VITAL ANALYSIS

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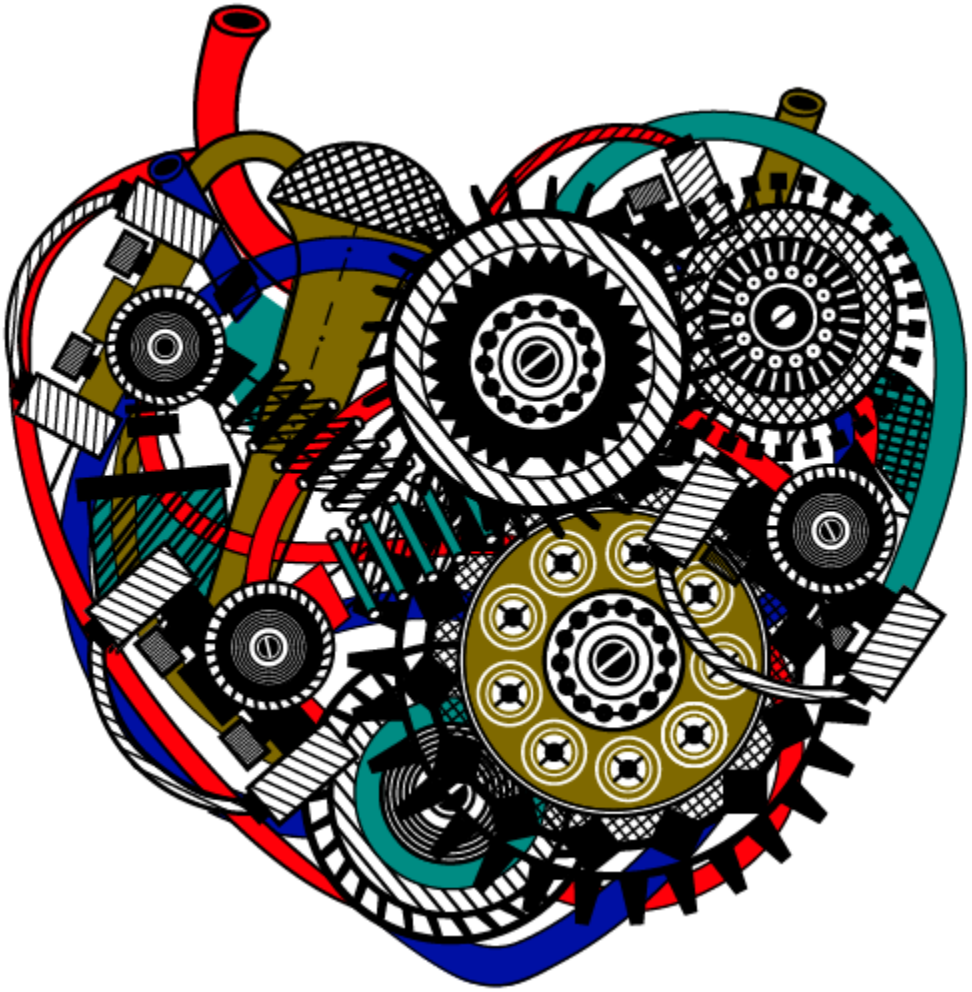
- Managing Litigation/Recalls
- SYSPRO and the Medical Devices Sector

A Special Report from Vital Analysis

The Medical Devices Sector & Its Tech Buyers

Sector Overview and SYSPRO Case Study



Operating a medical devices firm *successfully* may be one of the hardest business challenges possible. The amount of regulation, documentation and approvals that must be shepherded from initial product ideation through the product's entire lifecycle can be daunting. Regulatory requirements change seemingly by the minute and even efforts by governments to harmonize regulations across borders sometimes create additional short-term cost and difficulty for these firms. It's hard to grow a medical device business profitably when the company is constantly playing catch-up to new regulations.

There are numerous other challenges facing medical device manufacturers (see Exhibit 1). Like their colleagues in other industries, medical device firms are scouring the planet for lower-cost R&D, testing and productive capacity. Part of this activity is to get access to talented people or first-class facilities. The entire operational capability of this effort is the need to improve the cost structure, productivity and effectiveness of the business functions and processes of medical device firms.

