BatchMaster ERP
for Pharmaceuticals

BATCHMASTER®
ERP Software for Process / Batch Manufacturers

Introduction

BatchMaster Software offers an industry specific ERP solution that helps pharmaceutical companies streamline their operations and bring products to market, faster and more efficiently, while complying with ever more stringent regulatory mandates. Whether you private-label, co-pack or produce your own line of over the counter medications, brand prescription or generic drugs, BatchMaster ERP for Pharmaceuticals supports your unique manufacturing requirements in product development, production, quality, costing, and compliance, while supporting all of your sales, accounting, warehousing and distribution needs.

Overcome Industry Challenges

Whether pharmaceutical manufacturers are heavily investing in pre-clinical development and clinical trials or producing generic drug and OTC medicines, these companies are looking to streamline and optimize the various financial and manufacturing processes run at their plants or their contract manufacturing plants in order to manufacture superior products more efficiently. This enables manufacturers to increase sales volumes to their customer base of healthcare professionals, physicians, commercial stores and pharmacies.

From a financial and liability perspective, there are pharmaceutical companies that are organized into multiple divisions or business entities, ranging from sales to marketing to manufacturer to distributor, where manufacturing and distribution may be managed by one or more outside contract manufacturers. Each business partner wants to manage their own process requirements (e.g. product development, production), and wants the means to easily transfer ownership of products and share data amongst partners.

Here are some of the challenges that were faced and overcome by pharmaceutical customers employing BatchMaster ERP:

Maintaining a complete set of Master Batch and Batch Manufacturing Records

Growing pharmaceutical manufacturers who rely on paper-based and people-intensive processes to document every step in their production processes are finding it ever increasing difficult to comply with ever more stringent FDA regulatory mandates, especially in terms of managing Master Batch and Batch Manufacturing records. These manufacturers are looking for an electronic method to efficiently document and associate formulas, production jobs, procedures, processes, transactions, and journals in a way that is compliant with 21 CFR Part 11 Regulations.

Ensure Product Efficacy

Product developers are sometimes challenged by formulas for tablets, capsules, powder and liquid blends that contain one or more active ingredients with varying potency levels. They are looking for help in quickly and easily adjusting formulas to reduce costs while maintaining their effectiveness.

Ensure Product Quality

Pharmaceutical manufacturers want preventative controls in place to quickly and effectively test products and ensure optimal equipment settings, as well as have the means to quickly investigate and determine the impact of all encountered quality issues, then adjust existing settings and procedures.

Ensure Product ePedigree

Lot traceability is of major concern due to the impact of these products on the lives of the public. The creation and assignment of lot numbers at the time of receiving and production is one challenge faced, so automating these processes is critical. When performing a product recall, the ability to quickly track and trace suspect products from suppliers to customers, from customers to suppliers or anywhere within production in minutes, is a necessity.

Optimize Production Scheduling

Demand planning and production scheduling of various stages, such as mixing, encapsulating, compressing, polishing, and packaging, are all important whether manufacturing is make to stock or make to order. Companies that make their own gel encapsulations or outsource their production need to effectively calculate the weight requirements, then schedule their production with the liquid blends that will fill them.

Increase Margins and Profitability

To increase the bottom line, pharmaceutical companies need to analyze their expected vs actual costs from conception thru production to customer shipments. Managers want better visibility to raw material costs, based upon last purchased, standard and projected prices, and accurately capture and track the static, scalable and tiered costs associated to labor, energy and other resources. In addition, purchasing wants to negotiate better terms for those raw materials for which demand planning has determined there is a consolidated demand. And to increase the top line, sales recognize that they can retain existing customers and gain new ones with demonstrated predictability, scalability and compliance across their company's operations.

Key Manufacturing Features

BatchMaster ERP for Pharmaceuticals streamline samples, formulation, production, quality, costing, compliance, planning, and scheduling using preconfigured templates, automated processes, and customized dashboards and reports.

Master Batch and Batch Manufacturing Record Management:

To facilitate the accurate capture and reporting of transactional information, the system provides built-in document management, automated workflows, audit trails, electronic signatures, versioning control, and archiving.

Item Physical Properties:

The system allows users to define the unique physical characteristics of their finished goods in terms of soft gel capsules, tablets and other product types. Prebuilt templates support product size, shape, color, and thickness, as well as rows, cavities and other Bills of Material (BOM) properties. These physical properties are all addressed in the product development, production, QC, QA and planning processes.

