MEDICAL ERP BUYER'S GUIDE

Your guide to selecting medical ERP for your healthcare business

GUIDE **HIGHLIGHTS**

A list of the top medical ERP systems, and their features

A compliance checklist for medical manufacturing ERP

Medical ERP requirements and features

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This guide will cover the basics of medical ERP, including:

WHAT DO WE MEAN BY MEDICAL ERP?

As a catch-all term, medical ERP largely relates to resources-oriented software systems that deliver and manage information in concert with products and services throughout the medical industry. However, within this general category, several subordinate, yet highly-specific categories exist.

ERP-BASED MEDICAL DEVICE MANUFACTURING

The use of ERP in medical device manufacturing is quite sophisticated, particularly since these systems not only house traditional processes such as production control and inventory management capabilities, but also harbor dense sets of policy-based rule-sets that actively supervise, and validate internal manufacturing operations. This is primarily due to the fact that medical device production is highly regulated, and operationally supervised both by State and Federal administrators.

Consequently, ERP platforms must adhere to these rules prior, during, and after product delivery. To gain an understanding of this level of detail, here is a pro forma list of applied classification and type requirements from the Food and Drug Administration.

The FDA classifies approximately 1,700 different generic types of devices, grouped into 16 medical specialties referred to as panels. Each generic type is assigned to one of three regulatory classes based on the level of control necessary to ensure device safety and effectiveness. These classes include:

1. Class I General Controls

2. Class II General Controls and Special Controls

3. Class III General Controls and Premarket Approval

Within these classes, discrete device types are reviewed and validated on a recurrent basis, to ensure that quality assurance is maintained throughout a particular manufacturer's supply chain.

ERP-BASED MEDICAL MANAGEMENT RECORDS (EMR)

These ERP variants support general and specialized doctors, nurses, and administrators by storing, cataloging, and managing patient information related to individual consultations. Systems typically allow practitioners to establish comprehensive databases associated with discrete patient data,

manage, and index patient diagnoses and maintain various follow-on courses of treatments. All system data is secured and governed by covenants associated with the Health Insurance Portability and Accountability Act (HIPAA) in the United States, and International guidelines elsewhere.

ERP-BASED PHARMACEUTICAL DISTRIBUTION AND INVENTORY

Pharmaceutical and medical inventory software primarily relate to medical and pharmaceutical distributors/wholesalers requiring comprehensive inventory management and rigid product traceability. These systems feature elements related to; lot tracking (traceability), electronic data interchange (EDI) integration, and granular cost-tracking. They are usually internally-compliant with US and international FDA/ISO data security regulations.

Given the constant evolution in the medical space, there are often other subordinate categories joining the sphere of medical ERP. This whitepaper will address some of the needs that an ERP should satisfy for businesses in the medical and healthcare industry.

MEDICAL DEVICE MANUFACTURER ERP REQUIREMENTS

Medical device manufacturers have some ERP requirements at the top of their list that might be considered of lesser priority for other types of manufacturers. Many of these requirements are quality related as these medical device businesses are almost always tightly regulated by one or more government agencies.

Manufacturers will find that many general enterprise resource planning (ERP) best practices also apply to the medical device industry. However, several national initiatives focused on device cost, availability, the patient's treatment experience, and tracking of long-term outcomes present unique challenges for device manufacturers implementing ERP systems.

QUALITY PLANNING

Nearly all ERP systems have the ability to check off whether an inspection is passed or not. Medical device manufacturers will often look for the next threshold, a quality plan. A quality plan allows the user to design specific steps to be included in an inspection.

These steps can be qualitative, such as whether a C of C is included from the supplier. A simple yes or no answer is filled in. They can also describe, in detail, specific measurements to be taken along with the ability to enter those measurements directly within the ERP. Now those measurements can be analyzed from the same database as all other ERP-collected data. The measurements can also have limits and an alert when a measured value is high or low.

USER CERTIFICATION

Most ERP systems capture transactions in detail with an audit trail showing the user and time stamp for every transaction. A medical device manufacturer might need their ERP to go beyond that basic level and monitor if the user is qualified for a particular operation or inspection based on training, testing, or experience.

For example, if the user's certification requires an annual renewal, the user and the supervisor will be notified in advance by the ERP system and the user will not be allowed to process certain transactions after the renewal date.

