

# Operational Effectiveness:

ERP strategies and Best Practices for Emerging Life Science Companies

## Executive Summary

In support of its present and future customers, CDC Software sponsored this white paper to help emerging Life Science companies understand the ERP strategies and best practices being pursued by leading companies in the industry. Through the experiences of two of the customers highlighted in this paper, emerging Life Science companies can learn from and apply some of the best practices and lessons learned from peer companies.

CDC Software's Ross Enterprise suite provides cGxP compliant transaction processing and work flow for materials management, manufacturing, financials and the extended life science material supply chain. Our systems facilitate faster, lower cost approvals and reduction of risk through improved compliance.

# Beyond Science: The Drive for Operational Effectiveness

Scientific discovery is the fuel that drives the Life Sciences sector, including Biotechnology, Pharmaceutical, Diagnostics and Medical Device companies. Life Science companies must meet enormous challenges as they commercialize new discoveries. Overcoming daunting technical challenges, meeting complex regulatory requirements, and managing the multidisciplinary array of skills required to advance a product through development creates significant business complexity. While these challenges exist for companies of all sizes, emerging companies face a particular grueling set of challenges. Emerging companies, while lacking the experience and resources of their larger counterparts, must also establish the core business processes and systems they will need to manage the rapid growth arising from the commercialization of their initial products.

The savvy business and financial managers in today's emerging Life Science companies increasingly recognize the need to establish an effective business infrastructure early in the life cycle of the company. These managers recognize the inherent advantages to establishing scalable business processes and information systems early in the companies' growth. These advantages include:

- Lower cost to implement core business systems
- Lower risk of business disruption or implementation failures
- Ability to grow and scale the business from the basis of a sound foundation
- Improved operational performance of the business.

In addition, with today's heightened regulatory environment, including the impact of the Sarbanes-Oxley Act of 2002, companies must substantially increase the operational and financial control of their business.

Given the challenges and constraints, how can emerging Life Science companies achieve operational effectiveness? How can these companies achieve compliant, scalable and high-performing business operations? Achieving operational effectiveness requires addressing a fundamental set of business, operational and technology strategies & solutions:

1. **Overall business systems strategy:** How can we align our information systems infrastructure with our overall business, operations & regulatory strategies? What new capabilities will we need to add as we grow and when? Are we fully utilizing our current business systems? How can we extend the useful life of our existing technology investments?

2. **Business case for enterprise systems:** Can an investment in new or upgraded business systems be justified? How can we reach this complex decision in a systematic way? How do we build a consensus for such a critical decision? What are the business benefits, cost, return-on-investment and total costs involved? What is the right roadmap for moving forward?
3. **Evaluating and selecting appropriate solutions:** What are the essential elements we should consider in evaluating business systems? How can we cut through the "noise", and determine the right software for us? How do we best meet our needs today and still establish a scalable foundation?
4. **Best practices & lessons learned:** How are other Life Sciences companies utilizing information technology to improve efficiency and enable best practices? How can business systems help maintain compliance, and improve and accelerate business decisions? How can we better leverage our existing IT investment?
5. **Designing effective business processes:** Can we proactively redesign processes that have evolved over time? Can we leverage existing or new information technology solutions to streamline or automate our processes? Can new processes integrated with technology "raise the bar" in terms of discipline, compliance, productivity and performance?
6. **Implementing cost-effective solutions:** Can we implement solutions in a cost effective way? How do we prevent disruptions in our business, manage risk, and overcome resistance to change? What is the right roadmap for building out our infrastructure?

Addressing these issues requires integrating the knowledge and skills across virtually all business and IT functions into a systematic approach for:

1. Formulating a strategy
2. Understanding the business case
3. Selecting the right solution
4. Formulating a roadmap for implementation.

The application of a systematic process will enable the organization to develop a core business infrastructure that will achieve & sustain compliance, efficiency, flexibility & scalability over time.

