



FourthShift Edition™
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White Paper

ERP Software Acquisition in an FDA Regulated Environment



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Overview

The task of evaluating and selecting a business system that will essentially run your business and help you meet U.S. Food and Drug Administration (FDA) requirements can be a daunting project. The purpose of this white paper is to provide you with an overview of the process, based on the twenty two years of experience in helping manufacturing companies choose an Enterprise Resource Planning (ERP) system, including 100+ Life Science customers whose manufacturing must meet FDA requirements.

This paper assumes you are looking for an ERP system that supports FDA requirements. Non-regulatory issues common to the acquisition of an ERP system are also covered.

Whether your company is a diagnostic product manufacturer, a medical device manufacturer or a pharmaceutical manufacturer, you are well aware of the consequences of failing to meet current Good Manufacturing Practice (cGMP) requirements. The most critical requirement for an ERP system operating in an FDA regulated environment is “*cradle to grave and grave to cradle*” lot traceability. In order to submit this kind of information to the FDA, the system must be validated. Many companies are being proactive and getting their systems validated before an event such as an FDA inspection, a product complaint or in the most extreme case, when a product recall occurs. Having their ERP system validated gives the company and the FDA confidence and assurance that the company has control over their manufacturing processes and that they can quickly and easily identify product components by lot. However, the most useful task that lot traceability performs is quickly answering questions about the sources and destinations of all products and components.

What is “Validation?”

We define validation as the development and execution of a written plan to control your documentary evidence. This documentary evidence provides the confirmation that your computerized system will accurately, reliably and consistently perform the regulated functions that you require. You will maintain control of the system by assuring the security of the data and the proper administration and operation of the system by trained personnel who follow written standard operating procedures. Assembling your validation documentation during the software acquisition and implementation process is an easier and more cost effective way of meeting validation requirements than waiting to do it after the system goes live.

Software Acquisition

For the purposes of this paper, we will assume you have decided to select a high quality, widely distributed “commercial off-the-shelf” (COTS) product rather than develop a custom software application. Purchasing a COTS software application product offers two significant advantages:

1. System design and functionality already exist and can be objectively and subjectively evaluated.
2. It is likely that a COTS application is being used by a variety of customers in many different business applications and has a record of performance that can be verified.

These significant advantages reduce the time required to get the system working, and greatly increase your confidence that the system suits your purposes and is free from defects. The downside to COTS software is that your business procedures may have to be modified to accommodate the product’s existing design and functionality. However, software that allows users to create custom functions greatly reduces this downside.

Having decided to purchase a COTS product, you still face the major decisions of how you will:

1. Select the best product
2. Get the selected product operational in your facility

Software Acquisition Life Cycle

Selecting, implementing and operating an ERP system that supports your business for years to come can be overwhelming. This white paper presents a five phase Software Acquisition Life Cycle model to help you accomplish these objectives as efficiently as possible.

1. The **Planning** Phase is concerned with developing a complete list of functions the selected software product will be REQUIRED to perform. The primary deliverable is the Requirements Specification document needed for both evaluation and validation purposes.
2. During the **Selection** Phase you identify potential vendors, research and analyze these vendors, see vendor demonstrations and conduct customer and vendor visits. You rate vendors on their ability to meet your requirements and then select a vendor.
3. The **Implementation** Phase ensures that all requirements are met and users are trained.

4. The **Product Acceptance** Phase is a final review and test of the complete system to ensure that it has delivered the expected capabilities. Validation is the final step in this phase.
5. The **Operational** Phase is from the point when the software is placed in regular service until it is finally retired. Validation updates are completed each time a significant change is made to the system.

This White Paper covers the Planning and Selection phases.

Planning Phase – Starting Your ERP Selection Process

Your organization may be starting manufacturing for the first time after coming out of research and testing, or perhaps you've been using manual processes to run your business. Individual departments within your company may have their own spreadsheets, databases or specialized systems, leading to islands of information with no integrated visibility to your inventory, cost, customer requirements, shipment history, etc.

Once you have identified the need for an ERP system, it is time to start the selection process. The first decision to make is whether to undertake the process yourself or hire an outside consultant. There are advantages and disadvantages to hiring an outside consultant as listed below.

