ERP Issues For The Mid-Sized Life Science Company with an analysis of Microsoft® Business Solutions–Great Plains® and Merit Solutions

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White Paper

Published: June 2004

Life Sciences

Trends, Issues and Analysis

Forward

The mid-sized life science company has most of the same business requirements and all the regulatory issues of a large life science company. However, the mid-sized life science company has fewer resources at its disposal to address these issues. While most enterprise resource planning (ERP) companies have made their name by providing solutions to large companies, only a few have flourished in the life science industries, and even fewer by meeting the needs of the mid-sized life science businesses.

The objective of this document is to help executives in mid-sized life science companies understand their needs and options they have for addressing them. As an executive in a mid-sized life science company, to satisfy your requirements, you need to balance the capabilities of ERP systems with both economic restrictions and alternative, human-based approaches. Larger companies can justify levels of automation that are not economically viable for the mid-sized company, as the larger company can extend a solution over many business units and higher business volumes. Compliance strategies that allow you to balance risk with cost will be explored, in addition to the process and consideration of selecting a solutions supplier.

Microsoft® Business Solutions–Great Plains® and Merit Solutions

A discussion of Microsoft Great Plains and Merit Solutions as a supplier of ERP systems to the Mid-Sized Life Science company is included below. This discussion is highlighted with a shaded box as with this text.

The opinions stated are that of the author and are based upon representations by Merit and Microsoft and should not be considered as a recommendation for Merit or any other solution. Nor are the features highlighted intended to be all inclusive of functionality available. The mid-sized life science company is urged to conduct the appropriate investigation.

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Mid-Market Life Science Enterprise Realities

What makes your ERP requirements difficult for most vendors to satisfy? When it comes to administrative applications, such as financial requirements, your company's needs are similar to those of a company in any industry. As a life science company, you do have operational differences from other manufacturing companies, in areas such as production, supply chain and inventory.

And, of course, you have regulatory requirements unlike any other industry. As a life science company you must be committed to compliance. Compliance is not optional; it is a cost of doing business.

However, compliance is not absolute. It is ambiguous, evolutionary and defined by interpretation. The challenge is managing compliance risks and compliance cost. For the mid-sized life science company, the questions are:

- What do you need?
- What can you afford?

Part 11, Opportunity Or Challenge?

21 CFR Part 11 specifies additional controls for electronic records and electronic signatures. Is Part 11 an opportunity or a challenge? The answer to this question is, "it depends." If you see Part 11 as a requirement that must be met, it will be a challenge. If you see Part 11 as a way to improve internal business processes, it will be an opportunity.

The FDA is permitting manufacturers to benefit from emerging technologies to streamline record keeping and compliance. This technology can increase the usability of the information gathered by integrating both business processes and audit functions, without compromising the quality of regulatory compliance.

The opportunity can be significant. Life Science companies should see Part 11 as an opportunity to improve business practices. Benefits may include:

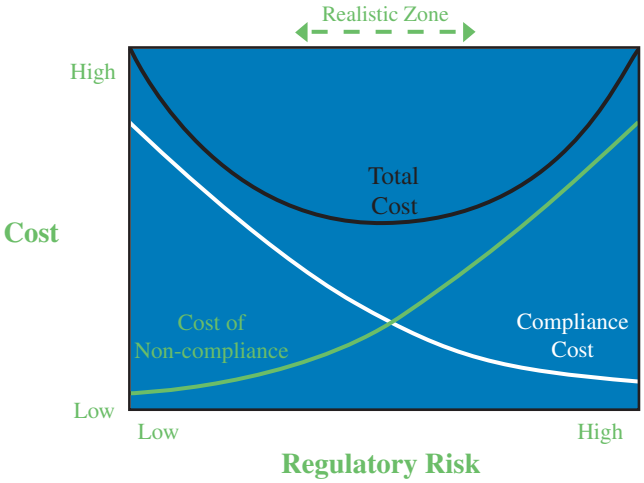
- Lowered cost of data collection
- Increased accuracy of data
- Increased data analysis capabilities
- Reduction of regulatory errors (misfilings, for example)
- Improved control over production, quality and other processes
- Quicker search of electronic records
- Improved information transfer between departments (for example - operations and quality)
- Improved information transfer between companies (for example - an external research organization and the sponsoring enterprise)
- Improved product recall

Why is Part 11 an opportunity? It allows a life science company to benefit from many of the technologies that have proven themselves in many other industries. It also can lower your long-term cost of compliance.