# Strategic Considerations

Most young Life Science companies begin operations utilizing a basic Financial system, while investing heavily in research and development and the necessary infrastructure. As these R&D efforts transition into clinical development, questions and issues often emerge which begin to put pressure on the rudimentary business systems and processes that are in place. Some of the business drivers for these issues include:

- Increase investment attractiveness with established controls, processes, and audit trails
- Growing employment and expense base of the company
- Increasing volume of purchased products & services
- Increasing volume of clinical supplies & inventory
- Establishing manufacturing, packaging and distribution partnerships
- Establishing or scaling up commercial supply capabilities

As the business grows in complexity, companies begin to seek more information, better control, and deeper insight about the financial and operating performance of the business. The manual processes, paper-based systems and basic financial software in place at these companies quickly reach their limitations.

Enterprise Resource Planning (ERP) systems are the core business systems utilized by virtually every company of any significance. These systems provide the Financial, Purchasing, Inventory, Materials Management and Manufacturing/Distribution planning capabilities that companies will need to manage their products and their businesses. Companies outsourcing manufacturing have the same compliance, lot control, and audit control requirements as those who manufacture in-house.

**For virtually all life science companies, selecting and adopting an ERP system is inevitable.** The capabilities provided by these systems will become increasingly critical to the success of the business. Among the capabilities provided by these systems are:

- More robust expense and fixed asset accounting
- More sophisticated financial reporting and cash management capabilities
- Project accounting and tracking
- Automated purchasing support, integrated with accounts payables
- Material management, quality control and inventory accounting
- Manufacturing process management

- Demand and production planning and activity control
- Support for product release and batch records
- Supply chain wide batch/lot control and genealogy
- Order management, integrated with receivables
- Management of the overall supply chain

These capabilities can be utilized to support management of clinical trial expenses, materials and production and will be required capabilities to run compliant, efficient and effective commercial operations. Most emerging Life Science companies recognize that they will inevitably need to invest in an ERP system. The typical questions that arise are:

1. When will we need to put such a system in place?
2. Which system will fit our initial size & needs while scaling with us?
3. How will we implement and deploy a system?

The experiences of other companies in the industry can provide useful reference points and lessons learned as they addressed these issues.

## Case Study: Cambrex Corporation

Founded in 1981, Cambrex Corporation (NYSE:CBM) is an innovative life sciences company dedicated to providing products and services to accelerate the discovery, development and manufacturing processes of human therapeutics. Cambrex helps its customers get their therapeutics to market quickly and cost-effectively. The Company measures its success through the success of its customers - through their research, clinical trials, and product commercialization.

Cambrex is headquartered in East Rutherford, New Jersey and has a global organization of approximately 1900 people in the US, Europe, Asia and South America. Cambrex provides products and services to innovative and generic pharmaceutical companies, including biotherapeutic and biopharmaceutical companies, universities, research organizations and the government. Most products serve as critical ingredients in the formulation of the customers' products.

For clients involved in research and drug discovery, Cambrex's goal is to provide an ongoing stream of innovative products and services that improve the productivity of their research. The company provides a line of over 1400 research products available from their web site.

For clients needing development and manufacturing solutions, Cambrex partners throughout product and process development, flexibly combining products and services to meet the client's objectives and timeline. This integrated bench-to-patient approach includes the process development, custom assays, cell-based services, analytical testing, regulatory services, drug delivery and taste masking systems that clients' need to expedite therapeutic development.

Cambrex generated just over \$400 million in revenue in 2003, operating across three business segments: Human Health, Bioproducts and Biopharmaceuticals.

**Human Health (60%):** The Human Health segment primarily consists of products derived from organic chemistry and regulated by the Food and Drug Administration (FDA) or other government agencies. Products are supplied to innovative pharmaceutical and generic drug companies. Active Pharmaceutical Ingredients (APIs) and Pharmaceutical Intermediates (Intermediates) represent over 90% of Cambrex's total Human Health 2003 revenue. Products in the Human Health segment are sold to a diverse group of more than 1,100 customers.

**Bioproducts (29%):** The Bioproducts segment consists of products and services supplied to the life sciences market to support drug discovery and disease research, drug development and the production of biopharmaceuticals. Bioresearch products for molecular biology and cell biology are supplied to customers in academia, the government, and biotechnology and pharmaceutical companies and are used in the discovery, screening and ADMET (absorption, distribution, metabolism, excretion and toxicity) testing of new drugs.

