

Medical Device Manufacturing Navigator

Medical Device Manufacturing companies come to Navigator when they find their ability to grow and or adapt is being limited by their current processes and systems. Some startups are running their startup systems consisting of Quickbooks and Excel and others mature businesses run a group of disconnected systems that need to be patched together with manual steps to get the job done.

Medical Device manufacturers, regardless of whether your company is a start-up or established operation; we understand the challenges of working with in dynamic product life cycles; from development and clinical trials through to distribution and revenue - all while maintaining compliance with regulatory requirements.

We work with you to understand where you are in your business trajectory, what your unique challenges are, and collaboratively identify the correct solution fit and partner with you to implement a configured ERP platform for business reality and future growth.

Not all Medical Device Manufacturing companies need the same ERP configuration to achieve optimal performance. Navigator has developed a solution package consisting of features that meet the needs of industry customers out of the box. This solution set has been developed through more than 13 years of industry experience, delivering integrated SAP Business ByDesign offerings configured to our clients current and future needs.

Solution Platform - SAP Business ByDesign

Features

- Financials and Analytics
- Multi-Company, multi-country, multi-currency out of the box
- Manages complex supply chains
- Ready to Validate Platform

Compliance

- Complete support of GMP Practices with compliant production processes
- Full and complete Track and Trace via lot/batch and serial number
- User Authorization and Login Controls/Management
- Every Transaction is electronically marked with date/time/user that created it
- A Change Log is maintained for every update to a document/master file record
- Corrective and Preventive Action (CAPA)
 - Action Plan Creation and Maintenance
 - Multi-Step Case Management
- Recall Management
- Product Sale / Source Restrictions
- Sales Tracings to Track Sales to End User
- Available Integration to Tracelink

Packaged Solution Value

- Standard industry specific solution for Medical Device Manufacturing
- Built on Industry experience and developed Best Practices
- Consulting team with Medical Device industry expertise
- Proven Implementation
- Configurable Industry specific processes

Not every company is a good fit for our expertise and solutions. Let's work together to identify the right fit for you.

Clients we've worked/implemented with

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Benefits

- A single configurable platform that allows for adjustment at every stage of the business life cycle
- Ready to Validate Platform supports regulatory compliance - CFR21 Part 11)
- End to End Traceability
- Ability to integrate with Enterprise Quality Management Solutions
- Suite-In-A-Box covering every aspect of your business
- Better decision making with real-time information and Analytics
- Mobility, Flexibility and Scalability
- True Validatable Cloud platform: accelerated implementation and Lower Total Cost of Ownership

Standard Industry Specific Package

Approach

Ideal for organizations that want to get started quickly, get the solution up and running and grow with their business. Perfect for companies that need to transition from their entry level accounting system and spreadsheets to an integrated platform.

Organization

20 users, 1 location

Services

Navigator's proven Fixed Scope/Fixed Fee Implementation Methodology providing a clear roadmap for accelerated implementation.

Implementation Time

As quickly as 90 days

Price Point

\$50,000 - \$75,000 implementation

Per User Subscription

\$20 to \$192 per month depending on access level

Platform

Cloud