Hiring an Outside Consultant to assist in the Selection and Implementation of a ERP System

Advantages

- Current resources are busy and you don't have the time
- A consultant can jump-start your selection & implementation process by being a dedicated resource
- Experienced FDA consultants can identify potential problems that need to be addressed
- Experienced FDA consultants can streamline your existing business processes

Disadvantages

- Time and cost of a consultant learning your business may cost more than a internal resource
- Time and cost of teaching a consultant your vision and current and future business requirements
- Time and cost for the consultant to learn enough about the ERP systems that potentially fit your business
- Consultants may lengthen the selection and implementation time due to other client commitments
- Consultants may see the relative importance of features and benefits much differently than you do
- Most consultants have limited knowledge relative to the many ERP systems and may recommend systems they have experience with, eliminating systems that best fit your needs

Using an outside consultant may be the right choice for your company. However, you still need to select a project coordinator to work with the consultant and coordinate internal resources. The more assistance and resources you can provide for the consultant, the easier it will be for him or her to deliver the information you require.

Many companies will select someone internally to find the right system. Just like hiring an outside consultant, there are advantages and disadvantages. An internal person knows your business, your people, your growth vision and your future requirements. They will understand how features and benefits of the right ERP system will benefit your company, and they can be a champion for change. However, they already have job responsibilities and will need to balance existing job demands with the time requirements for the selection and implementation process. In addition, an internal person may not have experience in selecting or implementing an ERP system.



Top Management

Top management involvement is essential to the successful completion of a software acquisition project.

The considerable monetary cost and time spent by everyone associated with the project warrants the attention of top management. Top management needs to be familiar with the status of the project, though not the daily activities. Furthermore, since an ERP system covers most of the departments in the organization, conflicts are almost certain to develop and an impartial referee is needed to ensure that balanced solutions are found.

Executive Sponsor

The executive sponsor is the individual who represents executive management and communicates the goals and objectives for the ERP selection and implementation set by the executive management team. The executive sponsor works with the project manager in choosing the selection team and ensures that they are empowered to meet their goals, that there are adequate resources for the selection process and that any roadblocks are removed. Finally, the executive sponsor will work with the project manager to ensure that the system is validated.

Select a Project Manager / Team Leader

The project manager should be an individual with a high level of manufacturing experience and be able to communicate, organize and document the selection and implementation project. This individual should have a vision for the benefits of the

ERP system and understand the work involved. Select an individual who is well respected, innovative, is a change agent and can work effectively with all employees.

Form the Project Team

The project team is responsible for determining system requirements, selecting the product that best meets those requirements and getting the product operational. The following functions are typically represented on the project team.

- Quality
- Information Tech.
- Sales
- Engineering
- Material control
- Purchasing
- Regulatory Affairs / Validation
- Finance and Accounting
- Marketing
- Production
- Inventory
- Shipping

It is not necessary to have an individual from every functional area on the team. If possible choose individuals that can represent multiple areas in order to keep the selection team to a manageable size. Members chosen for this team should have good depth of knowledge and experience for the functional area(s) they represent. Team members not only represent their functional area to the selection team, but also represent the selection team to their functional areas. As the selection and implementation process proceeds, they will need to function as change agents for their areas, teaching new functionality, coaching new processes and empowering their functional teams to reap the benefits of the new system. People who have been involved in an implementation have stated that it was one of the most fulfilling tasks they have had. We recommend the team consist of between four and six people.

Using Consultants / External Resources

A recurring misconception in budgeting system projects flows from viewing salaried employees as a fixed overhead cost. Extending the logic, any project task that can be offloaded to salaried employees by making them work extra hours will add no cost to the project. It is no surprise therefore that many companies are tempted to make the short-sighted assumption that the employees can handle all but the most technical project implementation tasks. However, further reflection may reveal serious downsides to this assumption, including the failure of the ERP implementation to deliver the intended benefits. In a later section, this paper will suggest areas where the use of consultants is advantageous, even though it is theoretically possible for employees to perform the activity. Keep in mind that the employees you will target for your ERP project are probably working extra hours already and considering that issues arise on a daily basis that require immediate attention in the employee's primary job, it is easy to see how the ERP project schedule can begin to slide.