**Biopharmaceuticals (11%):** The Biopharma segment consists of contract biopharmaceutical manufacturing services. Cambrex develops and manufactures bulk biopharmaceuticals under contract for biopharmaceutical companies. Biopharmaceuticals are therapeutics that are produced using biotechnology and include recombinant proteins, monoclonal antibodies, vaccines, recombinant enzymes, and peptides. Process expertise includes microbial fermentation and mammalian cell culture. Cambrex provides complete services from strain and process development through Phase III clinical and commercial production, including access to Cambrex' full range of development and manufacturing services.

## Selecting an ERP Solution

Cambrex's ERP journey began in 1994 when it was a \$100 million specialty chemical company looking to grow, primarily through acquisitions. As part of that strategy, Cambrex shifted its strategic focus from specialty chemicals to producing APIs and pharmaceutical intermediates. To support the strategic direction of the company, a team evaluated and selected an appropriate ERP system.

The criteria of this evaluation were to:

- Establish capabilities to support pharmaceutical process manufacturing
- Move away from a low-end financial system that had been heavily modified
- Prepare for expected growth of the company
- Overcome a lack of business infrastructure, especially outside of the US
- Establish a common business platform to support the current divisions and future acquisitions.

The team considered 4 leading ERP systems in their evaluation. Their goal was to select a system, which could provide the best combination of business fit, price and long-term scalability. Ultimately, the team selected the Ross Enterprise suite from CDC Software based on several key differentiators:

1. Best process manufacturing functionality that could be delivered immediately
2. Lower overall cost and better pricing terms than the leading competitor
3. Ability to immediately leverage an Oracle/Unix technology infrastructure.

## Preparing for The First Implementation

Once Ross Enterprise was selected, Cambrex began on a process of preparing to implement the package globally for current divisions. Among the preparatory steps were:

1. **recruiting a headquarters-based implementation core team.** The company established a core team comprised of representatives from the key functional areas addressed by ERP - Financial, Manufacturing, Materials Management and Sales as well as IT representation. The goals of the team were:
  - The implementation would be driven by functional team leaders, not by IT, and these team leaders would align themselves with functional site champions in the business units
  - Cambrex would build a self-sufficient capability for implementing Ross Enterprise across its current business and future acquisitions
2. **established an implementation strategy and approach.** Cambrex augmented its internal team with experienced consultants who could advise them on implementation alternatives and help in formulating the approach that they would use.

3. **conducted a conference room pilot.** The company elected to perform a conference room pilot for Ross Enterprise. The goals for this included:
  - Developing a deeper level of understanding of the software suite
  - Defining how the software would fit Cambrex' processes and vice versa
  - Developing and resolving an issues list regarding software features functions or business process factors that must be resolved
  - Working through differences driven by the different operating characteristics of the three primary business units: Continuous process manufacturing, batch chemicals, and pharmaceutical intermediates (primarily in Europe).

## First Implementation

After several months of preparation, Cambrex was ready to begin its initial implementation. The company chose the batch chemical processing unit located in New Jersey as its first project. The core team, working closely with the business unit team and implementation consultants worked through the following stages:

1. **developed detailed implementation approach.** A detailed plan was established in conjunction with the implementation team at the local division.
2. **conducted management introduction and functional review.** Review sessions were conducted with business unit and functional managers to understand the capabilities of the system, and discussed how the business process, data conversion, and training issues would be resolved through the implementation.
3. **conducted detailed business process evaluation.** Business unit processes were evaluated to assess the fit with the system and determine how the system would be configured to support the process or what changes in process would be needed to optimize use of the system.
4. **configured test system.** Based on the business process evaluation, the test system was configured to support the specific processes of the division.
5. **performed detailed training.** Using the test system, an initial round of training was performed for the business unit.
6. **surfaced and resolved issues.** At this point, any software, process or training issues were resolved. The IT team was also working through remaining

software installation and infrastructure tasks and issues at the business unit.

