

Impact of Formula-Based ERP Applications on Pharmaceutical Manufacturers

Executive Summary

Whether you're in the process of re-evaluating your existing ERP application or looking to replace your spreadsheets, it's important to focus your search on applications with capabilities to support the unique needs of your industry.

This practical guide links the unique business processes of the pharmaceutical industry to specific software capabilities available in process-based ERP solutions. Case study references provide insight into the capabilities needed to manage variability of ingredients and finished products and processes. It also addresses how the right ERP solution can significantly improve product costing, production predictability, and scalability, as well as compliance issues related to Good Manufacturing Processes, traceability, and validation.

Whether your company manufactures over-the-counter products, prescription drugs, or is taking a new product from research and development through clinical trials, this ERP essentials guide will help you choose a solution that is right for your needs. A checklist of specific capabilities is also included for use during the evaluation process.

Introduction

Today's pharmaceutical industry is faced with a multitude of challenges, including constant industry change, competitive pressures, increased governance, and the uncertainties involved in research and development to bring new products to market. Companies are also challenged to maintain high customer satisfaction while ensuring high quality, consistency, and efficient processes that enable profitability.

An ERP solution for the pharmaceutical industry needs to address its unique manufacturing and financial businesses processes, including manufacturing formulation, costing and quality control, materials and production planning, maintenance management, validation, accounting, budgeting, planning, and forecasting.

With the right solution in place, pharmaceutical companies can improve day-to-day operations; refine and standardize product development and processes; sustain or increase customer satisfaction; ensure high quality, consistency and efficiency; meet the challenges of stringent regulations; and improve bottom line performance.

Getting Started

Most ERP applications support the needs of accounting and financial functions, but when it comes to purchasing, inventory, manufacturing and sales, they don't always meet the needs of a pharmaceutical manufacturer. Why? Most "standard" ERP applications were designed for discrete manufacturing (typically physical products that go directly to businesses or consumers, or are used as assemblies in other products) instead of process manufacturing (using a formula using ingredients to create a bulk output). If you are investing in an ERP solution, you'll want to choose an application with best practices for your industry built into the solution, without adding extra cost and implementation effort.

This practical guide examines several key areas of process manufacturing in terms of key ERP functional capabilities, data model characteristics, and enabling technologies, specifically:

- The inventory, accountability, and management of common ingredients
- The ability to predict yields, scale production, and accurately cost products
- The effect of variable product characteristics and inventory attributes, such as package weights, expiration dates, and multiple units of measure, on inventory management, order management, production scheduling, manufacturing, QC management and product costing
- The impact of the ERP architecture and design on the application's functionality and maintenance
- The ability to track and trace ingredients as well as packaging materials

At the end of this document, a summary of these critical areas is provided as a functional questionnaire to be used during your software vendor's product demonstrations. As you select the perfect fit solution for your company, you should also consider a software provider's experience in life sciences, expertise, and support. This is an important consideration that will impact your ERP implementation, and it is as important as the product architecture and capabilities.

Manage Variability

Variability impacts the consistency and quality of finished products. A good indication that an ERP application is capable of managing product variability is that it supports an unlimited number of product characteristics for both raw material and finished products. It should support user-definable characteristics as well as industry standard characteristics, such as pH, potency, moisture content, and expiration date.

Formulation and process control are the primary concerns in pharmaceutical manufacturing operations, where variability creates significant challenges for process specifications. Raw materials are purchased and finished goods are produced in a variety of quantities, potencies, and qualities. The ERP application must be able to identify these variability's, in addition to the fluctuating cost of both raw materials and packaging materials, in order to adjust production jobs.

Managing variability starts with a purchase order for raw material with specific product characteristics. At the time of receipt, these raw materials are inspected and validated against a set of tolerances. Once received, lot numbers can be assigned to raw material inventory so that it can be tracked throughout the manufacturing process.