Medical device manufacturers cannot affect the magnitude or frequency of the regulatory changes impacting them. Likewise, they cannot impede the growing globalization of their business or halt the innovations and pricing pressure forced upon them by a growing number of competitors. *Given just these changes alone, medical device manufacturers must possess a different set of capabilities and technologies that allow them to easily keep pace with mandated changes while simultaneously improving their firm's operations and results.*

Common Business Priorities of Medical Devices Firms

Product Ideation & Commercialization

- What can be done to shorten time-to-approval and time-to-market?
- How can offshore or third-party groups speed time-to-market?

Product Costs

- How can product unit costs be reduced over the life of the product so as to maintain price competitiveness?
- Are product costs defensible to group purchasing organizations (GPOs), consumers and regulators?
- Can contract or offshore manufacturers produce lower-cost product at necessary quality levels?

Adverse Costs

- How can recall costs be minimized?
- How can better documentation and quality controls minimize litigation expenses?

Data

- How can distributors, doctors and other customers gain enhanced visibility to product, order and account data?
- Can returns, warranty claims, defects and other product characteristics be tracked fully through every aspect of the supply chain?
- Are full audit trails maintained not only of product lot and serial numbers but also of design and engineering changes?

Compliance

- Can all processes be fully documented to the satisfaction of regulators domestically and abroad?
- Will regulators be satisfied with the type and quality of compliance systems and ERP software currently in use?

Sales

- What does the company actually know about the ultimate end consumer of its products and all intermediate players within its value chain?
- Could/should the company take a more direct role in selling to these intermediate or final consumers?

Exhibit 1

Top executives in medical device firms need a new kind of business capability - a capability that provides state-of-the-art compliance with current and emerging regulations while simultaneously facilitating growth, changes in business models and process improvements. At the core of this capability is a technology solution that permits firms to become operationally excellent without being bogged down by the numerous external market pressures affecting their industry (see Exhibit 2). Medical device makers need a solution that keeps their businesses from becoming sub-optimal or dysfunctional.