Compliance Strategy

The FDA regulations are not a fixed target. Compliance is a key objective for any regulated company, but the requirements to meet this objective are subjective, based upon product, production processes and, perhaps most importantly, your tolerance for risk. Regulatory risk is the risk of being found out of compliance. If you accept very limited risk, your cost of compliance will be high. With more risk, compliance cost is reduced but the potential cost of non-compliance increases.

Executive management has the responsibility for setting the organization's risk tolerance and allocating the required resources to satisfy that tolerance. Your compliance team, made up of individuals responsible for aspects such as quality and legal, needs to set the regulatory strategy for your company based upon an interpretation of the regulations relative to your specific situation, balancing the cost of compliance with the cost of noncompliance.



Cost vs. Risk

When reviewing compliance cost, the total cost of ownership is an important consideration. These include one-time costs to initiate the system plus continuing operational and maintenance costs. One-time costs include implementation, training, acquisition of any equipment or software involved, and validation. Continuing costs include personnel, continuing training, and maintenance of any hardware or software utilized.

Continuing costs also include the effort to keep the compliance system in synch with evolving Standard Operating Procedures (SOPs). The computer component of the compliance system will need to be evolved with the SOPs. There are two ways in which alteration of the computer component would have a major impact. First is the cost of the effort itself -- does making a change require a day or a week or several months of effort? Second, and perhaps more important, is the time lag between the decision to change the SOPs and having the system ready to support the changed SOP. If this lag is significant, it can seriously impact your ability to improve operations.

The costs of non-compliance are those costs that would be incurred if you were found to be out of compliance, factored by the risk of being found out of compliance. The cost of non-compliance can include additional inspections, lost production, unsellable product, recalls, plant shut downs, fines, or even jail time for executives.

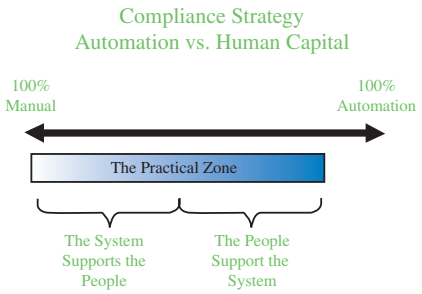
Public relations can be uncontrollable and costly. The media may decide to feature your non-compliance, regardless of how serious the problem may be. What will be the impact on your brand and what that brand means to your success? The financial impact of non-compliance on a mid-market business has the potential to be catastrophic, and could cause the small manufacturer to go out of business.

Remember, compliance is not about computers; it is about procedures that involve many elements, one of which is computers.

People vs. Systems

Compliance will always be a mix of automation and people. The proper balance of automation with paper records and human capital keeps costs under control and yields a flexible but controlled set of procedures. These two extremes both have their characteristics and costs.

Computers do a great job of handling repetitive tasks and organizing, storing and retrieving standard documents. People do a great job of handling exceptions. Evaluation of the characteristics of operations and products will reveal the mix of standard versus exceptional circumstances. The most effective procedures will allow computer systems to assist in repetitive operations while integrating manual or semi-manual approaches for exceptions. Exceptions should be captured in digital form to facilitate, where feasible, the storing and retrieving of documents.



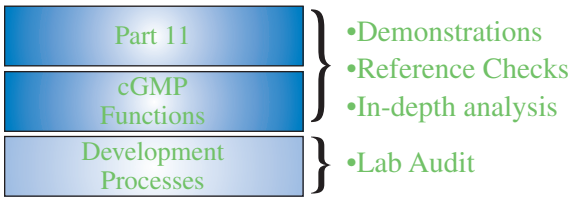
Information systems can lower the people cost but generate costs of their own. People and information systems must be balanced to yield the correct level of compliance at the appropriate cost. Remember, compliance is not about computers; it is about procedures that involve many elements, one of which is computers.