Pharmaceutical manufacturers are often required to deliver finished products to customers that meet certain requirements. A raw material might meet one process specification, but it might not meet another. An ERP solution can provide full visibility into available raw materials inventory and their product characteristics, so that manufacturers can deliver products that meet customer requirements.

An ERP application based on formulas can be used to manage all raw materials, packaging materials, and multiple finished goods, while delivering a high level of predictability and repeatability. This formula should define the manufacturing, yield, quality, routing and costing processes. Variable product characteristics, such as potency grade, pH, or moisture content, determine the ingredient proportions and equipment settings in certain process stages.

To manage this variability during production, the ERP application should allow pharmaceutical manufacturers to make adjustments to the base formula specifications in terms of ingredient proportions and equipment settings, without affecting the definition of the original "base" specifications. Variations of a formula specification can also account for differences between plants, shifts, production lines and equipment, as well as customer requirements, such as private label products.

Improve Predictability of Scaled Production

In process manufacturing, a formula specification is designed to produce one or more finished products in bulk quantities. A batch run is expected to produce a quantity of finished products within a given range in a certain time period. For example, a chemical reaction within 10 liters of a solution takes the same time as 50 liters of the same solution in the same vessel. When batch runs are scaled up or down, the batch quantity ranges and the production times follow a "step" function rather than a linear function.

When a pharmaceutical manufacturer scales production, they must be able to rely on their ERP application to predict finished product yields and deliver consistent results in terms of quantity and quality.

Example

Since implementing their ERP solution, NexGen Pharma, a leading contract manufacturer of pharmaceuticals, vitamins, and other nutritional supplements, has achieved a 60 percent revenue growth while streamlining their manufacturing processes. The ERP application's ability to manage raw materials in its formulas was a contributing factor. For example, in situations when a formula calls for an ingredient with 10% potency but finds only ingredients of 20% potency in stock, the formula can be adjusted based up on this alternate agreement. By directing operators to dilute the inventory to achieve the specified final potency, the desired potency can be achieved. In addition, the formula can be adjusted to maintain other key product characteristics, such as total volume or size of the final product. The ability to adjust formulas is especially important to the company's over-the-counter products, since its pills and caplets must be produced to meet specific size tolerances, therefore the internal ingredients must be varied to maintain a specific strength and expected yields.

Deliver Accurate Product Costing

Accounting for all material and operational costs in the manufacturing process is one of the biggest challenges facing many manufacturers. Without accurate and up-to-date cost information, they cannot make informed decisions on key business issues, such as new product pricing strategies. A manufacturer needs to be able to link finished products to research and development costs, insurance contracts and chargebacks, cost of raw materials, and customer incentives and rebates to determine profitability.

The ERP application should include multiple costing models supporting a variety of valuation methods. All product/process costs related to ingredients, work in process, packaging, labor, overhead, quality tests, and waste streams should be captured electronically assigned to the appropriate product. Typically there are no by-products or co-products produced in pharmaceutical manufacturing, but for those that do produce such finished products, the ERP application should capture, assign and compare actual and standard costs to these products as well. Access to this information gives companies an accurate picture of the effect their manufacturing processes have on margins and profitability.

Flexible Specifications Support Multiple Processes

For discrete manufacturers, assembly and packaging are the standard processes that are executed in an ERP application based upon a multi-level bill of materials and routing instructions.

It's much more complicated in the pharmaceutical industry, when different products are being processed to meet different customer specifications. For example, a pain medication might be pressed into a tablet or it might fill a capsule; it might be packaged in a large container for a pharmacy or packaged in individual sealed plastic bottles for another customer.

The ERP application should be able to employ formula specifications to manage processing and packaging. By linking production and packaging specifications, but maintaining them separately, pharmaceutical manufacturers are able to:

- Produce different finished products that are similarly packaged
- Produce product for future private labeling
- Produce and track intermediates (such as product packaged in bulk unit that will be dispensed into smaller units after key additives are introduced)

Flexible formulas allow pharmaceutical manufacturers to model their unique manufacturing processes in a series of controllable and repeatable process stages.