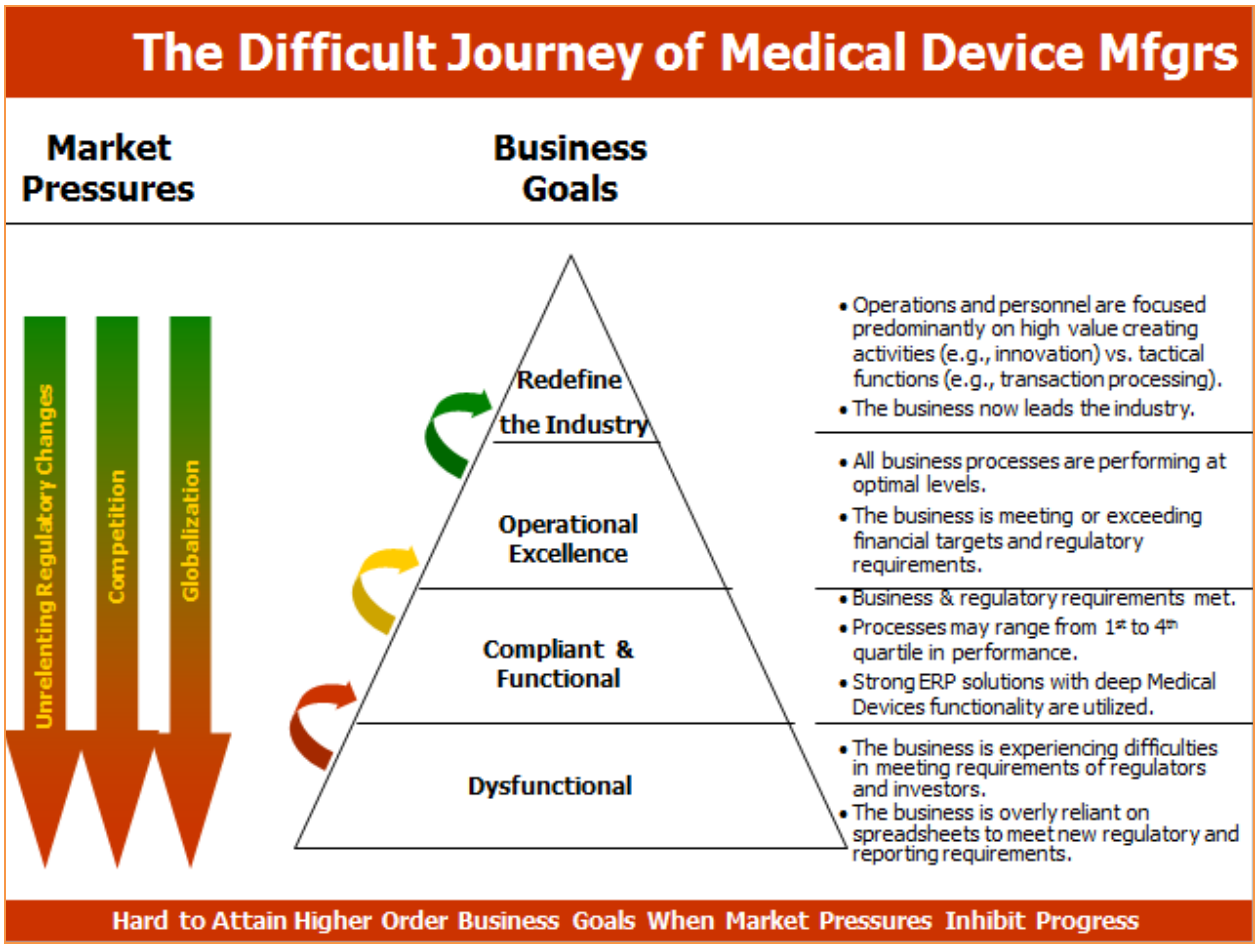


Exhibit 2

Why Spreadsheets and Entry Level Software Won't Meet the Requirement

Many industries have an easier time when it comes to regulation when compared to the medical devices sector. The number of regulations that US medical device manufacturers must comply with is significant, but for those firms competing on a global scale, the regulatory hurdles multiply. Regulators in Canada, United States, the European Union, Australia and other countries have developed a significant quantity of regulations and reporting requirements that encompass the entire lifecycle of a medical device. Even regulators blush at the sheer weight of these demands and several have attempted to harmonize these requirements across multiple jurisdictions. Fortunately,

there is an international effort through the World Health Organization (WHO) to simplify and streamline diverse statutory and regulatory compliance issues.

Entry-level solutions provide only foundational technology capabilities for medical device firms. These solutions often support back office accounting and HR applications as well as some front-office capabilities. Better ERP products also provide a host of manufacturing and distribution modules. But, it is the industry-specific and regulatory requirements above that line that define what a medical device technology solution should support (see Exhibit 3).

