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Sage X3 - an ERP system for medical device manufacturers

Improve quality control, manage short product lifecycles, support FDA compliance, manage multiple subcontractors and much more.

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Introduction

The medical device manufacturing sector is unique among many industries in that there is little room for error. In some cases, getting a product to market on time can be a matter of life and death.

The industry needs to operate with unerring precision and detail to ensure full industry standard compliance, high levels of traceability and device quality. A 2017 McKinsey report showed that the medical device industry's direct cost of quality is approximately 6.8% to 9.4% of industry sales which equals $26 to $36 billion annually.

The entire medical device manufacturing supply chain is an operation that requires absolute precision, from design to production and distribution. Each aspect of this unique supply chain heavily relies on the element before and the smallest error can lead to damaging consequences.

To deliver a quality product that complies with stringent and ever-changing industry regulations, medical device manufacturers need to embrace technologies such as Enterprise Resource Planning (ERP) solutions.

This guide explains how an ERP system, like Sage X3, can help to overcome many barriers to success for today's medical device manufacturers who collectively are facing a raft of complex issues.

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Barriers to success in the medical device industry

There are few industries that operate under the extreme pressures associated with the medical device sector.

Many of the barriers to success for medical device manufacturers are outside their control, such as regulations, supply chain issues and more. There are many growth opportunities, but it's critical to address the issues that these barriers throw up. Below are some common barriers to success:

1. Supply chain disruptions

The medical device sector can struggle to identify quick solutions to supply chain disruptions, whether it be a new supplier or a minor adjustment to a manufacturing line.

Once a medical device has received clearance, its production must adhere closely to the procedures stated in the regulatory submission after it has been cleared, with any change to production requiring re-qualification and validation. A disruption or delay in the supply chain can cause medical device Original Equipment Manufacturers (OEMs) serious setbacks.

Today, medical device manufacturers should be cautious and ready by beginning their procurement as early as possible and continuously assessing and addressing any supply chain weaknesses.

2. Omnichannel selling

Leading medical device manufacturing companies are moving to omnichannel models to build personalised engagement and stronger relationships with healthcare professionals, which will ultimately translate into improved patient care.

The medical device sector is moving away from a sales representative-centric business model and towards an omnichannel environment in which healthcare professionals can access information as and when they need it.

This shift is intended to enable stakeholders to make better and faster decisions for the benefit of both patients and healthcare systems.

3. Regulatory compliance

The risks to patient safety associated with medical devices have led this industry to be one of the most tightly regulated. A medical device firm may need to adhere to several different standards depending on where it markets its products.

The medical device sector is under increasing pressure to address market uncertainties in the face of growing product complexity and ever-changing regulatory requirements. There are shared concerns that the processes as dictated by broad and evolving regulatory and governing bodies (such as FDA, GMP, EU MDR, IVDR, etc.) negatively impact time to market and development time.

4. Cybersecurity

The healthcare industry has long been the target of cyber-attacks because of its vast amounts of health information and data such as patient health, product performance, or data from other devices connected to the same network.

Medical equipment has traditionally lacked the security seen on other network devices, making it simple for hackers to access an entire server. In the event of a compromised device and a server takeover, hospitals risk equipment outages and patient data breaches.

With a cyber-attack happening somewhere every 44 seconds, every time a medical device incorporates software, caution is needed because they can be subject to cybersecurity risks and attacks. Therefore, medical device manufacturers have an important responsibility to ensure any digital devices are equipped with the appropriate cybersecurity software going forward.

5. Increasing calls for sustainability

The industry association MedTech Europe has summarised what constitutes sustainability in medical technology as follows:

'Good health and well-being, responsible consumption and production, climate action and partnerships are the goals that we see as particularly relevant for our trade association.'

Medical equipment can have a significant environmental impact, and manufacturers must work to develop more sustainable products and manufacturing processes, but it's not straightforward.

When considering medical device sustainability, often people think about the end of the lifecycle and whether the device is recyclable or reusable. What are the associated costs involved, and long-term environmental impacts associated with disposal? As medical devices get more complicated and integrate more electronic components and mixed materials, waste from these devices is becoming a global issue.

However, sustainability also means considering how to reduce carbon emissions, energy and water use, and material waste across its entire lifespan, from design and material selection, to supply chain, to manufacturing and distribution. Sustainable medical devices can save money, be more appealing to investors, boost brand recognition, and provide producers with a competitive edge. They are also better for the environment and appealing to customers.

6. Quality and recalls

Poor quality in a medical device is a serious issue, as it could result in end-user injuries or worse. This is particularly crucial for high-risk medical devices such as pacemakers, coronary stents and artificial heart valves. To guarantee that such products are secure and dependable for patient use, they must undergo a particularly stringent regulatory assessment procedure. After a batch has been shipped, if a quality issue is discovered, a product recall should be issued right away. Both a brand's reputation and the business's bottom line might be shattered by such an incident.

