



Top 5 Reasons to Implement ERP When Scaling Your Medical Device Company

The medical device industry continues to grow as new markets emerge - and while businesses are often presented with new opportunities, they are equally confronted with several challenges that can impede their growth. Regulatory compliance, cost of product development and the competitive landscape are just a few of the common issues medical companies must manage and overcome. Doing so requires strategy and commitment, and forcing companies to devise new ways to add value to their offerings.

Having solid systems in place to manage not only the inevitable challenges, but also daily functions and business processes, is necessary to stay ahead of the competition. Dr. Joseph V. Gulfo, MD, MBA, CEO of Breakthrough Medical Innovations, led a webinar based on the challenges medical device companies face when scaling, and the key reasons they should implement an enterprise resource planning (ERP) solution early on in their business prior to the growth stage. An ERP solution can be that competitive edge as it provides scaling medical device companies the ability to streamline their business processes, and features a host of other valuable benefits.

Top 5 Reasons for Scaling Medical Device Companies to Implement ERP

During the webinar, Dr. Gulfo spoke about the benefits of implementing ERP in the early stages of the business. Noting the challenges with doing so, he also expressed the ultimate gains that can be made by using an ERP system to help manage a medical device company. With the right ERP system in place - businesses can unify and streamline their operations, and ultimately focus on the growth of their business.

1

Meeting FDA Requirements



The Medicines and Healthcare Products Regulatory Agency (MHRA) of the United Kingdom and the Food and Drug Administration (FDA) of the United States are the regulatory authorities in their respective countries responsible for authorisation, renewal and suspension related to any medical device product. Meeting their requirements and adhering to regulations requires numerous steps and processes, and having an ERP system provides the appearance of control. If the MHRA for example, or International Organisation for Standardisation (ISO) auditors are evaluating a business, they are provided with a level of comfort when they recognise an ERP solution is in place. They then know that a business has the proper controls, most specifically for CAPA collection, analysis, resolution, reporting and trending. Implementing an ERP system allows medical device companies the ability to produce documents and evidence that illustrate standard operating procedures (SOP) are being followed.

2

Quality Control



Medical device companies must adhere to strict guidelines and process controls, and require systems in place to ensure all requirements are satisfied. They must provide quality management for their class I, II, III, and IV medical devices, and this includes quality standards compliance such as TS14485 and ISO 9001. Implementing an ERP solution can help these companies safeguard against any possible issues during production. For example, an ERP system will configure workflows and provide quality check procedures, and once measurements are defined within the system, the system will set up the Acceptable Quality Level (AQL) during each production checkpoint. Doing so will ensure that a particular component can not move on to the next step until it meets the criteria at a certain checkpoint. An ERP system provides the communication, control, updates, tracking and documentation that is necessary to guarantee a safe, quality product is produced and brought to market.



3

Traceability and Product Recalls



Given the medical device industry, and the nature of the products, industry regulation requires that medical device products are tracked from the beginning. Once a product enters the supply chain, it needs to be marked and tracked with unique identifiers, providing a more effective means for customers, product manufacturers and healthcare providers to identify and report devices that have certain issues. Having an ERP system that includes serial number traceability can help companies ensure products are tracked accurately through all stages. An ERP system can manage UDIs, guarantee traceability, and allow manufacturers the ability to properly and efficiently manage a recall.

4

Efficient Business Operations



Not only can an ERP system help medical device companies in the early stages of business operations with traceability and FDA approvals, but it also manages all aspects of the business to ensure quality products and superior customer service. An ERP system essentially manages your entire business, everything from inventory control, production and customer relationship management. An integrated ERP system can automate processes and can bring together all sales transactions, supply chain logistics, warehouse management and accounting capabilities under one platform. It can provide reporting capabilities that are necessary for medical device companies, offering access to real time information and the ability to view operations through one single system. With an ERP system, businesses can use incorporated tools for strategic decision making and identifying inefficiencies and areas of optimisation.

5

Management of the Growth Stage



Implementing an ERP solution in the early stages of development is crucial and helps support a business during the growth phase. Having this in place soon enough to help transition from product to customer focus is key, and will help manage the business during the expansion phase. ERP solutions can scale with you and supports business operations without hiring additional resources. It provides a unified view of the organisation, streamlined operations and can ultimately adapt to an ever-changing market.

Tips to Consider

Sometimes choosing, and implementing an ERP system can seem like a daunting task, therefore it is vital to consider certain strategies to ensure a successful deployment. During the webinar, Dr. Gulfo talked about the benefits of using an ERP system for your medical device company, and tips to consider when implementing the system.



Implement Early - Before the Growth Phase

Implementing ERP early was Dr. Gulfo's main tip - and one he stressed multiple times throughout the presentation. His thoughts were to implement early on - even before you think you should. Choosing to implement an ERP system into a small medical device company can go up against a lot of inertia, and often various departments are competing for resources. The goal is for your business to become customer centric - and by implementing ERP early you are ultimately moving towards this goal.



Every Project Needs a Champion

As mentioned, deciding to implement ERP can often come up against various challenges. There is competition for shared resources and sometimes people within the organisation can be against it and resist the implementation. The key is to have a champion for the project, someone who will go to battle for the cause. This person will have to stress the importance and need of ERP, and help others see the power of the solution.



Detailed Blue Printing Sessions

The blue printing sessions are when the most important work happens. Choosing the right ERP partner and subsequently working with them to accurately plan the implementation phase is essential to success. Your ERP partner and their consultants will have to collaborate with you and learn your business. They will need to understand how you operate, what your SOPs are, and what your various dashboards will look like. Early blueprinting sessions are critical because it can unearth issues that you might not have considered. By having a detailed plan and scope, and mapping out the implementation, your business will be ready for any unforeseen challenges that may occur.



Sarbanes compliance

Sarbanes Oxley Compliance are extremely difficult audits, and if your business must undergo this audit, checks and balances will need to be in place. These auditors need to ensure that a business is operating appropriately, and by having an ERP system in place, it validates your operations. An ERP system provides a level of confidence to the auditors that you are taking the correct measures to operate your business. Also, even if you are not a public company, but you plan on going public in the future, you need to be able to show your readiness. Implementing an ERP system reduces the risk to investors, and ultimately proves that you are taking your business seriously and operating it efficiently.

CONCLUSION - CHALLENGES WHEN IMPLEMENTING ERP

When most businesses begin to think about implementing ERP, it is typically at the growth stage. During this time, businesses feel like they need a more inclusive solution that can manage all aspects of their business. In reality, it is best to do so at the inception of the business, but this is not without its challenges. This webinar hosted by Dr. Gulfo introduced these challenges associated with scaling medical device companies and offered reasons as to why adopting an ERP solution can help. Dealing with any change in an organisation needs adjustment, and there are often individuals that can resist change, even if it is for the better. There might be people within the company that are product focused, and believe they have crossed the finish line once the product has been approved or cleared during the MHRA/FDA audit, but this is not the case. The key is to move these people, and the business in general, from product focused to customer centric. By doing so, the business will move towards continued growth and success.

The adoption of an ERP solution can help your medical device company overcome common industry challenges and remain competitive in changing market conditions. Deciding to implement an ERP solution early on in your business growth can not only help your business streamline operations, but also help avoid the common challenges and obstacles businesses in the medical device industry face. The right ERP solution can help you better manage traceability, compliance and quality control, and will support your plans for growth and expansion.

About Vision33

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