QAD | Redzone

A New Era for Midmarket MedTech Manufacturing

ERP evolves with agentic AI, native QMSR compliance, and predictive actions.

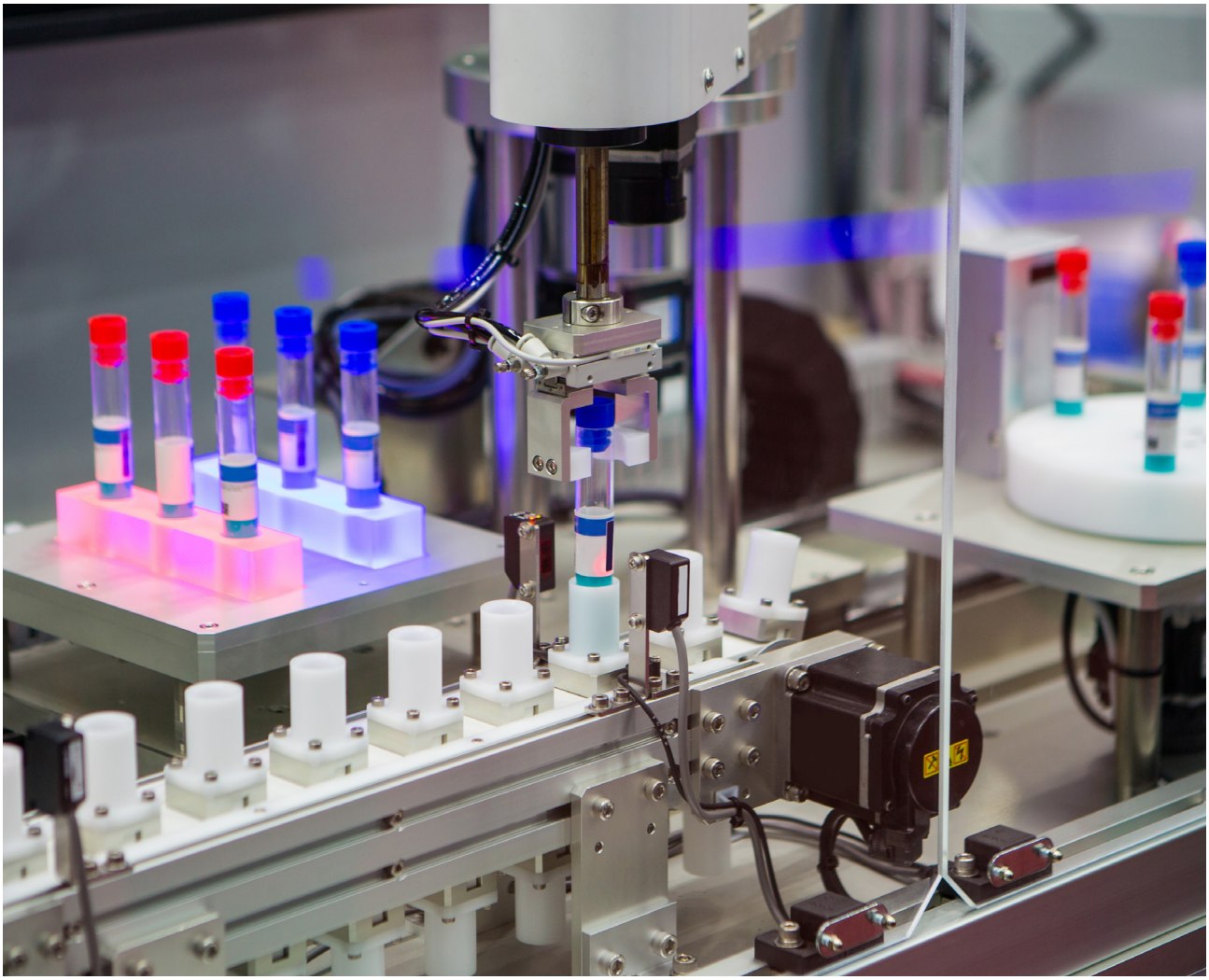


image: Shutterstock/Itsanan

What would you do if your enterprise resource planning (ERP) system could automatically match purchase orders with received goods, monitor supplier responses to RFPs, and flag only exceptions for review and approval? Or help you anticipate bottlenecks and interruptions by running scenarios to achieve different cost-optimized supplier network combinations to minimize supply chain risk associated with supplier location, weather, or other factors?

Key MedTech Business, ERP Challenges

The reality in the medical technology (MedTech) business is that ERP systems have been rigid and originally designed for relatively stable market conditions. These were mainly systems of record: they standardized transactions, enforced workflows, captured production data, and reported what had already happened. In contrast, this discussion offers a view of how an adaptive ERP platform can help medical device manufacturers increase productivity and improve profitability in actively changing market conditions.