Lab and Samples:

Internal and external requests can be managed from sales quotation and formulation to production and acceptance, including recording all customer communications during this cycle. Finished goods formulas address serving sizes, product types and size, and thousand quantity yields. In addition, formulas can create any required intermediate gels, powders and syrups used as a base in your finished goods. With visibility to ingredients' physical characteristics and potency levels, formulas can be quickly adjusted to meet their specifications, based upon expected losses (e.g. potency degradation). Developers can perform "what if analysis" and compare formulas side by side. And when necessary, theoretical items and substitutions can be used in the formula calculations. Multilevel workflows expedite the review and approval of formula raw materials, costs, quality and packaging across departments. Most importantly, all formula transactions, including management sign offs, are captured and maintained in the Master Batch Records.

Inventory:

BatchMaster ERP captures, manages and reports on inventory levels in terms of weight, volume and units, as well as quality statuses, lot numbers, and strengths.

Planning and Scheduling:

Standing orders, sales orders and forecast entries can be used as finished goods demand inputs; inventory levels, batch production jobs, and receipts can be used as supply inputs. An accurate, detailed plan for batch production orders can be generated down to the various production steps or process cells within the production lines. Planning and scheduling takes into account the rates and capacities of mixing, encapsulating, compressing, polishing, and packaging process cells. Multiple batch jobs can be sequenced and scheduled in series or parallel, based upon the final step in producing a finished good. For example, gel cap production can be produced in parallel with fill liquid products as well as managed independently. To ensure these batch jobs yield their expected results, the system can generate the required purchase requisitions of specialty ingredients, hard caps and other raw materials to avoid shortages or rescheduling.

Batch Production:

BatchMaster ERP aggregates demand for finished goods, creates the optimal number of batch jobs across the production stages or process cells, allocates the best inventory and back schedules the batch jobs. To assist in production calculations, the amount of gel required to produce the formula batch size is automatically calculated based upon serving sizes, batch sizes, active ingredient potencies and user defined losses. Recipes can be dynamically adjusted to compensate for available inventory characteristics (e.g. pH, strengths, etc.) in order to meet specified target characteristics. Batch job releases and completions can be managed on an individual basis, which initiates all the necessary inventory pulls, QC tests and manufacturing instructions. Certain batch jobs can be linked together and back scheduled or sequenced using our Super Batch feature. Manufacturers can manually capture inventory usage or automatically back flush inventory when closing batch jobs, as well as capture actual costs and other batch job data.

QC, QA, Nonconformance and CAPA:

System libraries and approval workflows for sample vendor inspections, equipment checklists, CAPA procedures, product QC tests and acceptance quality limits (AQL) can be established within BatchMaster ERP. Instructions and tests can be planned and executed against receipts, order shipments, stored inventory, and production line equipment. Sample vendor inspection results will validate vendor certifications. Instructions can be informative in nature, such as printing a relevant document. Some may simply require acknowledgement after presenting the information to a user. Product QC tests for potency, hardness, thickness, and disintegration require user data collection and system validation. When a nonconformance situation arises, QA performs a root cause analysis, revises procedures and dispositions the affected goods, based upon defined CAPA procedures. Customizable COAs can be generated upon batch job completions. Most importantly, all production and quality related transactions, including management sign offs, are captured and maintained in the Batch Manufacturing Records.

Costing:

Raw materials costs based upon last purchase price, standard costs, or projected costs are rolled up along with fixed, tiered and scalable labor costs. Cost estimates can be managed during product development of product formulas, including intermediate bases, and packaging bills of material. Actual costs, yields and other KPI's are captured during production, and can be compared against projections in a variety of analytic reports.

Compliance - Lot Traceability and Labeling:

Lot number information is captured or auto generated at the time of receiving, auto generated for intermediates and finished goods, and then validated during finished goods distribution. A bi-directional view of lot controlled inventory enables users to track the creation and movement of suspect products from delivery to shipping, shipping to delivery, and anywhere within production. BatchMaster ERP generates FDA, GFSI and GS1 related documents, customized recall reports and personalized customer letters. All key transactions are maintained in history logs for auditing purposes, including formula approvals, batch job changes and QA releases.

Mobile:

Warehouse activities that support receiving through production to shipping tasks, including manufacturing related inquiries, QC related inspections and instructions, can be executed via mobile devices.