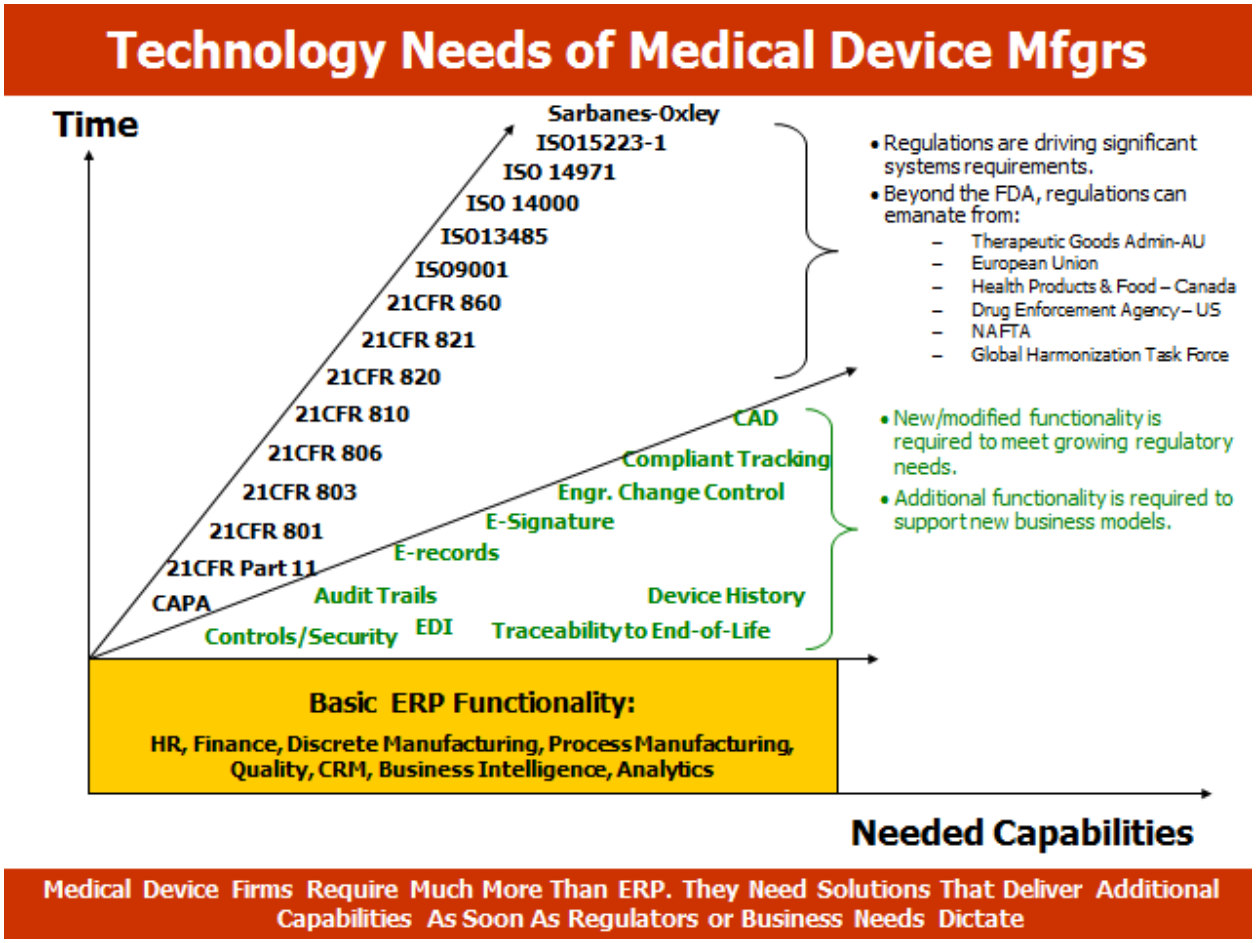


Exhibit 3

Entry-level software limits the operational opportunities of the medical devices sector. These products do a solid job of tracking accounting events but do not necessarily support the intense product movement data of medical devices or the elaborate documentation required to facilitate design change information. Users of these basic systems often use scores of inexact and/or disconnected spreadsheets to meet ever-changing regulatory requirements. *The longer that firms use these feature-limited solutions, the more they hinder their firm's ability to compete.*

The medical devices sector has already taught us some important lessons. Many companies know that some software products are not up to the regulatory compliance

requirements of the medical devices sector. ERP vendors that do not anticipate these needs build products of great rigidity which is of little market consequence and value to users.

SYSPRO Case Study: Female Health Company

Lot/serial number traceability is a key functional requirement of medical device/product manufacturers. In the United States, medical device manufacturers must frequently submit to FDA (Food and Drug Administration) audits. A key focus of these audits requires access to detailed material tracking data.

Bobbie Annonson, Accounting Manager at Female Health Company (FHCO), told us that her firm maintains meticulous records from raw materials, through manufacturing and into distribution. "*Lot traceability is huge*," she stated. Data is retained across the entire life cycle of the product. She added that regulators even inspect finished goods inventory to ensure the company is following the FIFO (first in, first out) inventory management method.