DEVICE HISTORY RECORD

Many industry executives and entrepreneurs are medical practitioners or engineers focused on patient outcomes, not manufacturability or costs. Therefore, manufacturers developing new devices need strong record keeping via a device history record (DHR) that demonstrates a sound technical concept, patient benefit, attention to cost of materials and production, and long-term results. Building a DHR that ensures a successful design and FDA compliance, requires an ERP system that incorporates document management, engineering bill of materials (BOM), planned process routing, cost estimating, and failure modes and effects analysis (FMEA).

SUPPLIER MANAGEMENT

Supplier management is another area where a medical device manufacturer will want a little more from their ERP system. The particular certifications a supplier might hold can be an integral part of the company's government certifications. The medical device manufacturer might not have a specific kind of manufacturing in their core competency, meaning outsourced competency is required for approval of their device. Often the reporting requirements to maintain government approval are very specific so the capability of the ERP reporting process is also very important.

INTEGRATIONS

A capable ERP system with integrated engineering, purchasing, accounting, and project management is critical for medical device firms. This provides the needed visibility into overall financials, R&D costs, project milestones, and status of agency filings to manage the "burn rate" of funding and assure investors that risk is being minimized. Additionally, integration between a computer-aided design (CAD) platform and the ERP system's engineering records can accelerate design and development work while minimizing the risk of errors in key product data.

QUALITY CONTROL

Through automated sharing of critical production, inventory and quality data, manufacturers gain real-time insights that minimize the risk of product errors.

Integrating modern manufacturing systems with ERP software can also error-proof the production process set-up. Under this methodology, the system prevents production from starting until the operator is presented with correct work instructions and confirms that the specified material, correct tooling, right packaging, and labels are all present.

Then, as the work order is produced, the operator should conduct quality checks with calibrated gauges and instruments to ensure that statistical process control (SPC) is updated consistently. For quality assurance, consider using affordable smart sensors and automation software to automate process monitoring and predict potential quality problems and equipment failures before they happen.

These closed-loop systems can alert technicians of an impending issue, so they can quickly plan downtime to prevent disruptions in production or, worse, undetected product quality problems. With medical devices, it's imperative to have an ERP system that alerts and then helps to prevent future issues using the corrective and preventive action (CAPA) methodology.

TRACEABILITY AND TRACKING

The FDA's intense efforts to protect patient safety can result in surprise audits, product safety investigations, and recall actions. An ERP system optimized for medical device manufacturing needs 'track and trace' reporting. This functionality enables fast, accurate extraction of material certifications and process traceability records to support any inquiry from a customer or regulatory agency—while limiting the scope of the investigation to only those products in question.

Medical device manufacturers have requirements much like any manufacturer, but with particular emphasis on a few domains that might be less important to another business. Make sure you factor these areas into your requirements analysis and don't lump yourself in with the rest of the manufacturing industry.

FEATURES OF HEALTHCARE ERP

Healthcare is a diverse industry: a manufacturer of medical devices will have different ERP software priorities than a drug manufacturer. On the other hand, all healthcare businesses have common ERP requirements that are unique to the industry as a whole. Below are four functional areas of medical ERP which most businesses in the healthcare industry will find useful to consider during their selection process.

LOT TRACKING

All incoming items from suppliers are identified by a unique lot number. That number might be assigned by the supplier or assigned internally as the purchase order is received. In a similar vein, all material from production or processes gets a unique lot number. Healthcare ERP can track a purchased lot and know which manufacturing process lot it was used in and which customers received any of that lot in the SKU they bought. If a customer reports a problem, ERP lot tracking allows you to track back to every lot number and SKU that particular item was used in. You can then quarantine drug inventory or recall sold devices from customers.

Lot tracking is a legal requirement for many healthcare businesses, so should be the first area of prospective systems you consider. The FDA requires that complete tracking for devices already delivered to a customer must be completed within ten days. Compare the performance of your shortlisted ERP systems on this task. If your products are pharmaceutical, your lot tracking requirements go beyond your inventory through distributors, logistics parties, pharmacies, and other retailers. With this in mind, it is important to assess the ease with which prospective systems can integrate with supply chain partners.

SUPPLIER MANAGEMENT

First tier and many second-tier suppliers manufacture products to your specifications. Your customers purchasing a heart monitor and regulators, who help ensure the safety of such products outside your business, want assurance that their requirements are met by your suppliers as if you were the producer. ERP supplier management provides a set of tools which enable you to monitor and track your supplier compliance.

