

O2 Life Sciences ERP



Escape Velocity Systems

"The heavily regulated environment that Life Science companies operate in requires a structured approach for implementation of ERP. Risk assessment, configuration specifications and change management during implementation result in a quality documentation package that withstands FDA scrutiny, reduces implementation costs and provides the foundation for managing the system throughout its life cycle...that's what O2 Life Sciences ERP provides."

*- Phil Sumner
Director/Sr. Validation Engineer
Mangan, Inc.*





Elevate Performance,
Productivity & Profitability
with
O2 Life Sciences

Life science manufacturers face more complex and critical requirements than any other industry. Regulatory compliance, quality control, risk mitigation and Good Manufacturing Practices (cGMP) are challenges that require operational visibility that not only includes current data, but gives a glimpse of the future. Managing information in external databases doesn't meet the real-time needs from across many departments and function. O2 Life Sciences is a complete enterprise management solution tailor-made for life science manufacturers. The solutions to solve your business and regulatory challenges require more than a complete knowledge of your industry. It requires a thorough understanding of how your business operates. O2 Life Sciences was developed to help life science manufacturers manage their entire operations with insight; the competitive advantage that can make the difference between surviving and thriving.



Life Science Industry

Business Issues

Focused on Industry Challenges

Meeting strict global regulations, launching new products, quality management and reducing risk are key challenges to a life sciences manufacturer's profitability. To meet the challenge, you need clear, accurate and timely visibility across your whole enterprise; from sales and production quality to purchasing and inventory control. Real-time access to information from all corners of your organization will help you keep your finger on the pulse of your company.

Escape Velocity Systems understands the needs of life science manufacturers are unique and require a great understanding of customer demands, quality and regulatory requirements, and current Good Manufacturing Practices (cGMP). Inherent in the O2 Life Sciences ERP is that understanding, which comes from years of industry expertise developing tools and real solutions that have helped life science manufacturers realize a competitive advantage.

Where you are today, where you're going tomorrow, Escape Velocity Systems is uncompromising in its commitment to be your business partner for life.

O2 Life Sciences Industry Divisions

The O2 Life Sciences ERP provides solutions for life science manufacturers in the following segments:

Pharmaceuticals: Includes both emerging pharmaceutical/ biopharmaceutical and generic pharmaceutical manufacturers. O2 Life Sciences ERP supports the planning, material controls, production and visibility from the shop floor and distribution.

Biotechnology: O2 Life Sciences ERP can help biotechnology companies manage rapid growth in very short time frames. Our ability to provide automation with full validation makes us attractive to biotechnology companies experiencing tremendous growth.

Medical Devices: O2 Life Sciences ERP supports Class I, II and III device manufacturers. The solutions allow for lot and serial number tracking and shop floor control to ensure you are operating in compliance and in accordance to cGMP.

Risk Mitigation & Recall Protection

- Cradle to Grave Lot Tracking
- Auditing & Security
- Validation

O2 Life Sciences ERP automates your most critical functions enabling you to minimize the risks of non-compliance while keeping your operational costs down to maximize profits and facilitate growth. Potential costs associated with recalls are growing increasingly higher. O2 Life Sciences helps you monitor, control and track your vital resources and enables full traceability of activities and materials.

Operations throughout the entire supply chain must be addressed in order to increase your control and minimize risk. The O2 Life Sciences ERP is an auditable and secure solution providing manufacturers with the tools to manage all aspects of the process to reduce risk and cost-effectively manage compliance.



“When we found out that the company we hired to implement a new ERP system didn’t have the resources to complete the job, we reached out to EVS for help. That decision turned out to be a smart one. EVS understood how vital it is that our ERP system accurately reflect our business model. If you are going to invest time and money to implement an ERP system, I recommend your first call be to EVS.”

*- Deb Kastelic
Training Director, ARSO
NAS Medical*

Inventory Management, Production Efficiency & Managing Costs

- Inventory Forecasting
- Sales Forecasting & Inventory Requirement Planning
- Certificate of Analysis Tracking (C of A)
- Multiple Unit of Measure Calculations and Batch Sizing
- Capacity Resource Scheduling
- Flexible Pricing

Daily challenges of a life sciences manufacturer are numerous and complex; with multiple products and formulas, ever changing production planning, operational capacity scheduling, product expiration dates and batch yields.

O2 Life Sciences ERP understands the complex and unique inventory requirements of a life sciences manufacturer. Effective inventory management requires an ability to forecast product demand and inventory levels, to notify of product expiration, to manage product specifications, quality control status and raw material vendor certificates of analysis (C of A). To make the inventory management even more efficient, O2 Life Sciences provides Business Intelligence tools for powerful, flexible and graphical management reporting.