Remember that during an ERP project there is always plenty of work to go around. Taking care not to overload your employees can pay huge dividends in making the project a success.

Project Plan

Acquisition of commercial off-the-shelf software is a relatively straightforward process compared to a custom software development project. A schedule or Project Plan may seem to be unnecessary. Scheduling, like validation, is an activity that many ERP users forego. It is a mistake to think that just because there are no assigned dates to the various tasks, activities, milestones and deliverables, the project will automatically proceed at an acceptable pace. It simply means that significant project points will pass unnoticed.

From a validation point of view, maintaining a schedule and tracking the project against it is one more building block of confidence in the system, since scheduling provides assurance that an important aspect of the project won't be missed.

Budgeting

Your selection and implementation project should have a budget. Typically budgets address dollar amounts, but a key resource that should also be budgeted is time. Selecting an ERP vendor is not easy and is something companies do not do often. The selection team will spend time analyzing and documenting their current business processes. Using their understanding of the current business processes they will spend time determining immediate and future requirements. Once requirements have been defined, time will be spent selecting vendors for review and choosing a final vendor.

Selection Phase Expense

During the selection process, you may want to visit the vendors you have selected for your final review. This is typically only two or three vendors. Visits to these vendors involve a limited number of people because you are evaluating the size of the vendor and reviewing the vendor's financials and background. Visits to companies using the vendor's software typically involves a larger group and ideally, the entire selection team will participate. If you are in a major metropolitan area, the vendor probably has customers within driving distance. If your manufacturing facility is more remote and air travel is involved, determine your available budget and decide if the entire selection team or a subset of the selection team will conduct the visits.

Implementation and Product Acceptance Phase Expense

The implementation budget consists of four components: software, hardware, implementation and training and validation.

Software: ERP software can cost from \$25,000 to over \$2,500,000, depending on the size of your company, required functionality and planned future growth. Software costs can be accurately budgeted once the User Requirements Specification is finalized.

Hardware: Hardware costs can vary depending on the size and age of your current system. Hardware costs can be budgeted with good accuracy. If your servers or workstations are over five years old, they will probably need to be upgraded or replaced. Due to rapid changes in technology, budget for upgrading servers about every five years. Workstations may need to be added as more areas of your operation access and integrate with the ERP system. The network may need to be expanded and upgraded to support these new workstations. ERP systems generate a lot of data as you integrate all areas of your operation. Make certain your backup system can handle this additional data and support your future growth. To reduce the cost of adding servers, backup equipment and dedicated IT staff, many companies are taking advantage of remote hosting options, where the vendor hosts the application, databases, database maintenance and backups at their facility.

Implementation and Training: Implementation and training for your new ERP system are critical elements. You will want to ensure adequate investment during this project phase. Most companies will spend as much on consulting and training as they do on the software. Later in this paper when vendor selection is discussed, we will review services some vendors offer to reduce cost and maximize implementation and training effectiveness.

Validation: Computer system validation, like your manufacturing process, consists of both fixed and variable costs. Consequently, at the low end of the software price spectrum, validation costs can easily exceed software price, while at the upper end, validation may account for as little as five percent of the price. Within that range, the actual cost of validating your system will hinge on the validation team's familiarity with: 1) your operation, 2) the functionality of the software and 3) the software developer's operation.

On-going Maintenance and Support Expense

From a validation standpoint, it is essential you plan and budget for on-going maintenance and support. Technical support from your ERP vendor is typically 20 percent of the list price of the software per year. This gives you access to technical support and upgrades to the software. Most software companies offer a major upgrade to their software once a year. Depending on the size and scope of the upgrade, some consulting or training assistance may be required. During the selection process, ask vendors how often they offer major upgrades and what, if any, services they recommend for each upgrade. If extensive consulting and training is required for each upgrade, it can have a costly impact on your annual ERP operating budget.

To ensure the on-going integrity of your initial validation, as well as to maximize your investment in your ERP system, you should plan and budget for continuous improvement and training. As you continue to use your new ERP system, and as your business grows, you will take advantage of additional features that weren't important to you during the initial implementation. You will need to train your people to take advantage of these features and train new people when they join your organization. An estimate of 1/100 of a percent of total revenue is a good guideline for an on-going training budget. Example: if your company generates \$50 million dollars of annual sales revenue you should budget \$5,000 per year for on-going training. This may need to be increased if your company is growing rapidly and quickly adding people.