In order to compare supplier management between different healthcare ERP systems, you must first document your supplier relationships and requirements. This information will give you a

foundation on which you can evaluate the document management, communication tools and supplier workflows offered by your shortlisted systems.

INTERNAL PROCESS COMPLIANCE

You have carefully defined processes to assemble or mix your healthcare products. Your regulatory compliance depends on following those processes. The right ERP for your business should track the production processes used and the ERP users who performed those processes. When an operator's active certification is required, ERP can check the employee database and help ensure that the person performing an operation has that certification. Your internal compliance requirements will almost definitely go beyond these examples, so it is important to test systems you compare to ensure they meet your most stringent requirements.

EXTERNAL COMPLIANCE REPORTING

Your healthcare business could already report to government agencies, industry groups and customers through regular reporting, possibly as a result of an audit. Ideally much of the reporting you require should be built in to your healthcare ERP. During the ERP selection stage, you should compare the business intelligence tools offered by shortlisted systems. Can they handle the data throughput you currently produce? Can they produce reports in the formats required by government regulatory bodies? Can the system monitor all the metrics required to produce these reports? All these questions need to be answered before your final selection decision is made.

Despite commonalities, healthcare ERP requirements vary wildly between healthcare sectors. Because of this variation, key functions and ERP features, such as those discussed here, are only of value when used in the context of your business requirements.

MEDICAL MANUFACTURING ERP COMPLIANCE CHECKLIST

There are many ways ERP can help a medical manufacturer. Compliance is only one, but is a central element to success. Most medical ERP suites provide for general feature sets that support compliance and quality as core operating characteristics. These elements define inter-system communication, while at the same time, applying various functional rules during direct and indirect collaboration between work-centers.

However, med-tech is quite dense at a policy level and is typically more rigid than most other ERP platforms. For example, let's look at compliance requirements your ERP should help your medical device manufacturing business meet.

ISO COMPLIANCE

ISO 13485: This operating standard directly applies to the ERP-based manufacture of medical devices. The standard defines "...an International Organization for Standardization (ISO) doctrine, initially released in 1996. The protocol establishes requirements for comprehensive quality management systems in the design and manufacture of medical devices. The standard supersedes earlier less stringent documents including; EN 46001, EN 46002, and previously ISO 13485 and ISO 13488."

This standards framework is typically integrated and applied within all comprehensive med-tech ERP platforms, and specifically applies to function sets associated with risk mitigation, and enhanced compliance.

ISO 9001: In concert with ISO 13485, ISO 9001 also applies, and in particular associates itself with non-domestic med-tech manufacturing systems. In this case, the standard defines "...a family of quality management standards, designed to help organizations ensure that they meet customer quality requirements, while also ensuring that statutory and regulatory requirements associated with a medically relevant product or service."

Again, this standard is typically applied with all comprehensive med-tech ERP platforms, but more specifically; overall process quality, and asset tracking.

COMPLIANCE TO CODE OF FEDERAL REGULATIONS (CFR) TITLE 21

Because med-tech processes call for end-to-end quality assurance throughout the manufacturing

chain, regulations associated with how electronic records are managed and stored. In this case, CFR Title 21 applies directly to low-level compliance within most comprehensive med-tech systems. The regulatory frames establishes "...regulations (and) criteria, under which agencies consider electronic records, electronic signatures, and handwritten signatures executed to electronic records to be trustworthy, reliable, and generally equivalent to paper records and handwritten signatures executed on paper."

This regulatory constraint applies directly to ERP operations associated with the production of Class 1, 2, and 3 medical devices. In this case, particular business values are integrated throughout all med-tech ERP processes.

ELECTRONIC DOCUMENT CONTROL

Electronic signature/document control CFR Title 21, Part 11: This supporting section relates to electronic document control, and typical of med-tech ERP business rules. To wit; "this part applies to records in electronic form that are created, modified, maintained, archived, retrieved, or transmitted, under any records requirements set forth in agency regulations. This part also applies to electronic records submitted to the agency under requirements of the Federal Food, Drug, and Cosmetic Act and the Public Health Service Act, even if such records are not specifically identified in agency regulations. However, this part does not apply to paper records that are, or have been, transmitted by electronic means."

This particular policy constraint applies to both ERP-based asset-track processes, in addition to ensuring that proper security and 'chains of evidence' are applied through the manufacturing continuum.