At the extremes, the balance between automation and people could result in a compliance system that is 100 percent manual or 100 percent automated. The 100 percent manual option has been used for years and has proven acceptable in many cases. That option still exists and should never be ignored. However, leveraging the strengths of automation can lower the total cost of compliance and should be part of the compliance strategy. A compliance system that is 100 percent automated is neither achievable nor practical. The practical zone ranges from a system that is 100 percent people to a system that is automation-based with people feeding the system and handling exceptions.

For mid-sized companies, the appropriate balance between people and systems typically leverages automation to handle normal and repetitive situations and relies on people for variations. Automation cost is usually an issue with these companies; therefore, trade-offs are often made to allow automation to support people-based systems. For example, a company may opt for a fully automated system, with workstations at each step of the production process to record compliance information; another company may rely on hard copy shop packets with compliance information captured on paper and selected information entered into an automated system at the completion of production.

Understanding Vendors

All companies have target markets. Vendors cannot afford to target every market -- some trade-offs must exist. In attempting to target the life science industry, most ERP vendors have chosen breadth over compliance depth. The ideal vendor will have the breadth of function you will need today and in the future. More importantly, the vendor will offer the regulatory depth required to match your regulatory strategy.



Vendors also define their target markets in terms of the size of the intended customer—large, mid-sized or small. The majority of vendors and most of the "big name" vendors started with a target of large (Fortune 1000 or maybe even Fortune 100) companies. Therefore, they correctly built the needs of these large target companies into their software. In these products we see many multi-division, multi-national, multi-site tools. We see a focus on standard processes across the extended business. While these tools are very important to large companies, they can present an extra burden to the mid-sized company.

Microsoft Great Plains and Merit Solutions

The Microsoft Great Plains and Merit Solutions focuses on the mid-sized life science company. The solution provides business software for life sciences companies requiring FDA cGMP compliance, supporting a range of compliance strategies. As appropriate to the mid-sized company, the solution supports the people rather than forcing the people to support the system. The solution allows companies who must adhere to the stringent data validation, security and process integrity requirements mandated by the FDA to leverage the power of Microsoft's integrated business systems.

The Microsoft Great Plains and Merit Solutions approach is an attempt to take the best from both sources. Microsoft provides a broad array of applications that are appropriate for most companies. Microsoft built these applications using an architecture that is appropriate for the extension or the creation of complementary solutions by either end-user companies or application providers. Merit has leveraged this architecture, and its knowledge of the needs of a life science company to yield a solution specifically for life science companies.

Life sciences specific functionality from the Microsoft Great Plains and Merit product set includes areas such as:

- Part 11 Audit Trails
- Electronic Signatures
- Password and Login Controls
- Quality Material Management
- Adverse Event Reporting
- Batch and Lot Records Management
- Advanced Lot and Serial Track and Trace
- Product Life-Cycle Management

How should a life science company evaluate ERP vendors and their solutions? The focus of your search should be on what differentiates your business – those things that, if not taken care of, can be called fatal flaws. A fatal flaw is not a reflection of your business; it is a potential shortcoming on the part of an ERP package in an area where, if functionality is lacking, your implementation will fail. The vendor's flaw will be fatal to your success. Fatal flaws are usually limited to a very small part of the vendor's total product, but that

part is absolutely necessary for success. Typically, fatal flaws are found in the operational areas of the business and, for life science companies, cGMP and Part 11 compliance. Therefore, most of your attention should be focused on those areas.

Potential Fatal Flaws – Compliance and Software

For many vendors, you will find that their fatal flaws are related to production and compliance issues. These combined issues impact inventory and production areas as covered by cGMP and Part 11.

Are meeting Part 11 requirements necessary for compliance? No. Under Part 11, the use of electronic records is optional. Therefore, your compliance strategy will dictate the need for Part 11 functions in your ERP system. ERP function deals with cGMP for all life science companies, and this will always demand a close look during the evaluation process.

Part 11

Since many companies will want to undertake Part 11 compliance to minimize total cost, what are some of the fatal flaws related to Part 11?