As to their ERP solution, FHCO uses SYSPRO. In fact, they have been using most all of SYSPRO's applications since 2009. FHCO's three locations (US, UK and Malaysia) are all running on one, on-premises instance of SYSPRO ERP. The UK operation originally chose SYSPRO ERP for its manufacturing operations.

Auditors, regulators and FHCO employees access FCHO's SYSPRO databases and applications to perform inspections. Different SYSPRO modules track different parts of the product life cycle with data continuity maintained across modules. These industry-specific capabilities help FHCO improve their operational performance, support regulatory change and compete more effectively.

The technical infrastructure of ERP solutions must be modern to provide value to medical device firms. *The business environment of medical device companies is highly volatile and the technology supporting these firms must be malleable as well.* Beyond the continuous regulatory changes, these firms experience a multitude of other change demands that affect virtually every aspect of their businesses and business models. Older technologies often lack the appropriate infrastructure needed to support the rapidly changing regulatory and business environment of this industry. The best products provide flexible technical architectures that permit rapid connections to web applications, partner systems and more.

The best medical devices companies choose their technology solutions very wisely. Specifically, these smart technology buyers look for solutions that:

- Enable all current regulatory requirements for all countries in which the buyer operates.
- Possess powerful workflow and process design capability.

- Contain a full-suite of enterprise capabilities from back-office, front-office, shop floor and distribution.
- Have rich, function solutions accommodate changing needs.
- Provide timely, low-cost and trusted lot and serial traceability.

Managing Litigation & Recall Concerns in the Medical Devices Industry

How big is the liability risk? One device maker reported in early 2014 that they created a $520 million defense fund to help them challenge claims against their vaginal mesh product.[1] And this amount may need to be increased over time.

Product claims often involve one of the following issues:[2]

- Design (product design may cause injury).
- Marketing (manufacturer failed to disclose specific risks about the product).
- Manufacturing defects (the manufacturing process produced an unacceptable item).

Potential product claims dictate that medical device manufacturers maintain exacting records that detail the entire supply chain history of what went into their products. Moreover, detailed records of where the product went post-sale are also needed to facilitate a potential recall. Lot/serial number tracking is a must-have capability.

Medical Device Recall Reasons

From 6/12/2014 – 8/26/2014

- May reverse directions after surgery
- Possibility of mold
- Sheath may fracture during use
- Hyaluronic acid concentration
- Microbial contamination
- Labelling error
- Valve may stick & prevent air getting to patient
- Catheter may separate during use
- Tubing may disconnect
- May be damaged during use
- Not cleared for marketing

Source: http://www.fda.gov/medicaldevices/safety/default.htm

The audit trail requirements don't stop there. Detailed records as to which workers and equipment were involved in the making of the product must be maintained. Specific sign-offs should be tracked too. The cost of poor tracking could be financially devastating for medical device manufacturers with inadequate ERP systems.

[1] Source: http://www.fiercemedicaldevices.com/story/endo-stocking-least-520m-cover-vaginal-mesh-lawsuit-legal-costs/2014-02-24

[2] Source: http://www.drugwatch.com/drug-lawsuits.php

SYSPRO and the Medical Devices Space

According to SYSPRO, their solution is designed to help medical device manufacturers manage the five key components of a medical manufacturing business: Design, Manufacture, Distribution, Maintenance and Service. SYSPRO for Medical Devices is a flexible business software solution that provides the tools and scalability needed by manufacturers and distributors (see Exhibit 4).

SYSPRO possesses several critical medical device ERP applications that:

- Accurately manage the design process
- Comply with Medical Safety Regulations
- Optimize material planning and visibility
- Control costs to increase profitability

SYSPRO offers an integrated approach to enforcing inspections that assure item conformance to any required characteristics, operational tolerances or expected results. Automating the compliance process reduces the risk of warning, recall, or customer issues. Failure to comply with FDA 21 CFR Part 11 could seriously damage brand image or financially cripple an organization.