Dashboards and Reporting:

Customizable role-based screens provide visibility to critical manufacturing data, including inventory consumption and balances, actual versus expected yields and costs, and quality control results and trends.

Key Front Office Features

Available as a total financial and manufacturing ERP solution, BatchMaster ERP for Pharmaceuticals adds a tailored front end to its back end and manufacturing capabilities. Front office modules include:

Accounting and Financials:

Capture, measure, analyze and report the cost of doing business with functions for GL, AP, AR, Multi-Currency, Bank Reconciliation, Budgeting and more. The complete solution serves every facet of your ERP system requirements.

Sales:

Efficiently and accurately capture customer demand from business partner EDI transactions, eCommerce websites and customer portals. Convert sales quotations into customer samples, then track and report on the status and profitability of every customer campaign, quote and order shipment, including their discounts and promotions.

Purchasing:

Employ economies of scale to purchase raw materials from approved, certified vendors to feed planned batch production jobs created from demand planning.

Maintenance:

Plan, schedule, and execute predictive and preventive maintenance activities against production line and warehouse equipment to optimize equipment availability and utilization.

Distribution:

Effectively manage store replenishments, inbound and outbound activities across one or more facilities, as well as warehouse transfers.

Recognize These Benefits

BatchMaster ERP for Pharmaceuticals enable companies to recognize greater profit margins, gain greater market share and improve their bottom line.

Rapidly Develop New Products:

Your team of product developers will have the tools to quickly introduce new brands, generics and OTC medications to the marketplace, as well as develop line extensions of your existing portfolio. Advanced programming reduces your time spent on tedious, error-prone manual calculations in designing, updating and approving products that meet your targeted physical and financial characteristics.

Better Inventory Control:

You can gain control over the storage and movement of narcotics and other high security products in restricted areas within your plants. Accurate, granular demand planning and production scheduling optimizes your procurement and production of raw materials and finished goods, respectively, which will give you better control over inventory balances and space utilization within your plants.

Quickly Scale Up Production:

Automation of your batch and continuous flow production processes reduces the need for manual intervention. Dynamic recipe adjustments, gel cap optimization, auto sizing and scheduling of batch job all work together to streamline production, while reducing the delays, risks and costs of operational downtimes. The establishment of a comprehensive, online quality program allows you to improve current processes, keep production line equipment settings at their optimal settings and ensure your manufacturing processes can meet the increased in demand.

Improve Product Quality:

Ensure your corporate standards are being met in terms of your finished good sizes, shapes, colors, and thicknesses, as well as container rows, cavities and other packaging properties. Continuously monitor your inbound deliveries, product lines and outbound shipments to ensure continuous flow of quality products to your customers. With an established comprehensive quality program you will reduce the cost of chargebacks and returns.

Avoid Customer and Industry Fines and Penalties:

Keep compliant with FDA-21 CFR, USDA, HACCP and other federal regulation. Bi-directional lot tracing enables you to zero in on suspect products in minutes - minimizing the scope of any possible recall. You can now establish effective mock recall programs with your suppliers and customers to ensure product ePedigree across the supply chain. And with a thorough and easily accessible audit trail of key business transactions, you will be in compliance with your auditors' record-keeping requirements.

Increase Sales and Reduce Overall Costs:

Leverage BatchMaster ERP's quality, traceability and compliance capabilities not only to retain your valuable customers, but to gain new ones. All this while reducing your costs, first during product development and continuing to realize savings by utilizing demand planning and production scheduling to optimize your manufacturing process. And by electronically maintaining Master Batch and Batch Manufacturing records, you can significantly reduce the costs associated with paper document printing, storage and retrieval.

Improve Management Reporting and Analysis:

Customizable role-based screens provide you with accurate, real-time visibility to those key metrics that will help you to make better informed decisions, faster, and maintain your competitive edge.

Take The Next Step

BatchMaster ERP for Pharmaceuticals is a leading, off the shelf solution for your business. It's designed for your industry and gives you greater control over your business, from procurement and manufacturing to sales and customer service. This end to end financial and manufacturing solution will deliver adaptability, accountability, reliability, scalability and traceability - resulting in greater profitability.

As an industry focused solution provider, BatchMaster Software is ready to help you meet your business objectives, so *please contact us today* to discuss your business requirements:

BatchMaster Software
Tel: +1 949.583.1646
Email: info@batchmaster.com
www.batchmaster.com