A business case report from McKinsey outlines the industry-wide costs in clear terms:

'Non-routine quality events - such as major observations, recalls, warning letters, and consent decrees, along with associated warranties and lawsuits - ***cost the industry between $2.5 billion and $5 billion per year on average****. This includes $1.5 billion to $3 billion per year on non-routine costs, plus $1 billion to $2 billion in lost sales of new and existing products.'*

7. Cost of innovation

Speed and time-to-market are more important for medical device producers than in any other sector. This responsiveness, though, needs to be maintained by a persistent drive for innovation.

Many companies look to manage production, shorten lead times, and lower costs, as well as improve their competitive edge through collaborative partnerships and outsourcing, but this is no longer sufficient to meet the increasing market demands.

One proven efficiency strategy is better reuse of technology, such as standardising parts and systems, and reusing components, leading to simplified (and less time-consuming) regulatory and validation processes.

8. Counterfeiting

The rise of counterfeit medical devices poses a severe risk to patient safety. In 2010, the World Health Organization reported that 8% of all medical devices in circulation are known to be fake. The current number is anticipated to be significantly higher, even though more recent data is difficult to find.

In addition, medical devices are an extremely broad category that includes everything from tweezers to ventilators. This means the implications of counterfeiting can vary greatly in severity. At best, a product won't perform as well. At worst, it will pose a serious risk to both patients and, in the case of false PPE, the doctors who are attending to them.

For manufacturers of medical equipment, safeguarding intellectual property can be difficult, especially when more businesses are entering the market and competition is increasing. Fortunately, anti-counterfeiting technologies are helping the industry fight back against these fake, mislabelled, or tampered-with devices.

Solving key challenges with Sage X3 ERP

Medical device manufacturers need a 360° view of their business operations from internal traceability of all materials to external visibility for the entire supply chain, to ensure flexibility, deliver constant innovation and meet compliance and quality needs.

Medical device manufacturers require an ERP system that can accurately monitor the entire business and supply chain with the same level of detail required throughout the medical industry. Sage X3 is particularly suited to the nuances of the medical device sector. Below are some core capabilities Sage X3 offers for medical device manufacturers:

1. Subcontracted operations and supply chain management

Because the production of a medical device depends on each component, every material order must be delivered on time. Visibility across the supply chain is therefore imperative and Sage X3 effortlessly supports this.

Features such as supplier management, sub-contract processes, purchasing, inventory management and production scheduling planning help to ensure the availability of critical components and materials, reducing the risk of production delays and compliance issues.

2. Quality management

The success of a business depends on its ability to manufacture quality products with few recalls. To create and produce goods that adhere to the highest quality standards, business processes need to be closely controlled.

Quality management helps to create and enforce quality standards across the organisation. It helps ensure that all products meet regulatory and industry standards and can track defects and recalls in case of any issues.

Sage X3 has fully integrated quality control processes that can trigger the enforcement of inspections, ensuring that items conform to required characteristics, operational tolerances and expected results.

3. Support management of unique device identification (UDI) requirements

Sage X3 helps you comply with UDI requirements without causing too much of an interruption to your manufacturing and tracking processes. More specifically, Sage X3 offers several features that streamline UDI-compliance tasks so you can make this a passive, automated process for the medical devices you manufacture.

"Inixion understood our company and international challenges. We came to a solution that was really good; good for us, but also good for our customers, because we are minimising any potential delays with those cross border shipments, we are doing that in a more cost effective manner. That benefits our customers as well as BioIVT"

Nick Ariganello
Senior Director, Enterprise Applications

4. Full traceability and transaction workflows

Lot and serial number tracking is not just an integrated part of managing quality and regulatory compliance, but serial numbers also help to distinguish real products from fake ones.

Serial number tracking is an integral part of ERP functionality, which also records the full history and current status of an item, whether it's a component or a finished product.

The complete forward and backward lot traceability functions in Sage X3 help minimise the risks of a product recall. Full audit trail and archive of historical transactions are maintained for multi-year periods.

5. Centralisation of data flows

One of the key benefits of Sage X3 is that it supports omnichannel selling and centralisation of data flows throughout the organisation. Back-office workflows can be synchronised with sales channels, which helps to manage an omnichannel business centrally and efficiently.

6. Regulatory compliance assistance

In the medical device industry, maintaining traceability and ensuring regulatory compliance of processes is crucial.

An ERP system can help medical device manufacturers maintain quality data and track all product information across the entire supply chain to assist in showing their processes, especially those where the ERP system is a key part of the process, comply with government and industry regulations*.

