

# 7 Questions to Ask

When Upgrading to an ERP  
for Medical Devices





When it comes to enterprise resource planning (ERP) solutions, one size does not fit all. This is especially true within the field of life sciences, where medical device manufacturers must navigate some of the world's most highly regulated compliance and quality standards. While the search may seem daunting at first, finding the right ERP can prove to be critical for the quality, efficiency, and profitability of your growing company.

As you plan your journey into compliance, take a look at these key questions and solutions when evaluating ERP for medical devices.

## 1 Will it support my company's growth?

An ERP can help plan for a multitude of trajectories to help your business grow profitably and effectively. When selecting an ERP, find one that is scalable and will grow your business. With SAP Business ByDesign—SAP's integrated ERP solution, available in 9 languages and used in 98 countries—your company can grow from startup to global organization on a single, scalable platform. With SAP Business ByDesign, you don't have to pay for more software than you need and you won't outscale the platform.

## 2 Can it help me stay compliant?

ERP solutions become critical once a company is ready to go to market. The ideal solution and implementation will schedule audits and check compliance. SAP Business ByDesign comes with built-in process flows and approvals to ensure that you meet key criteria for compliance, including 21 CFR Part 11, TS1385, and ISO 9001. In addition, SAP Business ByDesign can integrate with top software solutions for extensive and sophisticated international and U.S. Federal Compliance. All of SAP Business ByDesign's business processes are well documented, including 35 end-to-end work flow scenarios, such as Procure-to-Pay and Order-to-Cash, which streamline the validation process.

## 3 How does it handle quality control?

Quality control is a process that is either embedded or integrated in an ERP application. SAP Business ByDesign comes with embedded quality control functionality. This enables quality inspections to be built into processes such as receiving, shipping, returns, and production. Once you create an inspection, the software automatically generates logistics tasks, allowing device manufacturers to perform inspections with pre-designed quality levels. Customized approval processes can be included as well. With that in mind, some quality control, like tasks tied to compliance, might require a dedicated quality application. In these situations, look for an ERP provider that can partner with platforms to meet your specific needs.

## 4 Can it help me manage research and development (R&D)?

An ERP is essential when tracking costs and process flows, especially during the "research-to-field trial" phase of medical devices. SAP Business ByDesign is the digital core platform for growth with a built-in product development work center specifically designed to help you track R&D costs. The work center fits the needs of a small to medium sized company but supports a large business's intricacies and is fully integrated with logistics so you can easily issue materials directly to your project. You can also incorporate SAP Jam for enhanced collaboration.





## 5 Does it support subsidiaries in different countries?

If your company decides to run a subsidiary in a different country, you will need a global ERP that can handle multiple tax schedules and aligns with the latest regulatory requirements. SAP Business ByDesign is a natively multi-company, multi-country, multi-language system. For example, if you choose to set up a company in a foreign country, the software lets you post in your local country and the consolidating company at the same time. This allows you to meet multi-gap requirements and not rely on a single gap system. With SAP's trusted global support, multiple systems are always in alignment.

## 6 How can it help me achieve operational excellence?

When selected properly, an ERP with built-in best practice processes can improve the efficiency and profitability of your growing company. SAP Business ByDesign uses a standardized approach built on over 40 years' experience, allowing you to come in and start using it while you build out your life science company. In addition, the core business processes are embedded and are inherently scalable and auditable, making ERP an efficient process for complex organizations.

## 7 Does it allow for tracking and traceability?

Medical device companies must maintain a high level of traceability when producing and moving multiple components. With SAP Business ByDesign, tracking and tracing materials and transactions comes standard with the system. The solution natively tracks the genealogy of your items through serial and batch numbers. Every time your items are shipped or received, the system will record that history. If customer returns are needed, serial and batch numbers are compared to what has been sent out to verify that the items returned are indeed the same as what was shipped out. In addition, SAP Business ByDesign natively tracks the user, date, and time for every transaction. E-signatures can be used for acceptance of quotes and orders, and can be enhanced to meet compliance guidelines.

## We have your ERP solutions down to a science.

Navigator understands the unique challenges facing the life science and medical device industries. That's why we provide comprehensive yet simple solutions to help your growing company stay compliant, safe, and ahead of the curve. With more than 500 customers, and more than 100 years of combined experience, Navigator has the expertise and award-winning reputation to send your company in the right direction.

**86%**

increase in operating  
margin through  
Navigator platforms

**98%**

on-time, on-budget  
project completion

**10+**

years of SAP award-  
winning service

**Worldwide  
leader**

in Cloud Based ERP  
system implementation



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