Determining System Requirements

The User Requirements Specification is the required basis for validating a computerized system. Producing the User Requirements Specification should be seen as a critical activity of the project – it is the key deliverable of the Planning Phase.

Model your current business/organization processes

Now that the team is selected and your budget established, it is time to start understanding your current processes so you can better define your future requirements. Flow-charting is a simple, graphical way to define your processes. Gather a small group of key people who are the experts in their functional area of the company. Use a white board or a flip chart to diagram your business flows at a high level. Go back and add detail until you have an accurate description. Once the business flows have been accurately charted it is a good idea to electronically record the flow charts, perhaps using flowcharting software like Visio for ease of communication and archiving.

While time is a precious commodity and we never seem to have enough, the more time and effort that is put into understanding and documenting your current business processes and other requirements, the easier and faster the selection and implementation process will proceed.

During this process, you will identify several business processes that need improvement. You may want to improve some of them right away. However, do not lose sight of the higher goals by stopping the ERP project to get every process perfect. Keep the analysis and improve the relative business processes when implementing the ERP system.

Functional Requirements

Once you have modeled your existing businesses processes, you can start defining your immediate functional requirements. Companies seeking FDA validation are concerned with tracking their products from “*cradle to grave and grave to cradle*”. Lot trace and product serialization that is integrated within the ERP system and provides audit history is a critical system capability.

Future growth and the associated functional requirements should also be reviewed. Estimate your future growth and strategy not only in terms of size, but also modes of business. Will your ERP system need to support repetitive manufacturing, engineer-to-order and make-to-order environments? As your company grows, will you need EDI, multi-language, multi-currency or engineering workflow? Identifying future requirements will assist later in the vendor selection.

You will not know the answer to all these questions as none of us know the future with any degree of accuracy. The objective is to select an ERP system that fits your business today and can grow and adapt along with your business.

Regulatory Issues (FDA / Sarbanes-Oxley)

Complying with FDA regulations is the primary incentive to validate the implementation of your ERP system. Depending upon the particular type of regulated manufacturing a given customer engages in, ERP systems need to support one or more sections of Title 21 of the Code of Federal Regulations including among others, Part 11 (Electronic record keeping) and Parts 210 and 820 (Quality System). Collectively the regulations are also known as current Good Manufacturing Practices (cGMPs).

Note that the FDA does not regulate commercial software vendors, whether or not they sell their products to regulated customers. System compliance and validation are the regulated user’s responsibility.

Although validation is not required to comply with the Sarbanes-Oxley Act of 2002, legislation has introduced stringent new rules with the stated objective: "to protect investors by improving the accuracy and reliability of corporate disclosures made pursuant to the securities laws". This act requires publicly traded companies to meet financial reporting and certification mandates. While this act is for publicly traded companies, private companies will also be impacted as the Sarbanes-Oxley requirements become accepted as good accounting practices. Board members, venture capitalists and banks are starting to require the companies they work with to meet these new requirements. ERP systems and vendors who can help you meet these requirements provide security and a full audit trail, support good manufacturing

and accounting practices and have documented business procedures and processes to accelerate your compliance initiative.

Selection Phase

Typically, the software/vendor selection and implementation process is one where significant documentation deficiencies are encountered. Failure to document the linkage of the selection process to the User Requirements Specification gets the entire validation process off on the wrong foot, since a major determinant of confidence in the system is that selection was decided in an orderly and objective manner.

Some companies try to save time by purchasing generic Request for Quotation (RFQ) documents for ERP systems. These RFQ documents can be hundreds of pages long and still lack detail. These were not written to meet to your company specific requirements, so time will be required to review the document to determine which of the requirements apply to your company. Due to the time required to answer RFQs, many software vendors may not even respond, or will quickly answer the questions, giving themselves the benefit of the doubt, negating the original purpose of the RFQ. Moreover, you will need to take extra time to ensure that you fully understand what the vendor actually quoted. There really are no shortcuts to choosing a system to run and grow your business. Taking the time to eliminate errors and misunderstandings at each stage of the project will pay big dividends in shortening the overall time to implement, reducing project risk and, in the end, actually saving you money.

