Optimization

Many associate cost savings with headcount reductions, but real savings often originate from smarter inventory management, tighter vendor collaboration, and operational efficiency. By deploying automated inventory systems and demand-driven replenishment, raw material stockouts and carrying costs can be reduced across critical supply chains, providing significant financial gains.

Businesses can thrive from having live visibility into inventory levels, material consumption, and supplier lead times—empowering purchasing teams to make smarter and faster procurement decisions.

Conclusion: Excellence is Engineered

Manufacturing excellence isn't a destination—it's a discipline. It's the fusion of engineering innovation, digital intelligence, and operational rigor. By investing in automation, embracing data-driven decision-making, and building smart, lean operations, companies won't just keep pace, they'll set the pace. The future of manufacturing will be won by those who can deliver precision at scale, adapt to disruption, and continuously improve.

KYLE RAGAN is the director of manufacturing excellence with Cordica Medical. With a passion and mission for automation, Ragan oversees the capital processes for equipment and facilities across Cordica Medical. Certified as a Six Sigma Black Belt, he ensures Cordica Medical's operations meet safety, quality, cost control, and efficiency standards for both the company and its customers.

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The Critical Role of AI in Medtech Supply Chain

Optimizing supply chain management is no longer a competitive advantage, but rather a necessity.

ESTELLE BLACK | BUSINESS OPERATIONS DIRECTOR, MEDWORLD ADVISORS

Veteran medtech industry professionals have learned how to handle the “increased pressure” associated with the sector: increased pressure from regulatory changes, from clients, and from innovation. Two significant pressures medtech companies are currently grappling with are (1) creating high-quality, next-generation, cost-effective products faster, and (2) improving supply chain management for current legacy products to ensure price optimization for customers while maintaining margin improvements for stakeholders.

Intrinsic value is critical to the long-term success of any medtech enterprise, whether the exit timeline is next year or a decade down the road. Intrinsic value impacts all aspects of the organization on a daily and annual basis. Effective supply chain management is both a key part of R&D execution and a critical part of a company’s day-to-day success. Accordingly, effective supply chain management continues to be a critical driver of value that all medical device manufacturers must address consistently and proactively.

Not surprisingly, artificial intelligence (AI) can help to bet-

ter manage medtech supply chains. Optimizing supply chain management is no longer a competitive advantage but rather a necessity, particularly in the medical device industry, where global complexities are entwined with patient outcomes and regulatory compliance. Effective AI implementation is uniquely positioned to drive smarter, safer, and more agile operations for today’s product catalog as well as for bringing new innovations to market sooner.

There are various reasons for (and advantages to) incorporating AI into supply chain management. A discussion of AI’s contributions to a company’s intrinsic value follows.

Innovation—Speed to Market

Design: To use a 90s term—Unplugged! The ability to use AI to explore alternative designs for next-generation designs is now “off the charts.” However, companies must still ensure their smart manufacturing technology can reproduce the AI-enhanced design.

DFM: Emphasizing that last sentence (above), it is critical

that AI-enhanced innovation teams can help successfully transition to the Design for Manufacturing (DFM) stage. DFM is an important component in this model, and the right AI tool could possibly accomplish this task more effectively.

Materials: There are countless novel materials but only a limited number have already been tested and accepted for use in medical applications due to possible patient implications. AI can help identify an appropriate material for next-generation design and suggest some that may already be compliant or could be compliant without undergoing years of testing.

Time to market: The appropriate AI R&D solution can assist through all phases of the R&D design phases to move next-generation solutions to market sooner.

Cost-effective: AI can make design processes more cost-effective and, more importantly, ensure that next-generation devices are price-competitive while increasing product margins.

Supply Chain Operations, Delivery Performance, and Cost Optimization

Demand forecasting: AI enables predictive analytics that can process historical sales data, seasonal trends, clinical adoption rates, and external signals (think atypical pandemic data or regulatory changes). These predictive models can forecast demand with greater accuracy. For the long-term, medtech firms that minimize stockouts or excess inventory will be ahead of their competition and boost their bottom lines.

Supplier risk management: Risk management is always part of the supply chain conversation. How can companies successfully minimize supply chain risks that could negatively affect customers and patients? One of the most critical lessons from the COVID-19 pandemic was the vital importance of resiliency. AI-powered platforms can continuously monitor supplier performance, financial stability, geopolitical events, and regulatory alerts. Doing so allows procurement teams to proactively mitigate risk by identifying alternative sources before disruptions occur—critical in an industry with long lead times and single-source dependencies.

Inventory optimization: Since many medical devices and components have a limited shelf life or are patient-specific, inventory optimization is considerably challenging. AI tools can help automate dynamic safety stock settings, flag expiring or obsolete products, and enable just-in-time deliveries in a much better way than human supply chain managers.

Logistics and distribution: Machine learning algorithms can improve route planning, track temperature-sensitive shipments in real time, and anticipate delays across multimodal transportation networks. With biologics and diagnostic reagents, for example, these types of algorithms can be vital for ensuring

product integrity from development to end user.

Regulatory compliance and traceability: No conversation about medtech supply chains is complete without a mention of regulatory compliance. In many ways, AI can help organizations remain compliant. For instance, AI can automatically track serial numbers, lot numbers, and device history records, helping produce fast, accurate product recalls or audits. Natural language processing (NLP) also allows AI to parse regulatory documents to stay updated on evolving compliance standards across geographies. Whether a product is already in multiple countries or is eyeing new markets, AI can ensure that companies follow proper protocol regardless of their geographical commercialization plans.

Despite its potential, it is not always easy to implement AI. In the medtech sector, the technology's success in helping manage the supply chain depends heavily on data quality and integration. AI models can only generate reliable insights if they are fed with accurate, complete, and timely information. There are many companies (especially those with aggressive M&A strategies) that still struggle with siloed data spread across disparate systems such as ERP, CRM, MES, and logistics platforms. Without unifying these datasets into a single source of truth, AI tools risk producing fragmented or misleading recommendations. Doing so can undermine both operational efficiency and decision-making—problems that could outright negate AI's numerous benefits. Establishing robust data governance and integration processes is therefore a foundational step before AI can deliver its full value.

Looking ahead, AI is poised to play an increasingly strategic role in reshaping the ways in which medtech companies operate globally. One key opportunity lies in enabling firms to localize supply chains—bringing manufacturing and distribution closer to end markets—without sacrificing efficiency or cost-effectiveness. This capability will be especially critical as organizations work to navigate tariff and trade challenges. AI's ability to analyze complex market, regulatory, and cost data in real time will help companies adapt faster and more effectively to shifting trade landscapes. If all of this is done well, companies' intrinsic value will continue to rise, which will be attractive for all stakeholders—employees, customers, suppliers, and shareholders.

ESTELLE BLACK has a decade of experience working with companies and supply chains, mostly helping organizations ensure a positive contribution to enterprise value. She is currently the Business Operations director at MedWorld Advisors and can be reached at estelleblack@medworldadvisors.com.

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