In addition to the accelerated pace influenced by AI — which is impacting all manufacturing sectors — contract manufacturing organizations (CMOs), contract development and manufacturing organizations (CDMOs), and mid-market MedTech manufacturers are also impacted by these additional market dynamics:

- Evolving Supply Chains due to geopolitical shifts, tariffs, and reshoring initiatives.
- Customer demands for competitive pricing and cost efficiencies, while at the same time, manufacturing costs continue to rise due to inflation, tariff variability, and labor costs.
- Increased adoption of AI in medical device manufacturing speeds up processes and innovation, which intensifies competition, so speed to market is more critical than before.
- Regulatory complexity continues apace as the *FDA QMSR takes hold for products to be sold in the US market and more stringent lifecycle management requirements continue under the EU Medical Device Regulation.* (More on this below.)

The most advanced ERP solution, scaled for mid-market CMOs and CDMOs, can help MedTech manufacturers address these four industry challenges, while traditional approaches suffer from several hindrances.

First, many MedTech manufacturers suffer from fragmented systems and operational silos that limit their ability to scale, weaken their supplier pricing leverage, and locks data in separate departments/ plants/divisions or regions. Disparate systems and SOPs perpetuate inconsistency and increase product quality risk. Decision-making is slowed or skewed with an incomplete view.

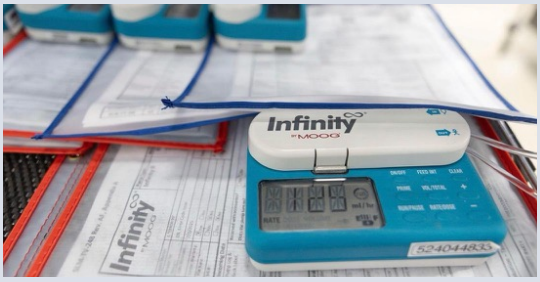
Next, manual workflows are often the result of difficulties related to the inability of ERP systems to support the workflows. Spreadsheets and reports generated outside of the system are created to satisfy the various data views needed by different parts of the organization. Without a single source to tie all of the various viewpoints together, it is difficult to have full visibility of business operations. Process inconsistencies across regions, and manual processes and reports, place a manufacturer at higher risk for errors, delays, and inconsistent quality. Manual workflows are also slower than automated workflows.

Aging systems also suffer from legacy constraints and may lag in their integration capabilities, limiting a manufacturer's agility for adapting to market changes.

Finally, and most importantly, ERP systems traditionally available to CMOs and CDMOs lack real-time insight capabilities that are available. This reduces forecasting accuracy, resulting in increased costs, among other shortcomings. The latest QAD offering, QAD Adaptive with ChampionAI, tackles these hindrances with significant solutions for all of the challenges above.

This discussion will explain how MedTech manufacturers benefit from an adaptive ERP system: (See Case Study: Moog Medical, next page.)

Case study: Moog Medical



Click for a video case study Moog Medical.

Moog Medical, a global leader in medical devices including feeding and infusion pumps, upgraded to QAD Adaptive ERP across its three core manufacturing sites in Salt Lake City, UT, San Jose, Costa Rica, and Vilnius, Lithuania.

The upgrade enabled the company to standardize systems across sites and improved overall agility. The company transitioned key processes from spreadsheets to automated workflows for greater regulatory audit readiness; supply constraints were better balanced with demand to optimize inventories and production scheduling; and more:

- Reduced service order entry from 7 minutes to under 30 seconds
- Standardized ERP across global operations
- Strengthened compliance with cradle-to-grave traceability
- Greater agility, efficiency, and user experience
- A strong foundation for continued growth in medical device manufacturing

"It used to take us about seven minutes to add parts for every depot order. Since the move to QAD Adaptive ERP, we've gotten that down to under 30 seconds. It's mind-blowing." says Jade Eldridge, Program Manager of Business Systems at Moog Medical.

For operational silos, the first step is establishing a single source of data-driven truth, a system of record. This can harmonize processes across disparate systems at multiple facilities that CMOs and CDMOs have acquired over time through diversification and expansion. The same applies to individual sites, where a single source of the truth solves the problem of legacy systems and a patchwork of fragmented solutions. (See case study: Noble Biomaterials)

The next step is to upgrade to an ERP platform capable of turning a system of record into a system of action. In short, QAD Adaptive with ChampionAI transforms ERP from a system of record to a system of action.

With native QMSR, Lookup is Easier

MedTech manufacturers have always had the need for a master controller to manage all the quality management, performance reporting, and other quality management system-related tasks. Tasks such as complaint handling and instances of non-compliance or non-conformance.

Now that the former FDA 21 CFR Part 820 has been replaced with the new FDA Quality Management System Regulation (QMSR), it has been harmonized with ISO 13485:2016. It now includes the updated Part 820 and additional supplemental FDA information.

QAD Adaptive offers still another significant time saver: an immediate way to view the QMSR associated with various medical device manufacturing processes. Within QAD Adaptive ERP, each process is mapped to include what is now the current Part 820, plus the FDA supplemental and additional information requirements for key areas of the ISO 13485:2016, now that ISO 13485:2016 is incorporated by reference in the QMSR.