Generate a Vendor Long List

Now that you have a list of your functional requirements, it is time to start reviewing vendors. Putting together a list of vendors to review can be done by doing research on the World Wide Web and in industry magazines or talking with other manufacturers. Knowledgestorm.com is a business technology search site. A search for “*FDA validation*” will list software companies offering FDA validation. Devicelink.com is a website for the medical device industry and offers industry news and search engines for suppliers in the medical device industry. A search for “*ERP software*” will provide a list of vendors. You might also look in your industry-specific magazines and newspapers for ERP vendors that support the Medical Device and Life Science industry. Magazines like *MX* (Business Strategies for Medical Technology Executives), *Medical Product Manufacturing News* and *MD&DI* (Medical Device & Diagnostic Industry) are good sources for ERP vendors.

You may also have options with the type of vendor you use for implementation, original software manufacturers or resellers. Original software manufacturers sell and service directly to you, the end customer. They typically have high service levels, can resolve technical and software issues quickly because they wrote the

software and have the best understanding of their software and how to apply it. If the vendor doesn't have consultants in your area, it may take longer to get someone to your site and you may have to pay higher travel costs. Resellers have a local presence so travel costs are usually minimal and they can offer quick on-site support. Resolving technical issues may take longer if they have to be elevated to the original software manufacturer and the reseller's level of expertise with the software is rarely as high as the original manufacturer. If you use a local reseller, ask how long they have been in business, how long they have been reselling and implementing the software you are considering and how many customers they have implemented. Stability and longevity are very important characteristics to look for in a local reseller.

Make the Final Short List Selection

After reviewing and analyzing as many vendors as is practical, it is time to narrow the list down to the two or three vendors you feel can meet your business requirements. Identify those vendors who can meet your software functional requirements, i.e. their software will do what you need it to do, and they are a good fit for the size of your company. The manufacturing market space is roughly divided into three tiers, with Tier One being the large Fortune 500 manufacturing companies with annual revenues over 500 million dollars, Tier Two being the medium sized operations with annual revenues in the 50 million to 500 million dollar range, and Tier Three being the small companies with annual revenues less than 50 million dollars. Most software vendors service one or two tiers, so make certain the vendors you select are organized and geared to support your market space.

Determine whether the vendors are experienced in your Life Science market sector (medical device, pharmaceuticals, etc.). Compare the vendor's experience. A company that has done over 100 Life Science implementations has had more time and experience to refine their processes and procedures than a company doing only ten to 30 implementations.

As noted above, the FDA holds you, as the manufacturer of a regulated product, responsible for complying with cGMPs. Who can assist you in your compliance efforts? Does the vendor offer FDA validation support and what does that support entail? Some vendors provide a set of validation templates which, like canned RFQ templates, can take more effort than if you started from scratch to develop your own validation plan. *Remember that the validation is developed from your User Requirements Specification – not the vendor's user manual.* Other vendors claim that their software can be validated, and will then refer you to an independent consultant. If the vendor does not offer a validation program, you will need to use these outside resources. Validation consulting firms with no previous experience with your ERP software and/or your operation must spend considerable time developing the information needed to construct the validation documents. This can substantially increase the total cost and time of the validation project.

Vendors who have actually *integrated* the validation into their implementation process for FDA regulated installations provide you with several major advantages:

1. They are familiar with the operation of their specific software adding efficiency to the validation testing process, saving you time and money.
2. They will provide the support documents needed to demonstrate that their product was developed in an operation designed to produce high quality software.
3. They can leverage their understanding of your type of manufacturing, gained through their other implementations and validations, in designing your validation document package.
4. They can leverage their other implementations by including the collection of validation support documents demonstrating the proper software installation, data conversion, training, etc.
5. They will have developed and refined a Validation Plan, Protocol and Qualification Test Plan that efficiently delivers a complete high quality validation package *specifically tailored to your business*.

To reiterate, the best way to minimize the cost of validation is to produce and collect the many required support documents at the appropriate points throughout the software acquisition life cycle. You should plan for these activities separately if the vendor does not provide them, since the costs can significantly impact your project budget.