ERP companies addressing Part 11 have approached it in one of two ways – as an application issue or as an infrastructure issue.

With the application approach, the vendor decides which transactions demand Part 11 control. The prospective buyer's job is to make certain that the vendor's decisions are workable given the company's regulatory strategy. Are all the points of interest covered? If extra issues are addressed, can these be "turned off" to avoid excess and expensive controls? If you change your strategy or SOPs, will the issues now covered still meet your needs? The application approach may result in some trade-offs between the vendor's desire to serve the life science market and the limitations of development priorities and funding.

With the infrastructure approach, the vendor enables Part 11 as part of the base system and allows the user to implement Part 11 control at any point in the system that is deemed necessary. The Part 11 functionality can be triggered on any file or transaction. For example, if your compliance strategy is very conservative, you may want to implement Part 11 control on granting or maintaining security profiles.

Merit has leveraged Microsoft's technology in adopting an infrastructure approach to Part 11 compliance. The solution enables businesses to implement compliance features (such as audit trails and electronic signatures) in a manner compliant with FDA 21 CFR Part 11 regulations and in a way that supports the organization's specific SOPs. It provides audit trail tracking and reporting in all areas of the ERP system that are FDA significant, including batch records, engineering changes, quality records, inventory status transactions, process instructions and recording of results.

The infrastructure approach gives the business control over its approach to compliance. For example, a hard-coded compliance solution might require an electronic signature when signing off on a data entry to a batch record, even if the business keeps a paper batch record. The Merit solution infrastructure approach would allow the business to decide to eliminate the electronic control in that location because compliance is maintained in a paper copy.

Electronic signatures are considered to be system-required authentification

cGMP

The application functions of ERP address the cGMP regulatory issues. These issues and the related fatal flaws can be organized as follows:

- Security
- Work Orders
- Transactions
- Inventory
- Lot Tracking
- Analysis
- Proof of Compliance

cGMP - Security

If you choose to use electronic records, you must consider the security provided by the system. Part 11 calls for a layered security with parameters that can include:

- User authentication (user name and password)
- Window access
- Transaction access (in some cases, transaction type restriction)
- Field level security
- In-process controls including dual password authorization and reason code capture for certain transactions related to significant processes
- Automatic system time-outs
- Extra levels of system enforced control around certain significant processes, such as quarantine material that must pass a material review board inspection before being released as available

Security also varies with signatures. Electronic signatures are considered to be system-required authentification, such as the input of a password or multiple passwords. Digital signatures are authentifications that can also involve other human inputs, such as human fingerprints, retinal scans or actual pen-stylus input of a written name. Common issues include: How many electronic signatures does the system require for a transaction? Can the number be determined by the company and be changed on a transaction-by-transaction basis?

For transactions that relate to processes deemed “significant” by the FDA regulations, the system must store information documenting the transaction and the signatures, including before and after images of the data. The regulations specify what information must be maintained for the signatures. The identity, time, date, location, device, and reason for the data change must be stored for each signature. Regulations call for secure storage and rapid retrieval of documents. Although not specially called for in the regulations, the capability to assemble documents as outputs that can be printed and stored electronically in standard formats, such as PDF or XML documents, is strongly advised.

Microsoft Great Plains provides a variety of advanced security options, including the ability to assign security by user or user class. These security settings allow the administrator to control which windows, modified windows, reports, modified reports and files any individual can access. Effectively, this gives control over which types of transactions the user can access based on the windows into which they are allowed access.

Field level security in Microsoft Great Plains allows you to apply a password or to make a window or form unavailable. It also allows you to apply password protection to specific fields and even lock them or hide them from the user's view.