** Sage X3, like many ERP solutions, cannot be shown to provide or prove 'compliance' with any specific regulatory requirement; as many (but not all) processes in the manufacture of medical devices involve the use of functionality from the ERP system, then the proof for compliance compatibility can be assisted by the consistent manner of those system-based aspects of the processes. Customers need to be aware that neither Inixion nor Sage offer or imply any guarantee that regulatory compliance will be achieved through the use of Sage X3 and do not offer any services specifically in respect of regulatory compliance per se.*

7. Post-sale service and support

Sage X3 efficiently manages warranty claims, complaints, returns and service contracts and integrates all of these key processes in CRM.

8. Extensive device history

Sage X3 helps you employ strong recordkeeping via a Device History Record (DHR) that demonstrates a sound technical concept, attention to cost of materials, production and long-term results.

9. Sustainability

By providing real-time data on energy use, waste creation, and other environmental parameters, ERP systems can help organisations to reduce their environmental impact. This data can then be utilised to pinpoint areas that need improvement and to optimise procedures.

10. Cost management

Sage X3 can help to manage the cost of innovation to meet increasing market demands by providing visibility across the company.

Some of the areas it helps are providing better control over inventory management and ensuring that products and components are not losing money by sitting on the shelf. Furthermore, by accurately tracking and analysing R&D costs against budgets, a medical device manufacturer can keep a handle on where it may be losing money.

'Activity Based Costing' functionality also enables the evaluation of the profitability of each product.

Thrive and be agile

A medical device manufacturer can become a more agile organisation by ensuring that its processes are well thought through, operate at peak efficiency and perfectly align with the strategic goals of the company. Using Sage X3 to manage all business processes can greatly reduce the burden of compliance whilst enhancing the effectiveness of standard business processes.

Why partner with Inixion for your ERP project?

We help our customers with every aspect of Sage X3, from selection through to implementation, and for the lifetime of their system. We ensure that you start with the right solution for your unique requirements and assist you to ensure that Sage X3 stays fit for purpose whilst your organisation expands and evolves.

Reasons to choose inixion

Laser-like focus on Sage X3

Sage X3 is the only solution Inixion works with. This laser-like focus ensures that we know the intricacies of Sage X3 inside and out and how it can be applied to various industries, with the ability to think 'outside the box' to help solve more complex business challenges.

Partnership and quality approach

Our focus is on building partnerships with customers and acting as an extension of their team and in-house capabilities. This approach has served us very well - we boast an impressive 'zero-failed' projects to date accolade.

Unrivalled product knowledge

We have a combined experience of over 250+ collective years and many of our Inixion employees were previous end-users of Sage X3, giving us the advantage of unrivalled product knowledge. Additionally, many from the Inixion team have worked in the industry and have a real-world insight into the complex processes faced by businesses.

Inixion helped us with phases of optimisation. Specifically embedding more of the ADC [Automated Data Capture] and scanning components into our manufacturing and warehouse function in the UK. The UK unit has probably become our most sophisticated, using the most of Sage X3's capabilities and they have become a model, for the rest of the organisation."

Nick Ariganello
Senior Director, Enterprise Applications

BIOIVT

About Inixion

Inixion is a leading global Sage X3 partner. We focus on Sage X3 only, meaning we do one thing – better.

Our focus is on helping your business to transform and grow using innovative ERP technology. Our team boasts extensive Sage X3 knowledge, and many of our team members were once end-users of Sage X3 – a powerful and unique combination.

We serve a variety of industries including, but not limited to, manufacturing, distribution, services and pharmaceutical industries. Our 250+ years of collective Sage X3 experience and knowledge of these sectors ensure we can provide best-practice advice and implement Sage X3 for your unique industry and business needs.

If you would like to partner with a specialist manufacturing ERP vendor, then get in touch with our team today: enquiries@inixion.com.

Alternatively, view our case studies to see for yourself, how we have helped numerous manufacturers and distributors transform their operations with Sage X3.

Useful resources

Sage X3 demo and briefing

Our free 2-hour demo and briefing will highlight the key functionality available in Sage X3 and demonstrate the areas relevant to your organisation.

Book your demo here.

ERP selection checklist

Our comprehensive ERP selection checklist highlights three critical categories and has been created to help guide you in selecting the right ERP system with the right functionality to give you a head start during your ERP selection due diligence.

Access your checklist here.

Buyers guide to a manufacturing ERP system

14 essential questions to ask vendors to ensure you choose the best system.

Access your guide here.

Signs it's time to upgrade or replace your ERP system

Discover the pain points our customers experienced that signalled it was time to upgrade or replace their ERP system. Includes video case studies.

Download the guide here.

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