Research, Interview, and Analyze Vendors

After you have gathered the short list of vendors that appear to meet your requirements, it is time to do a thorough evaluation. Create an evaluation checklist of key criteria so that all vendors are evaluated on the same criteria. During the initial overview demonstrations, does the vendor demonstrate a proven solution for your requirements? Are they comfortable with the type of manufacturing you do and the size of your organization? Detailed proof demonstrations will be done at a later date, but you should gain a level of confidence that the vendor can satisfy your general requirements.

Evaluate how the vendor will assist in your implementation. Do they have a proven, documented implementation methodology? How long does it typically take them to implement? There are implementations that have taken over a year with all the associated cost of both time and money. The best systems are usually implemented in six months or less. Remember, time costs money!

A major reason that some vendors can implement quickly is the quality of their consultants. One of the top reasons that implementations struggle is the quality of their consultants. Make sure the vendor has experienced consultants. Inquire about the length of time the consultants have been with the company and how many years they have been in manufacturing. Do the consultants have experience in your manufacturing sector of discrete and process manufacturing and the medical device or pharmaceutical industry? Verify that the vendor has consultants with all the skills necessary. Today's software is too complicated for one person to be an expert in every facet of an implementation. Make sure the vendor has consultants with expertise in manufacturing, financial, technical, EDI if required and of course, FDA validation experience. Check if the vendor offers remote consulting via the web for short, specific type consulting sessions. Remote consulting minimizes travel costs and offers quicker response times for specific issues.

Training options that a vendor offers can also be a key element in fast implementation and in maximizing your implementation budget. Does the vendor offer on-site training? This training is effective for training a large number of people. It is conducted in your environment or in a local training center with only your employees. It can focus on your specific training needs and minimizes travel costs, as the only individual traveling may be the instructor.

Classroom training is effective for a small number of people to be trained. It gives the students the opportunity to interact with other customers and learn from their experiences. In a classroom environment, students can be totally focused on the training and don't have the interruptions or distractions that can occur when training in their facility. Classroom training does take the person out of the plant for the length of the training and you will incur travel costs if the training is not local to you.

A good training option that combines both local and classroom training is live, instructor lead training via the Internet. This type of training is effective for a small number of people to be trained, gives the students some opportunity to interact with other students and has no travel costs. Training is typically done in half-day sessions so the student can be in the plant for the remainder of the day. One disadvantage to web training is interruption to the students because they are in the plant, at their computer during training. If a vendor offers Web-based training, be sure the training sessions are not just lectures to large groups of students, but small interactive sessions. People learn by doing, and web training should offer the students an opportunity to do hands-on exercises with review and assistance by the instructor. Computer Based Training or CBT is another effective training tool offered by some vendors. CBT is available on demand at any time by the students and is ideal for specific task training.

There is not one ideal training method. The top vendors offer a spectrum of training options, giving you the ability to choose the training option that works best for your particular situation. Companies may use a combination of on-site training for large

departments like manufacturing and web-based or classroom training for smaller teams like finance. By having options available, you can maximize your training budget and speed implementation.

The vendor's technical support should be given careful consideration. After the system has been implemented and your consultants are onto new assignments, the support team will be your main contact to the vendor's organization. Does the vendor have a proven, reliable response time to customer issues? Will they provide statistics of their support time and are they proud of their support team? In addition to quick phone and e-mail support, top vendors offer an on-line knowledge database where you can get answers to issues. They offer Internet access so you can access status of your issues and review your history of questions and issues. There are times when a phone conversation may not resolve your issue. Top vendors offer Web conferencing and remote access support where the support team can access your system and resolve issues over the Internet.

Evaluate Vendor's Support of the User Community

This is a particularly important consideration in the FDA regulated industries since the user group can serve as an effective forum for both system and regulatory issues (particularly when significant issues, such as electronic record keeping are in a state of flux). A critical element of validation is demonstrating that you, the user, are in full control of your system and are proactively monitoring its performance, accuracy and reliability. Being plugged into the other users is an excellent way of meeting this requirement. Questions that you will want to ask each vendor are:

- Do they promote and support regional user groups and meetings?
- Do they have an international users group conference and if so, how often?
- Can they supply marketing literature for these user conferences?
- How many users typically attend their conferences?
- Do they welcome and encourage customer suggestions and track the top customer suggested enhancements and report back to the users on the enhancement status?
- Do they encourage sector specific groups like medical device and pharmaceutical user groups?
- Do they support sector specific groups with virtual meetings via the Internet to encourage maximum user involvement?
- Do they encourage user suggestions for product improvements and do they have an easy to use, viable user enhancement mechanism in place?