Merit Solutions extends the advanced security options available in Microsoft Great Plains by adding the ability to ensure that passwords contain a combination of letters, numbers and symbols. The security can also be set to restrict the hours of system use so that a user can only access the software during allowed time periods.

cGMP - Work Orders

The manufacturing work order is a primary regulatory focus. This document ties together the information related to production. The work order should be integrated with all lot and/or serial number information from procurement to customer delivery. The work order must include all resources involved in production including materials, people, locations, and equipment. The work order is the primary collection point for production-related regulatory information and is usually a focus of regulatory attention.

cGMP - Transactions

Any and all transactions that relate to business processes deemed "significant" by the FDA regulations must be considered part of regulatory requirements. This generally includes transactions that span the material life cycle from procurement to customer shipment. Audit records for transactions related to significant processes must include the person, location, equipment used, time and date stamp, and before and after data values. This data must be organized for retrieval and retention. Since the transaction audit database is constantly growing with ongoing transaction processing, the size and management of the database is a major issue. The architecture of the Part 11 Audit system must be designed to efficiently manage a large transaction information database, and to do so within a "closed system environment" as defined by the regulation. Proper system architecture for a Part 11 Audit includes:

- The ability to track only the data for the transactions that support processes in your business deemed "significant," and not for transactions supporting processes that are not "significant." If the whole application (all transactions) is audited, the audit database size will be monumental and difficult to maintain and administer. It will also have a clutter factor that makes it difficult to use.
- An audit database that is distinct and separate from the production database. This is important because the sheer size of a self-updating audit database can quickly impact production performance of an ERP system. A separate database also allows much tighter and more specific controls around the audit database without restricting the levels and types of controls necessary for the production database to function.

- A search capability, usable by non-technical employees, that is powerful enough to enable the quick search and assembly of past transaction records. This includes the ability to search by multiple parameters across selective time periods. It must be user accessible to support timely assembly of transaction history in a situation where company officers must substantiate evidence of SOP compliance.

The Merit Solutions audit trail is unique in that it was designed from the ground-up with the specific goal of supporting 21 CFR Part 11 compliance. Some of its Part 11 specific design features are:

- Audit trail is maintained in a separate audit database. This facilitates easy backup of the growing audit trail, and even allows the audit database to be placed on a separate hard drive for performance.
- Audited transactions and records are maintained in "mirror" copies of their original tables. This makes reassembly of records, and reporting, much easier to accomplish versus the common one-table design audit trail.
- Its own security system allows the administrator to grant specific users access to view just some parts of the audit.
- The SQL-based audit captures all changes to the data regardless of the source. This contrasts to an audit trail created by the ERP application, which would only capture changes coming from the ERP software and not a change coming from a user directly accessing the database.

cGMP - Inventory

Inventory information must be retained across the material life cycle. Lot information, quantities, classifications (quarantined, approved, rejected, hold, etc.) and storage locations must be maintained. It is recommended that the type of inventory (Active Pharmaceutical Ingredient, or API, Inactive Ingredient or Manufacturing Materials) be designated to assist in security, retention and retrieval.

Microsoft Great Plains allows you up to six user definable categories for inventory items in order to specify types of inventory that make the most sense for your business. Inventory can be stored in multiple locations so a company may use one location for quarantine but other locations for material available for production.

cGMP - Recall/ Lot Tracking

An extremely important function is recall. Also called lot tracking and tracing by the software industry, recall must be error proof and must react quickly to your needs. The information retained for recall and its retention and retrieval must reflect the wide variety of roles it must play. It is suggested that both fast track retrieval methods and extremely flexible methods be available for retrieval and analysis. The recall database size will become an issue.

Lots can be assigned to manufacturing orders either before or after production and manufacturing orders can be pegged to specific sales orders. If a recall occurs, a user simply needs to enter in the range of serial or lot numbers to be traced and the window will show any transactions in the system that involved these serial or lot numbers including, but not limited to, inventory receipts, sales orders and manufacturing orders.

cGMP - Proof of Compliance

System testing and validation specific to your deployment and system documentation in accordance with your standard operating procedures are important aspects of compliance. The underlying technology and architecture of the software should consider the following factors:

- The ability to embed electronic versions of your standard operating procedures within the software, in order to directly support and enable workers to operate in accordance with the procedures. This object linking or embedding type of technology can yield considerable savings in administration time when changing and updating standard operating procedures.
- System enforced integrity. While basic and often assumed, some systems do not enforce data or process integrity. If the software cannot be proven to produce consistent, expected results, the company cannot pass validation testing, and the software cannot be used.
- Compatibility with desktop technologies. A company must prove that its workers understand and are operating in compliance with their standard operating procedures. When moving to an integrated business system, the ability to prove the workers' proficiency with the system becomes paramount. If the workers are already familiar with the screens, user interface and basic operations of your ERP system, based on their existing knowledge of desktop and productivity software used, the cost and time to maintain their proficiency on the ERP system will be minimized.