7. **performed data conversion.** Existing data was converted over to the new system and resolved remaining set-up items to be ready to go live.
8. **conducted second round of training.** A second round of training was conducted, with emphasis on end-user training, and the functional roles required for maintaining the system.
9. **performed final testing.** Final testing was conducted with the support of the end users.
10. **prepared to go live.** Final preparations for go live were conducted. An intense period of preparation was performed during a two-week window prior to "go live."
11. **cutover to the new system.** A weekend cutover was performed with everybody actually on the system the following Monday morning. The implementation team stood ready to assist with any issues or challenges resulting from the normal chaos of switching over to a new system.

For the first implementation, this process took about 6 months to implement the full Ross Enterprise suite. The scope of this initial implementation began with approximately 150 users and eventually reached 300 users.

From this original starting point, the Cambrex core team has performed approximately 25 separate implementations across business units and sites. The team has the ability to quickly implement Ross Enterprise in a newly acquired company over a period of 3-4 months. This has been a critical contributor to the company's ability to integrate and leverage acquisitions to achieve superior growth and business performance.

While Cambrex, overall, is a relatively large company, many of the company's units began as small, emerging companies. Thus, the company has been a witness to the kind of business transformation and improvements that are possible when a small company adopts its core ERP system early in its life and grows with it.

## Validation Program

A key element of Cambrex ERP strategy has been its overall validation program. The team took a proactive approach to complying with the requirements of Food and Drug Administration (FDA) 21 CFR Part 11 for electronic signatures and validation. As its ERP system is the focal point for manufacturing shop floor control, materials management, product quality release, and customer-facing processes, significantly impacting current Good Manufacturing Practices (cGMP), the ERP required validation.

The initial steps in its validation program were to formulate a methodology. The Company evaluated and selected

a consulting firm to assist developing and documenting the approach and methodology. Again, the company's philosophy was to be self-sufficient and to develop a repeatable process that could guide implementations across divisions and sites.

Using a cGMP validation methodology, the company worked through the Ross Enterprise data structure, performing a mapping to the cGxP predicate rules to the critical transactions. Cambrex has validated its system for those cGxP-critical transactions.

## Results

The standardization of its ERP platform has supported the Cambrex growth strategy:

- To date, the company has completed 25 Ross Enterprise implementations or upgrades. implemented or upgraded 25 operational sites/business units plus its Headquarters. The common ERP platform enabled:
  - Cambrex to better meet customer obligations through improved planning, inventory control and accuracy, and ability to control manufacturing and inventory costs.
  - A common platform and standards for a single approach to business practices, cGxP, validation, audit trails, security, and electronic signatures
  - The ability to conduct transactions in multiple languages and currencies, consolidate financials and provide detailed product costing across all business units.
  - The ability to support very detailed process specifications with as many as 12 processing stages, allowing for detailed costing capabilities and capture of all material, labor, equipment, quality testing, and waste disposal.
  - Cambrex to transact on the shop floor, streamlining operations by recording inventory movements, issues, job counts, process data, and quality test results
  - High volume transaction processing in the manufacturing and planning cycle - individual plants processing up to 400 jobs and 1000 orders per week.
  - Ross' eCommerce portal supports the Cambrex e-Commerce program. Today, over 28% of Cambrex orders are received electronically, through the Ross Enterprise Customer Portal web site, electronic trading partnerships, XML exchanges, and EDI.
  - The company implemented additional capabilities, including: electronic records and signatures, electronic batch records, integration to Laboratory Information Management (LIMS) systems, Bar Coding and weigh scale systems.
  - Ross Enterprise has become the core component of its overall IT Infrastructure.

Cambrex' ERP implementation program has been successful in supporting the growth of its business over the past ten years. Beginning with initial implementations at small, independent business units/sites, the company has been able to achieve a consistent platform across its business. With a growth-through-acquisitions strategy, Cambrex has been able to quickly integrate the acquired companies, installing the Ross Enterprise suite at the acquired company in as little as 12-16 weeks. The ability to rapidly gain visibility, control, and consistent business processes across acquired companies is a critical success factor in leveraging the business value of these acquisitions and existing Cambrex infrastructure.