Manage Multiple Units of Measure

Multiple units of measure are used in many pharmaceutical business processes: goods may be purchased in one unit of measure, stocked in inventory in another, issued in finished goods in one more, then sold in another. The ERP application should allow process managers to manage inventory in terms of bulk units of measure (weight or quantity), packaging units (bottles or packages) and random attributed (variable weights and potencies) at the same time. With this information, cost can be evaluated by potency, solid percentage, or any other unit.

Product variability plays a role in unit of measure conversions. Process-oriented ERP applications typically support user-defined and automatic UOM conversions (liquids to solids, gases to liquids) that are initiated within the manufacturing process, as well as from specific changes in inventory attributes.

From purchasing through inventory, order management through shipping, the ability to work with multiple UOMs improves both performance and customer service.

Manage Inventory Efficiently Thru Expiration Date Tracking

Managing expiration dates can be an on-going challenge for pharmaceutical manufacturers, as some substances may lose their effectiveness after a certain period of time. An ERP solution can help improve inventory management by offering better shelf-life control. It should offer basic inventory rotation methods (e.g. first in, first out (FIFO), last in, first out (LIFO), and first expiration/first out (FEFO)) when selecting ingredients for production based on the supplier or packer production dates. These selection criteria can also be carried forward when selecting product to ship to customers, such as shipping products that will have a certain amount of shelf life left once received by a customer. It should also provide alerts for non-permissible actions, such as shipping certain products or drug strengths to states where prohibited.

By ensuring that the best rotation methods and quality standards are met, the ERP application can provide tools to monitor customer specific distribution days based on the remaining shelf life of current products, significantly reduce customer charge-backs, prevent transactions for expired lots,

and automatically write off expired product. The result is improved product quality, greater customer satisfaction, and less waste from expired inventory.

Example

SeraCare Life Sciences, Inc., a manufacturer of quality control products for infectious disease testing, manages some 40,000 lots of blood related inventory. "Our ERP application enables us to manage inventory based on expiration dating of products for effective replenishing planning. The system calculates an expiration date based on the batch-creation date and typical shelf life. We can define re-test dates, because products can change as they sit on a shelf over time and their characteristics may need to be re-validated. We can even specify distribution days – the minimum number of days of shelf-life that must remain when an order is shipped."

Richard D'Allessandro
Vice President of Information Technology

Deliver Higher Quality Goods

When it comes to making quality decisions in process manufacturing, a higher degree of variability often results in a range of acceptability. An ERP application can help manufacturers to track the quality conditions of raw materials and finished goods and make better decisions about product quality. Greater variability requires more robust quality management capabilities, as well as lot management capabilities.

The ERP applications should support the definition of quality checks of raw materials and finished goods in the formula specification to ensure that they are executed in proper sequence in a certain process stage. By collecting and analyzing quality data, a manufacturer can identify problems with raw materials, finished goods, and equipment.

To reduce quality issues tied to production startup losses, manufacturing processes, and scrap and rework activities, manufacturers need real-time visibility into overall plant performance, including product quality and equipment performance trends. By collecting relevant real-time data from plant operators and existing automation, real-time performance management measures rates, yields, utilization, overall equipment effectiveness, and per-unit cost data. When this real-time performance data is evaluated, performance issues can quickly be identified so that repetitive problems can be eliminated and issues can be resolved.

Expedite Track and Trace

Traceability is crucial ERP function that is essential to the pharmaceutical industry; not only is traceability required by government regulations, it could be a matter of life and death in certain situations. The solution must be able to track the lot numbers and capture identifying information for every raw material, plus other data that is essential to the process. Due to the batch run quantities produced in process manufacturing, a process-oriented application must be able to trace and track an ingredient even if it is only present in miniscule amounts.