Proof of compliance relies upon audit trails to organize the relative information. The Microsoft Great Plains / Merit Solution's audit trails solution provides the ability to track, trace and report any changes associated with any data in Microsoft Great Plains, and for any data in third-party software or customized software resident within Microsoft Great Plains. This includes information related to a change, such as time, date, and user, as well as the 'before' and 'after' data values associated with a change.

Audit Trails is easily configured for tracking just the data required for each customer, and is designed for efficient but controlled ongoing maintenance and administration.

But, what really sets Audit Trails apart is that it is developed completely within Microsoft Great Plains and features the same user interface. This allows for easy adoption by your employees, and ensures technical stability and ongoing compatibility.

Audit Trails gives you an easy to use, complete track and trace capability

The software can operate with closed-looped controls, or as a 'closed system', as required by many companies when using an Audit Trails system.

Using Audit Trails, life sciences companies can adhere to the stringent data validation, security and process integrity requirements mandated by the Food and Drug Administration (FDA), including those requirements specified in regulation 21 CFR Part 11.

Some aspects of the Merit Solutions compliance offering that are compelling for the mid-size life science company include:

- The ability to track data for all transactions and all tables within Microsoft Great

Plains or internally resident customizations or third-party software

- The ability to be configured to track just the transactions and data deemed significant by the customer, contributing to ease of maintenance and the lowest impact on hardware performance and database size
- Technology and user interface that is the same as Microsoft Great Plains.
- Fast and easy access to any audit information, including the ability to narrow the data views down based on multiple sort criteria
- Adherence to FDA CFR 21 Part 11, including before and after transaction data values, and operation as a 'closed system'.

Additional functionality to support your compliance strategy

SOPs can be supported in a variety of ways within Microsoft Great Plains. For organizations that manufacture medical devices, drawings can be attached to items so that everyone has easy access to technical specifications.

Any organization that must adhere to SOPs will appreciate the ability to attach notes and other types of files to master records such as bills of material or recipes, routes at the individual sequence level, and work centers. These notes can be text files that outline SOPs, drawings, and even video clips describing the appropriate procedure to follow.

Other areas of functionality provided by Microsoft Great Plains that may be appreciated by the life sciences organization include:

Human Resources: In the Microsoft Great Plains human resources application, you can assign skills to workers. You can also assign skills to work centers in manufacturing denoting which skills or certifications are required to work at a work center. Even without the human resources module installed, a drill-down into the activity on any manufacturing order will show a history of the employees who worked on an order and at which work center.

Revision history for bills of material or recipes: You can save bills of material revisions to history, and you can view all revisions along with the details of the bills of material structure for that revision, the date changed, and the User ID that initiated the change.

Microsoft Great Plains Engineering Change Management: This will allow any user in the system to suggest a change to a bill of materials or a process to help ensure an environment of continuous improvement. The reason for the change as well as the anticipated impact can be recorded as well. These changes are routed through predefined approval steps and once a change is made, the revision number is updated and a history of the change is kept in the system.

For organizations that don't need the advanced functionality provided by Engineering Change Management, a history of revisions can still be kept when changes are made through the bill of materials maintenance screen.

Adverse Event Reporting

In addition to the functions of "traditional ERP", Merit provides the function required by the FDA to track information related to adverse events and to file FDA Form 3500A. Adverse Event Reporting provides the capability to track all adverse events, maintain a database of those events including disposition information, and produce the required FDA reporting documents associated with adverse events. Features include:

- Provides a central, secure and controlled system for tracking, analyzing and reporting on adverse events.
- Operates seamlessly with Merit Solutions Audit Trails. All changes to adverse event records are tracked, recorded and maintained in accordance with FDA 21 CFR Part 11 requirements.
- Produces form 3500A.
- Enables analysis of disposition and trend information for all adverse events.