COMPREHENSIVE CORRECTIVE ACTION/PREVENTIVE ACTION (CA/PA)

While CA/PA elements are not necessarily oriented to domestic and/or international standards per se; under FDA CFR 21, Section 800 specific CA/PA processes apply as compliance sets. Consequently, most comprehensive ERP med-tech systems apply CA/PA when developing internal processes including:

- Process Design/Re-design.
- Product Design/Re-design.
- Training and/or enhancement/modification of training programs.
- Improved validation of maintenance schedules.
- Improved material handling or storage processes.

These focus points are just the tip of the iceberg when it comes to compliance and quality assurance related to med-tech ERP platforms. Nevertheless, they do offer some guidance that should get you thinking in the right direction.

TOP MEDICAL ERP SYSTEMS

When a vendor says they supply ERP software systems to the healthcare industry, it is difficult to decipher precisely what they are offering. Is it a one-size-fits-all system for healthcare, medical device, pharmaceuticals, and life science industries? Or does the healthcare ERP offered cater to a specific subset of these industries?

Let's take take a look at some of the top healthcare ERP products and vendors, to help you figure out what sort of system would be the right fit for your company.

SYSPRO

SYSPRO provides healthcare ERP for the medical devices and pharmaceuticals industry, with individual ERP systems targeted at each industry.

SYSPRO's ERP for medical device manufacturing companies encourages collaboration with doctors and enables tracking of materials through the supply chain. The ERP software is also built to meet quality and safety standards expected of this market.

MCKESSON

McKesson offers a hospital-focused ERP targeted at improving operational efficiency to improve patient care decision-making, improve diagnostics and safety.

Users can benefit from a range of features which streamline operations - including inventory cycle counting, managerial dashboards, and self-service HR functions for both managers and employees. Reviews frequently mention its ease of use as a major plus point.

QAD

QAD provides ERP for the life sciences industry with its software offerings aimed at life science laboratories, medical device manufacturers, and pharmaceutical companies. For the life sciences industry specifically, a standard installed system is available as well as a hosted, on-demand system.

Reviews praise its extensive feature set - QAD offers supply chain management, warehousing, financials, manufacturing automation, production scheduling and more - as well as its longevity as a system.

EPICOR

Epicor provides its Tropos ERP system to the pharmaceuticals and biotech industries. The ERP system is focused on improving quality control and adhering to regulatory authority controls which are crucial for both industries.

The system is highly scalable and emphasizes flexibility as a major advantage. This is evident through its ease of customization and integration with other business applications, and through its functionality for multi-site, multi-currency and multi-language support.

INFOR

Infor's Cloudsuite for Healthcare is a comprehensive set of business solutions specifically designed for the healthcare industry. It offers financial and supply chain management, as well as core HR functions for talent management, scheduling, and predictive analytics. There is a strong emphasis on interoperability.

MICROSOFT DYNAMICS AX

Clients in the medical device manufacturing sector can maximize investment by leveraging ERP precepts. The system's flexible, scaled, and comprehensive solutions meet specific industry and regulatory requirements. The system enables the management of large-scale data-sets, streamlines operations throughout the medical manufacturing enterprise, ensures compliance with applicable regulations, and maximizes critical operational efficiencies.

ERP MEDICAL

ERP Medical allows practitioners to manage large volumes of records secured on the basis of HIPAA requirements. All relevant patient entries can be viewed on easy to use dashboards, in addition to the ability to transmit information electronically to remote sites, and/or produce paper reports as necessary.

WEBPT

WebPT is a leading rehab therapy platform specifically oriented to the support of patient care. The system offers scheduling, documentation, billing, outcome tracking, business reports, and system integration.

CHARTLOGIC

ChartLogic, Inc. provides a full ambulatory EHR suite including electronic medical record, practice management, revenue cycle management, e-prescribing, and a patient portal.

BLUE LINK

Blue Link offers robust accounting and inventory software as an integrated ERP software system. The system provides advanced functionality available out-of-the-box plus various optional components. Blue Link can also be completely customized to meet your needs. Specific features include; lot tracking (traceability), landed cost tracking, serialization, order entry and invoicing, revision control, inventory control, track national drug codes (NDC#), and DEA license # tracking.

This guide is by no means a comprehensive run-through of all the ERP products available for the healthcare industry - many of the biggest ERP vendors, including Oracle and SAP, also offer medical ERP as part of their extensive product catalog. But, hopefully, it will give you an introduction to some of the major products available and kickstart your selection shortlist.

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