The ERP application should be optimized for full lot traceability from raw materials through production, tracking finished goods from supplier invoice to customer invoice, and identifying the raw materials and resources that produced the finished products. As customers and regulatory agencies require process manufacturers to deliver 100% accurate lot traceability within a short period of time, bi-directional lot tracing allows manufacturers to respond to product recalls in minutes, rather than days.

An ERP application simplifies the procedures necessary to demonstrate compliance to customers and regulators. Thorough records of quality management and lot maintenance should be easily accessible, as well as an audit trail of changes that occur during the process.

Facilitate ever growing regulatory compliance

Pharmaceutical companies must comply with very stringent regulatory requirements designed to protect public health, including current Good Manufacturing Practices (cGMP), the U.S. Food and Drug Administration's 21 CFR Part 11 electronic signature requirement, and pending ePedigree requirements for prescription drugs. These requirements provide unique challenges to pharmaceutical companies as they attempt to balance compliance and profitability. Failure to meet these regulations can result in significant fines and missed opportunities.

The ERP application should help companies monitor and manage their critical manufacturing processes to meet the requirements of cGMP. The guiding principles of cGMP aim to build quality into a product while monitoring all aspects of the production process and material flow. These standards require an organization to demonstrate that its products are consistently produced and controlled following a set of guidelines that covers all aspects of the manufacturing process, product storage and transport, serial number tracking, and traceability.

The pharmaceutical industry is given a set of rigorously enforced regulations, such as 21 CFR Part 11, which establishes criteria for the FDA to accept electronic records as equivalent to paper records, and electronic signatures as equivalent to traditional handwritten signatures. While Part 11 does not require companies to automate their record keeping, it does require those who use automated systems to ensure that it is used in a compliant manner.

The ERP application should provide built-in electronic signature capabilities to help pharmaceutical companies take advantage of the benefits associated with electronic records while complying with FDA regulations. Electronic signatures prove proper inventory movement and quality checks throughout the manufacturing and delivery process. Look for robust security methods that include passwords, role-based accessibility to records, delegation capabilities, and network security. The application should also support complete audit trails, capturing all executed actions, signature histories, and approval signoffs.

In many states, laws have been passed requiring an ePedigree for certain drugs that protects the consumer from contaminated or counterfeit drugs. An ePedigree is simply an electronic document that includes specific information about the drug and its movement through the supply chain, such as the lot number, potency, expiration date, manufacturer, distributor, and a unique identifier of the unit. The ERP application should be able to facilitate compliance with ePedigree regulations through built-in capabilities or add-on packages.

Validation is another key aspect of the regulation process, requiring companies to demonstrate with a high degree of assurance that a specific process will produce a product that meets established specifications and quality standards. When validation capabilities are incorporated in the ERP application, companies can save time, energy and resources while maintaining FDA compliance. With inbuilt processes, the ERP application ensures that every step, process, and change has been evaluated and documented.

Support new product development and production

As the pharmaceutical industry undergoes intense change and competition, manufacturers are rising to the challenge of developing new medicines and processes, even in the face of lengthy development cycles and high research and development costs. To be successful, these manufacturers must accelerate new product development while controlling and tracking costs and maintaining compliance throughout the process. The ERP application can help pharmaceutical manufacturers to reduce operational costs, reduce risk, and maintain the records necessary to pass clinical trials and bring new products to market.

To be competitive in the pharmaceutical industry, manufacturers may rely on a network of business alliances, partnerships and ventures throughout the product lifecycle, enabling them to develop and bring new drugs to market in the most efficient and cost-effective manner possible. The ERP application should facilitate collaboration, allowing the responsible groups to segment and monitor the various tasks necessary to bring a product through the stages of regulatory approval, as well as manufacturing, packaging, and delivery.

Minimize system configuration

Look for an ERP application that includes predefined labels reflecting standard terminology in the pharmaceutical industry, extending from label naming conventions to database table and field naming conventions. Pharmaceutical manufacturers should expect to see formula and ingredients naming conventions reflected in the labels used in screen transactions and reports. These predefined labels can reduce the initial system configuration and ongoing maintenance costs, as well as reduce the risks involved in performing the activities.