Case Study: Noble Biomaterials

Click to read the full case study.

Noble Biomaterials, a leader in advanced antimicrobial technologies, including metalized textiles, grew from a single-product manufacturer to a diversified multinational. The company needed a much-needed solution to unify various software applications, spreadsheets, and paper-based workarounds.

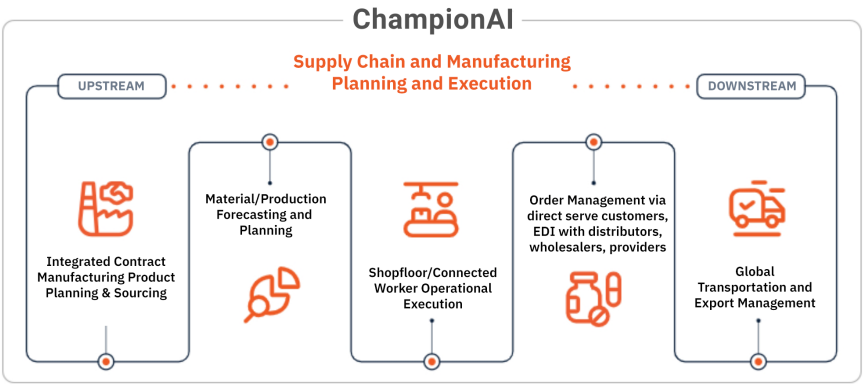
"Management doubted the accuracy of the manufacturing data produced by these disparate solutions," according to Chief Financial Officer Tom Bross. The company upgraded to QAD Adaptive ERP.

- The system replaced third-party sales forecasting software with greater data reliability and improved accuracy.
- The ERP and companion shop-floor software share the same platform. Native visibility to operational data and processes improves real-time management.
- The unified platform helps optimize resources, fulfill product orders more quickly, and reduce inventory costs.

Agentic AI Informed by Manufacturing Data

The latest innovation in software intelligence is Agentic AI for manufacturing. It can analyze data, make optimal recommendations, and even act autonomously — with a human in the loop to pre-select the agent's actions. Critical tasks are held for review, while rules-based agents often act directly on mundane chores at the direction of a human.

While top-tier enterprise giants are rolling out broad functions and agent marketplaces, and innovators are developing hundreds of AI applications, QAD has taken a more curated approach by offering a network of purpose-built agents specifically designed for midmarket manufacturing and supply chain environments to achieve specific business outcomes.



ChampionAI agents leverage data sources to drive high-priority actions.

What most distinguishes QAD Adaptive with ChampionAI is its focus on fostering "system-of-action" agents in key areas. These include areas of inventory optimization, procurement, and rapid implementation. Additional AI applications can enable users to simulate and evaluate the expected financial impact of actions based on market conditions.

Companies with a goal for business transformation now have a platform to do so without having to invest in time-consuming AI experiments or pilots. In QAD Adaptive with ChampionAI, the current collection of agents is offered in three categories:

- Implementation agents that can streamline project timelines by automating software implementation, data migration, and configurations.
- Productivity agents to automate repetitive, manual tasks and system updates.
- Optimization agents that can improve performance in specific areas by making recommendations to improve performance across the business.

Remember those "what would you do" questions above touting here-now benefits? Now ask: What would you do if you don't avail yourself of this highly proactive technology at a time when your competitors are rapidly adopting AI?

Welcome to the new era of ERP, designed and scaled expressly for the MedTech midmarket.

The MedTech Transformation Begins

Constant change and unpredictable interruptions are increasingly common in MedTech manufacturing. The shift from traditional ERP systems — focused on past events — to proactive systems of action has become critical for predicting, planning, and acting on your next move.

As more CDMOs harness AI to streamline operations, a widening competitive gap emerges for those who delay adoption.

The urgency around AI is not unfounded; it empowers companies to enhance efficiency, manage supply risks, and optimize profitability. QAD Life Sciences Director Robyn Coward aptly notes that the "genie is out

of the bottle and is not likely to be put back in," emphasizing the need for businesses to embrace this transformation or risk falling behind in a highly competitive and evolving market.

By reallocating resources from merely understanding past events to strategically planning for the future, companies can not only mitigate risks related to material costs but also thrive in an increasingly intelligent and automated environment. The imperative is clear: invest in AI-driven solutions now to secure a competitive edge and ensure long-term success.

It's why the new era of midmarket medical device ERP should evolve from a system of record to a system of action.

About QAD | Redzone

QAD | Redzone is redefining manufacturing and supply chains through intelligent, adaptive solutions that connect people, processes, and data into a single System of Action. With three core pillars — Redzone (frontline empowerment), Adaptive Applications (the intelligent backbone), and ChampionAI (agentic AI for manufacturing) — QAD | Redzone helps manufacturers operate with Champion Pace, achieving measurable productivity, resilience, and growth in as little as 90 days.

For more information, visit our website at qad.com and connect with us on LinkedIn.