The O2 Life Sciences ERP operates the way you do and offers robust tools to help manage your operations. O2 Life Sciences helps life science manufacturers maximize R&D and production efficiency with multiple unit of measure calculations. In addition O2 Life Sciences provides finite capacity scheduling to optimize production schedule based capacities and constraints of your plant.

Understanding costs from R&D through production make managing profitability a must for life science manufacturers. O2 Life Sciences offers real-time cost data helping you track material costs (including intermediates), labor, packaging and finished goods. In addition, "What-if" cost-analysis to help make pricing decisions easier, improve your bottom-line with better visibility throughout the entire budget, pricing, and analysis process.

Calculating fees, rebates and non-standard pricing can be difficult for complex life science manufacturers. Let O2 Life Sciences ERP reduce the difficulty of pricing, rebates and chargebacks by allowing you to better manage pricing at all levels including; customer, product, region, and calendar. Gain real insight into your profitability and identify variances quickly with real-time information.



Regulatory Compliance, Quality Control & Validation

- Formula Security & Management
- Restricted Lot Hold
- Enhanced Implementation Documentation (GAMP 5 Requirements for Commercial Off the Shelf (COTS) Software)
- Cradle-to-grave lot tracking

Customers, regulatory agencies and distribution partners insist on high product quality and delivery standards from your company. The O2 Life Sciences ERP was developed to easily satisfy these strict standards from the regulated environment of life science manufacturing and distribution. By automating processes such as lot tracking you can significantly lower the time and overhead associated with following your product's life cycle. The O2 Life Sciences ERP provides the tools to facilitate compliance while reducing your operating costs.

Quality control through security, audit trails and validation are critical and extend throughout O2 Life Sciences. Centralizing information enables better control and security by eliminating the need to maintain information in multiple databases, thereby reducing error prone manual tasks. The O2 Life Sciences ERP was developed to centralize information from all aspects of your organization and provide real-time information to all functions of your company.



O2 Life Sciences Solution

Quality Control

With the Quality Control Module you can define a battery of tests to perform for purchased materials or manufactured products and set the acceptable range for the QC results. If a test fails, the lot can be placed either on restricted or complete hold. A “work queue” can be used to help alert quality control personnel of products which need to be tested and automatically generate a test schedule for production batches.

Auditing & Security

O2 Life Sciences ERP provides the necessary tools and facilitates compliance with government auditing and security regulations, including the Sarbanes-Oxley and the FDA 21 CFR Part 11. There are many systems that can process your data, O2 Life Sciences goes one step further by helping you validate and audit your data.

Formula Management

O2 Life Sciences ERP combines powerful formulation and analysis with formula management capabilities such as formula group security and an R & D notebook. The formulation module takes full advantage of the strong physical property module. With O2 Life Sciences, you can formulate to multiple specifications, performing many complex calculations quickly and accurately, eliminating the need for complex and mistake-prone spreadsheets.

Production

The Productions module provides powerful operational and analytic tools to help process manufacturers maximize efficiency and

intuitively analyze historical operations. Whether you produce complete batches, require finished goods to ship before a batch is closed or operate in a “continuous flow” environment, O2 Life Sciences ERP can easily facilitate your manufacturing method. The “Active Role Interface” is a completely customizable workbench which provides a powerful tool to manage your operational schedule.

Costing Analysis

The Cost Set Module for O2 Life Sciences ERP allows users to define multiple standard cost sets. Each cost set can have the same inventory items or different groupings. A user can then use a cost set to roll up finished good costs to perform “what-if” scenarios. With each scenario, the expected impact of the cost change on finished goods can be determined. Simplify the updating process by utilizing a linked Excel spreadsheet. When done, simply click “import” and your standard cost set in O2 Life Sciences will be updated. The Cost Set Module can also be utilized to roll up costs to other inventory buckets such as replacement cost and landed cost.

Compliance Reporting

For many process manufacturers, compliance reporting such as MSDS, SARA and HAPS are a legal requirement. The Compliance Reporting module is a dynamic reporting solution designed for the complex demands of your organizations federally regulated requirements. With the Compliance Reporting module, you will save time and money by enabling your organization to quickly and accurately generate compliance reports, streamlining the compliance reporting process, eliminating duplication of entry and maintaining a seamless workflow.

The screenshot displays the O2 Lot Recall application window. The title bar reads "O2 Lot Recall". The interface includes a menu bar with "Main" and a toolbar with icons for Sales Orders, Purchase Orders, Production Orders, Lot Reconciliation, Implicated on Hand, Word Mail Merge, and E-Mail Merge. Below the toolbar, there are three main sections: "View Backwards Hierarchy" (showing a tree view of lot numbers), "Purchase Orders" (displaying a table of order data), and a bottom navigation bar with buttons for "Enter Items and Lots", "View Backwards Hierarchy", and "View Forward Hierarchy".