Field level definition is commonly overlooked when investigating an ERP application. For example, tracking a very miniscule or trace amount of an ingredient in a finished product requires certain data fields to be defined with the right number of decimals on file.

Summary

If you're a pharmaceutical company searching for the right ERP application or are in the process of re-evaluating your current ERP application, you should focus on applications with a strong process manufacturing foundation that easily manages the unique requirements of your industry.

By investigating available ERP applications, you will discover that a formula-based ERP application can successfully manage the variability of products and processes, accurately account for all raw material and finished products, and significantly improve product costing, production predictability, and scalability far better than a generic or discrete-oriented application. Designed with the right

baseline functional capabilities, data model structures and enabling technologies, a process-oriented ERP application can support your business requirements with minimal customization and consulting services. It can even help you establish and maintain the processes and records necessary to comply with industry regulations and standards. A focused solution will conform to your business rather than requiring you to change your business to use it, while reducing operating costs and improving customer service levels.

ERP Checklist for the Pharmaceutical Industry

To help you evaluate and select the ERP application that is right for your business, use this checklist to create your own side-by-side comparison of ERP applications.

Improving production through formula management

- When stages within a formula are linked together, can the output of one stage become the input for the next stage, without having to perform an intermediate inventory transaction or define an unnecessary intermediate product?
- How does the system handle “conversion,” where the actual output is converted from the planned/scheduled output?
- Can yield be measured by operation and across the process?
- Does the system support different units of measure throughout the process specification (e.g., variable weights, units, pounds, cases, barrels)?
- Does the system support input-driven (for supply) as well as output-driven (for demand) process specifications?

Managing the variable characteristics of products

- Can the system update actual product characteristics based upon QC values recorded during manufacturing?
- Can the system accept or modify formulas based on actual values, such as moisture content or potency?
- Reducing customer chargebacks and inventory write-offs with expiration date management
- Can distribution days (minimum days of shelf life that must remain when product is shipped) be defined separately from standard shelf life?
- Can the system net the quantity of product reaching expiration from available quantity if demand does not consume all available inventory of that lot/batch by its expiration date?

Improving product costing

- Can actual costs be tracked and compared to standard or estimate cost?
- Do you have options for standard cost, weighted average cost or actual cost by lot?
- How are costs for co-products and by-products handled?
- Can the estimated cost of a process specification be compared with the actual cost of a job/batch?
- Can future costs be used to provide what-if comparisons of total cost?
- Can costs be date driven?

Managing multiple units of measure simultaneously

- Does the system support different units of measure for receiving, producing, storing, and selling the same item?
- Can the system support catch weights with verification to minimum and maximum catch weight?
- Can the system support net weight or standard weight products (and track give-away)?

Meeting regulatory compliance

- Does the system provide adequate record keeping to meet FDA and customer requirements?
- Can product characteristics be used to force or limit the selection of specific lots/batches based on matching the actual characteristic values to a specific customer request?
- Does the solution have eSignature capabilities? Does it support necessary validation? Is ePedigree supported?

Accelerating product recalls through lot traceability

- Does the system maintain full forward and backward lot/batch integrity when product is converted during manufacturing, without losing any audit or trace linkages?
- Are lots tracked at every step in the process (from receiving to manufacturing to shipping), capturing materials, production resources, people, processes, steps, and time?
- Is the traceability program capable of handling recalls and mock recalls in minutes instead of hours?

To learn more about how CDC Software can meet your company's unique challenges, **contact us.**

CDC Software | The Customer-Driven Company™

www.cdcsoftware.com

+ 1 770.351.9600 | info@cdcsoftware.com

CDC Software | 2002 Summit Boulevard, Suite 700 | Atlanta, GA 30319 | USA

Copyright© CDC Software 2011. All rights reserved. The CDC Software logo is a registered trademark of CDC Software.

Order Number: CDC_ERP_FSWP_Essentials_Pharmaceuticals_US