What Your Software Vendor and/or Your System Integrator Should Supply Beyond Software

The ERP software must be specifically tested and validated for your company's use. Once your SOPs are developed and documented, system validation is largely a function of performing documentation tests of your processes within the software to prove that it acts in the expected manner. It is important that your vendor, and your system integrator if someone other than your vendor implements the software, offer the following:

- A deep understanding of the FDA regulations with which you must comply. If your vendor or system integrator doesn't understand the requirements born out of the regulations, it will be very difficult to successfully deploy a validated system.
- Pre-built validation tools. Your business will have its own unique processes and therefore unique tests, but as much as 60 percent of the required tests may be similar to those of other life science companies. If the vendor or system integrator can bring pre-built tools that can be directly used or slightly modified for some of your validation processes, the savings in consulting costs and time can be significant.
- Experience in deploying validated systems with other customers. There is simply no substitute for this experience. It will save you time and money in your deployment.
- An understanding of the initial and ongoing change management aspects of operating an ERP system in a regulated deployment. For example, each new version requires new testing, and specific change management processes must be followed to bring the new version online and into production.
- A deep understanding of the software, including the way the database is structured and the way the code is designed to behave. This is required to support the testing and validation process, and to support decision-making regarding which transactions must be tracked at the Part 11 audit level in order to support your specific validated deployment. Also, while you hope not to have to customize or extend the software, it is important that your vendor or system integrator be able to support your needs if you do. Customized software must be able to operate under the same audit trail capability as the core system, and must be tested and validated in the same ways.
- Long-term financial viability. Because of the added regulatory requirements of a life sciences company, the costs to change ERP systems are significantly more than for other types of firms. It is important that the software is able to scale to support your functional needs as you grow, but it is just as important that the software developer be around to support and maintain the ERP software that you commit to.

The mid-sized life science company needs to balance the ability of ERP systems with both economic restrictions and alternative, human based, approaches to satisfy their requirements.

Summary

As a mid-sized life science company you have most of the same business requirements and all the same regulatory issues as the largest life science companies. However, you have fewer resources at your disposal to address these issues. The reality is that only a few ERP vendors have proven that they can serve the needs of the mid-sized life science market.

The mid-sized life science company needs to balance the ability of ERP systems with both economic restrictions and alternative, human based, approaches to satisfy their requirements. Larger companies can justify levels of automation that are not economically sound to the mid-sized company because the larger company can extend a solution over many business units and higher business volumes. Therefore, systems that have proven effective for larger companies are often inappropriate for the mid-sized company.

This paper serves as a starting point for the process of evaluating your needs, fatal flaws and decision criteria.

The mid-sized life science company searching for a business solution is urged to place the solution from Microsoft Great Plains and Merit Solutions on their short list. We find the solution to be:

- Complete
- Appropriate for the mid-sized life science company
- Well-supported
- Provided by a stable vendor

[1] FDA's Mission statement, see - http://www.fda.gov/opacom/morechoices/mission.htmL

Appendix

Compliance Defined

The FDA's public health protection role and defined mission include ensuring that "human and veterinary drugs are safe and effective; there is reasonable assurance of the safety and effectiveness of devices intended for human use."[1] Today, the need to audit processes concerned with human health has become an even greater issue in light of current fears of bioterrorism.

To ensure that Life Science Products are produced in a way that supports its mission, the FDA has defined Good Manufacturing Practices (GMPs). Originally, GMPs were based upon the best practices of the industry. As technology and practices improved, the GMPs evolved as well. In the U.S., drug GMPs were formally introduced in 1963 and significantly rewritten in the 1970s.

GMPs define a quality system that manufacturers use as they build quality into their products. For example, approved drug products developed and produced according to GMPs are safe, properly identified, of the correct strength or potency, pure, and of high quality. At a high level, GMPs address:

- Proper design, maintenance and cleaning of equipment and facilities
- The development and approval of SOPs
- The need for an independent quality unit (like quality control and/or quality assurance)
- Qualifications and training for personnel and management

GMPs are defined as regulations that describe the methods, equipment, facilities, and controls required for producing. These regulations are found in the Congressional Federal Register (CFR) 21 in the following parts:

- Human pharmaceutical products and veterinary products (21 CFR 210-211)
- Biologically derived products (21 CFR 600 and 21 CFR 620)
- Medical devices (21 CFR 820)
- Processed food (21 CFR 100)

(See http://www.fda.gov/cder/dmpq/cgmpregs.htm for current regulations)

In addition, 21 CFR Part 11 specifies further controls for electronic records and electronic signatures.