Key SYSPRO Modules

Manufacturing
- Engineering Change Control
- Work in Process
- Lot/Serial Traceability
- Quotation/Estimating
- Scheduling
- Bill of Materials
- Requirements Planning

Financials
- General Ledger
- Accounts Payable
- Fixed Assets
- Accounts Receivable
- Cash Book
- Activity-Based Costing
- Electronic Funds Transfer

Distribution
- Inventory Control
- Sales Orders
- Purchase Orders
- Sales Analysis
- Landed Cost Tracking
- Forecasting
  - Optimization
  - Families & Groupings
- Product Configurator
- Returned Material Authorization
- Return to Vendor

Customer Relationship Mgmt.
SYSPRO Analytics
SYSPRO Workflow Services
SYSPRO Quality
Electronic Data Interchange
Executive Dashboards
Reporting Services

Exhibit 4

Management of electronic data is critical. SYSPRO offers a platform in support of certification and audit controls, including: comprehensive audit and change logs with time and date stamp, authenticated user's electronic signature, and approval criteria for key processes.

The need for product traceability is critical in a compliance-regulated environment as lot traceability for medical devices is a supply chain, as well as a manufacturing, issue.

SYSPRO provides a comprehensive framework for managing product innovation with product data management, quality process controls and cradle-to-grave product traceability.

SYSPRO Workflow Services automates many business processes. By enabling the application of rules-based control over business processes, status and performance information can be tracked and monitored through the workflow monitor. Using the tracking data, workflow processes can be analyzed to alleviate bottlenecks and streamline business processes.

Who is SYSPRO?

SYSPRO is an internationally-recognized, leading provider of enterprise business solutions for on-premises, cloud-based and mobile utilization. Formed in 1978, SYSPRO was one of the first software vendors to develop an Enterprise Resource Planning (ERP) solution. Today, SYSPRO is a global business solutions vendor, represented on six continents and by more than 1600 channel and support partners. Over 15,000 licensed companies across a broad spectrum of industries in more than 60 countries trust SYSPRO as the platform on which to manage their business processes.

Customer focus is a core component of SYSPRO's corporate culture and is one of the key reasons why SYSPRO maintains a strong leadership position in the enterprise application market. By focusing on people and building lasting relationships with customers and partners, SYSPRO consistently excels at guiding customers through all aspects of their implementation and ongoing utilization. SYSPRO’s mission is to deliver world-class software that gives customers the control, insight and agility they need for a competitive advantage in a global economy. As such, SYSPRO provides a unique combination of robust, scalable technologies that ensure minimal risk and a high return on investment.

About Vital Analysis

Vital Analysis is a very different kind of technology research organization. We are where exceptional technology market knowledge meets the executive suite. Where other 'analysts' replay vendor press releases, we give you the:

- impact new technologies will or won't have on your business
- reasons why you should or shouldn't care about specific emerging solutions
- business justifications why you may or may not want specific solutions

Vital Analysis was carved out of TechVentive, Inc. in 2007 as a new, but complementary business. As designed, Vital Analysis is the publishing, research and analytical arm of that company.

Our reach, like our blog readership, is truly global. We've consulted with top technology executives in Australia, Brazil, Canada, United Kingdom and the United States. We've been briefed by technology providers from virtually every corner of the planet.

About the Author

Brian Sommer is the CEO of TechVentive, Inc. - a market-strategy and content firm. Brian closely follows what C-level executives think, feel and need. Brian is a ZDNet columnist and renowned accounting software expert. He is a frequent keynote speaker numerous software conferences and professional society events. Brian has been an expert witness in major ERP software litigation and is one of the top research analysts in the ERP space. Brian was recently listed as one of Software Advice's Authority Award winners in the ERP area. Brian has published over 600 articles in the technology space including pieces for prestigious publications like Optimize and Wall Street Journal Europe.

Brian is a former partner with Andersen Consulting (now Accenture). He ran their global Software Intelligence, Finance Center of Excellence, and, Human Resources Center of Excellence organizations.

Brian welcomes your thoughts and invites you to contact him at brian@vitalanalysis.com.