## Lessons Learned & Best Practices

There are many significant lessons learned and best practices that can be gleaned from the Cambrex case study as well as from the experience gained by Maxiom Group over the years. The following 10 practices represent a summary list that can serve as a starting point for emerging Life Science companies contemplating embarking on an ERP journey of their own.

1. **formulate an erp strategy.** Adoption of enterprise business systems should begin with the formulation of an effective strategy. An ERP strategy should address key questions regarding business need & scope of an ERP solution, timing, resource requirements and a general approach to implementation. The ERP strategy should be closely aligned with the strategic direction of the company, as was the case with Cambrex.
2. **adopt core systems early.** The single most prevalent advice offered by both IT and functional leaders who have implemented ERP and other core enterprise systems is to put in these core systems early, while the company is still quite small. Lower cost, risk and resources required to implement are all major contributors to this advice. Additionally, by starting early, companies have the ability to avoid evolving inefficient, manual and paper-based processes that will need to be re-engineered later. Again, Cambrex began as soon as the business imperatives of preparing for growth through acquisition or technology breakthroughs became apparent.
3. **choose wisely.** Selecting an ERP solution should be based on a balanced set of criteria, including overall fit with the business, cost, implementation risk and the ability of the solution provider to effectively partner with your organization and manage the risk of implementation. In a recent ERP selection process for an emerging Life Science company facilitated by Maxiom Group, several vendors demonstrated deep product

functionality and industry experience. The selection decision, however, was driven by the client's confidence in Ross Enterprise's ability to manage implementation risk and be a flexible, supportive partner throughout the process leading to a better overall value proposition.

4. **let the business drive.** An ERP system is a business system. The selection and implementation process must be driven by the business functions that will be using the system to manage the business. IT must play a supporting role, but should not be driving the process. It is critical to get business buy-in to the selected system as Cambrex did.
5. **commit the right resources.** Apart from selecting the right solution, the quality and commitment of the right resources will be the determining factor for overall success. It is critical that the appropriate business and technical resources are committed by the organization. It is especially critical that an effective project manager is selected to drive the effort. Cambrex committed functional and IT resources in a way that was consistent with their approaches to implementation and had effective project managers.
6. **leverage outside resources well.** Most ERP implementations leverage outside consulting resources for successful completion. Use of outside resources can help mitigate (but does not entirely substitute for) the volume of internal resources required. Experienced consultants can bring knowledge of best practices and helps provide the organization with the confidence that they can succeed. Cambrex credited smart use of external consultants as a key factor in their successful implementations.
7. **plan the work and work the plan.** Developing a thorough implementation plan and following that plan are crucial for success. Effective planning helps retain focus, builds momentum, mitigates risk and serves as a communication tool for the organization. Whether the project will be a rapid, 12-16 week project like Cambrex or a time-phased, evolutionary approach, having an effective plan is crucial.
8. **design processes as you implement.** Which comes first, design of business processes or implementation of the system? Most quality implementations, today, utilize a parallel approach, designing processes as they implement the system. It is an iterative process designed to capitalize on the capabilities of the software without modifications while retaining the essential elements of a company's business processes. Most emerging Life Science companies have relatively immature processes that have evolved and are not based on best practices. Don't be afraid to change

these processes to capitalize on the software capabilities. It will most likely be an improvement.

9. **avoid/limit customization of the software.** Software modifications can be a source of risk and failure in major system implementations. Often, software modifications cannot be easily carried over into new releases, can create major headaches in validation, and can be a sign that business processes are not being designed in a way to optimize their performance. Successful implementations begin with a strong mandate against customization.
10. **address training in a comprehensive way.** In addition to selecting the right solution and obtaining business buy-in, training is a significant factor in user acceptance and adoption. A comprehensive, multi-level training program is critical for successful deployment and adoption of the system. The training program should be aligned with the overall culture of the organization and should be explicitly planned for.

## Conclusion

Eventually, every successful emerging Life Science company will select and implement an ERP system. Hopefully, the ideas, experiences, and lessons learned outlined in this paper will provide your organization with the confidence to develop your strategy, start early, implement wisely and effectively transform your organization to achieve commercial market success.

## About CDC Software

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