The set of regulations that is currently in effect is called Current Good Manufacturing Practices or "cGMPs," emphasizing that they are dynamic.

The following parts are of special interest for pharmaceutical products:

Part 210	Current Good Manufacturing Practice In Manufacturing, Processing, Packing, Or Holding Of Drugs; General
Part 211	Current Good Manufacturing Practice For Finished Life Science Products
Part 11	Electronic Records; Electronic Signatures

As automation began to replace paper-based systems, Congress feared a loss of documented control over safe pharmaceutical production processes. With an initial focus on medical devices and life science products, Congress mandated a verifiable, trackable plan that would allow digital signatures and automated audit trails to replace the volumes of regulatory paper work. This plan was published as 21 CFR Part 11, simply known as "Part 11." The impact of Part 11 on manufacturers will be great as or greater than the Y2K issue.

Part 11 is a loosely written regulation that intends to add a layer of security to the production processes of the pharmaceutical industry through audits and authorized sign-offs. Part 11 is not mandatory. It is called into play if a company chooses to use electronic records. A company may decide to stay with paper-based records and in that case, Part 11 does not apply.

GMPs change formally and informally. The U.S. medical device GMPs were formally changed when Congress rewrote them, making them more compatible with the ISO-9001 quality document. The medical devices GMPs were then renamed to the Quality System Regulation (QSR).

Changes also come about through the evolving expectations of inspectors. In the U.S., these changes are communicated through agency guides and guidelines and by presentations and papers presented by FDA personnel. More informally, cGMPs evolve as new practices become "feasible and valuable." One other way industry personnel can keep track of changes in expectations is by watching the FDA-483s (inspectional observations: http://www.fda.gov/ora/frequent/default.htm) and Warning Letters issued to firms by the agency (http://www.fda.gov/foi/warning.htm).

Life sciences manufacturers will see increased attention to their systems as the estimated 700 FDA inspectors trained in computer systems and Part 11 become available.

Although the FDA does a thorough job of setting forth regulations, these regulations should be viewed as a set of guidelines, not as an absolute statement of requirements. The FDA, compliance executives, lawyers and others interpret the regulations in a variety of ways depending on a number of factors including the product produced, the manufacturing processes used, and the risk involved.

Does cGMP Impact Your Company?

Does cGMP apply to you? If you manufacture human pharmaceutical products, veterinary, biologically derived products or medical devices, you need to understand and comply with cGMPs. If these products are manufactured outside the U.S. but are marketed domestically, these rules apply. (For a list of regulated products, see http://lifesciencecioforum.com/products_regulated.htm.)

Does Part 11 apply to you? Congress has mandated that the manufacture of drugs and medical devices – products with the potential of causing physical harm – require audit trails and digital signatures. Nutraceuticals, biologics, companies involved in bone extensions, body part harvesting, blood banks, skin graphs, and others are currently excluded.

Most assume that cosmetics and food and beverages will soon be added to the list of affected industries. Debate is ongoing as to the appropriateness of pharmaceutical regulations in food and beverage. The debate is not about the need for more control; the debate is about whether this is the right set of regulations.

For contract manufacturers of drug and medical devices, compliance should be regarded as a competitive weapon. Patent holders are exposed to risk from non-compliant contract manufacturers and will look more favorably upon sources that meet the patent holders' definition of appropriate compliance.

About the Author

Olin Thompson is a principal of Process ERP Partners. He has over 25 years experience as an executive in the software industry. Olin has been called "the Father of Process ERP." He is a frequent author and an award-winning speaker on topics of gaining value from ERP, SCP, e-commerce and the impact of technology on industry. He can be reached at Olin@ProcessERP.com.

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