Top vendors are delighted when their users make suggestions and track the top customer suggested enhancements and report back to the users on the

enhancement status. A vendor that supports and encourages the user community is a vendor committed to the user's success.

Proof Demos

Once you have narrowed the vendors down to the two or three vendors, you will want to see detailed proof demonstrations. Based on your business requirements, select the features and capabilities you have determined critical to your success. Convey these issues to the vendors in advance so they can prepare a demonstration to prove their ability to meet your requirements. During the demonstrations be sure you understand exactly how your critical issues will be addressed. Understand that no ERP vendor is able to provide every capability "out of the box" exactly as you might envision it. Be wary of vendors who claim they can do this. If a vendor talks about modifying their software to meet your requirements, determine if they are configuring their software, or customizing it. Configuration is selecting the right setup of standard functionality and code to meet your specific requirements, and is a normal part of implementation. Customization is modifying or writing custom code to meet your requirements and carries significant long-term implications.

From the standpoint of validation, modifying the core code of a COTS product is not a good idea. A key determinant of software quality is Maintainability (the ability of the software to meet the users' needs over its entire service life).

As noted earlier, nearly every ERP package you will be considering for your project involves the vendor supplying periodic upgrades to the software. Contracting with the supplier to customize the core code is usually expensive and a one time proposition. As long as the user is satisfied with the custom system, everything is fine and the standard software updates are simply not installed. The problem comes when the custom code user really needs to install an upgrade that almost certainly does not support their customization. At that point, the user must decide to forego the custom feature they have come to depend upon in order to pay for a new version of the custom code (if it is even possible to replicate) or to stick with the old system which may eventually become unstable. In the final analysis, while modifying your business procedures to accommodate the software's design may seem problematic, in the end it is definitely preferable to risking future problems with a non-standard COTS core software package.

Recognizing that custom core code is a problem, forward thinking COTS software vendors provide tools that allow the customer to define unique features that are not common to every installation and implement them as add-ons. The evolution of the computer industry towards technologies such as browser interfaces further support this approach to customization.

Customer Visitation and Vendor Audit

Vendor demonstrations and proof demonstrations will give you a good overview of the software and how it works, but do not compare to seeing the software in action in a manufacturing plant. Visit a vendor's customer and get a first hand feel for how they like the software and how they are using it. Discuss with the customers the challenges they faced during the implementation and how they overcame them. Ask what worked well for them during the implementation and what changes they would have made in retrospect. This is a great opportunity to learn for their experience!

Finally, you will want to visit the vendor. This is the opportunity to meet their top management, get a feel for their corporate culture, meet their customer service team and understand their future direction and growth strategy. Get an overview of their financials and make certain they are a solid business that is in your market sector for the long haul. You want to feel comfortable that they are an organization you can partner and grow with.

As a major validation objective of your visit, conduct and document a Quality Assurance Systems review against the vendor's written Software Quality Assurance Plans for each software product that will be included in your installation.

Select Vendor

After you seen all the proof demonstrations and visited both vendors and customers, it is time to choose! Get quotes from each vendor and make your decision including the following in your list of selection criteria:

- Is the product suitable? There is no right price for the wrong product
- Can the product be validated?
- Does the product represent the best value?
- How much adjustment of your business procedures does the product require?
- How does the Software Price compare to Total Project Cost?
- Does the vendor provide the required support services?

Weighing the above factors and others specific to your business, rate the vendors on how they meet your business requirements and how they will partner with you. Select a vendor, and get started with your implementation!

This paper is a guideline to help you in selecting an ERP system for your FDA validation. Our project managers, technicians and consultants have helped over a hundred customers through this process. Our focus on Total Cost of Ownership throughout the implementation and validation process provides our customers with the highest level of service and maximizes their investment. You have a challenging but rewarding task ahead of you. Stay focused on your objectives and you will succeed!

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