Vendor	Stock Qty Received	Stock UOM	LotNo	Received	Received By	Address	City
Advantage Consulting	100000.00000000	Pound	01-849434	03/04/2007	admin	110 City Blvd. West	Huntington Beach
Advantage Consulting	25000.00000000	Pound	01-8954	03/04/2007	admin	110 City Blvd. West	Huntington Beach
Advantage Consulting	25000.00000000	Pound	09-7655	03/04/2007	admin	110 City Blvd. West	Huntington Beach
Advantage Consulting	20000.00000000	Pound	89-3636	03/04/2007	admin	110 City Blvd. West	Huntington Beach
Advantage Consulting	10000.00000000	Pound	14-8952	03/04/2007	admin	110 City Blvd. West	Huntington Beach
Advantage Consulting	45000.00000000	Pound	70-89151	03/04/2007	admin	110 City Blvd. West	Huntington Beach
Advantage Consulting	75.00000000	Pound	01-71812	03/04/2007	admin	110 City Blvd. West	Huntington Beach
Advantage Consulting	2500.00000000	Pound	40-8514	03/04/2007	admin	110 City Blvd. West	Huntington Beach
Advantage Consulting	6500.00000000	Pound	01-4514	03/04/2007	admin	110 City Blvd. West	Huntington Beach
Advantage Consulting	8500.00000000	Pound	01-25152	03/04/2007	admin	110 City Blvd. West	Huntington Beach

Advanced Planning & Scheduling

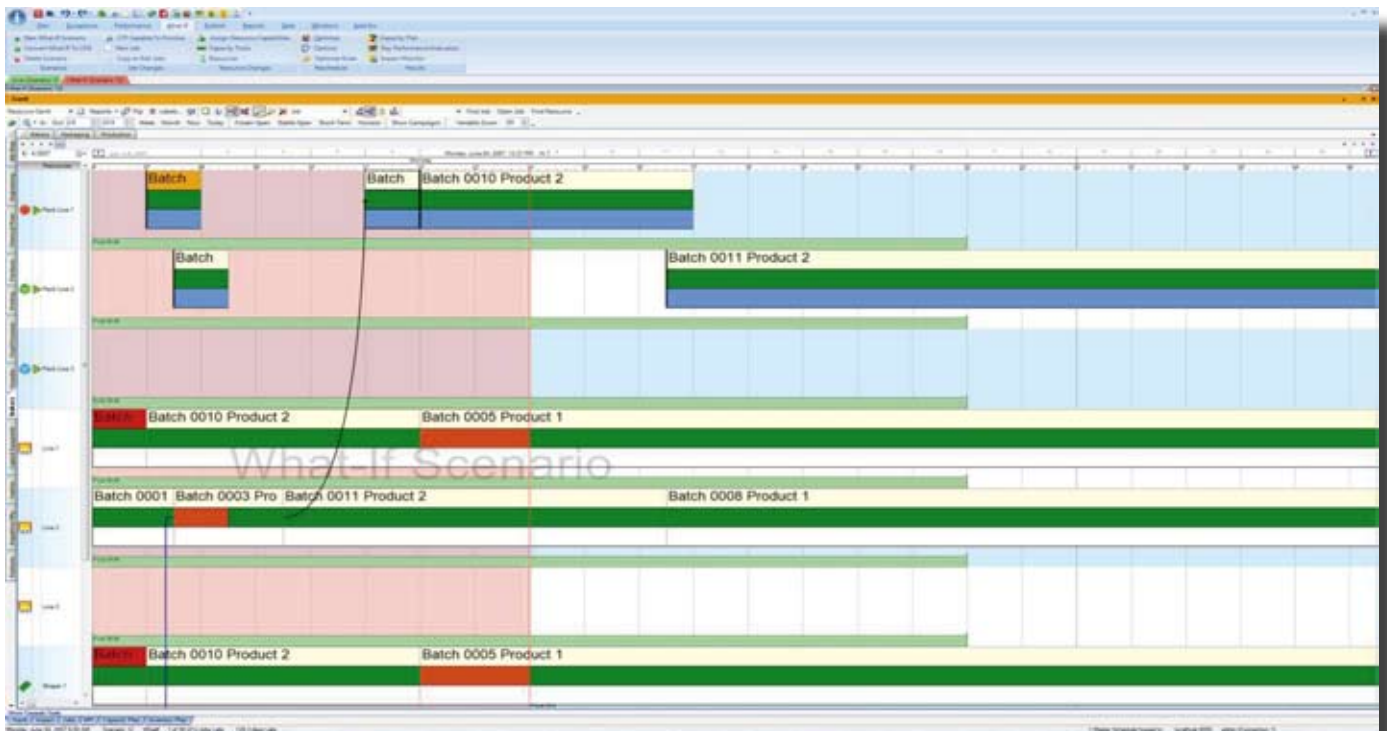
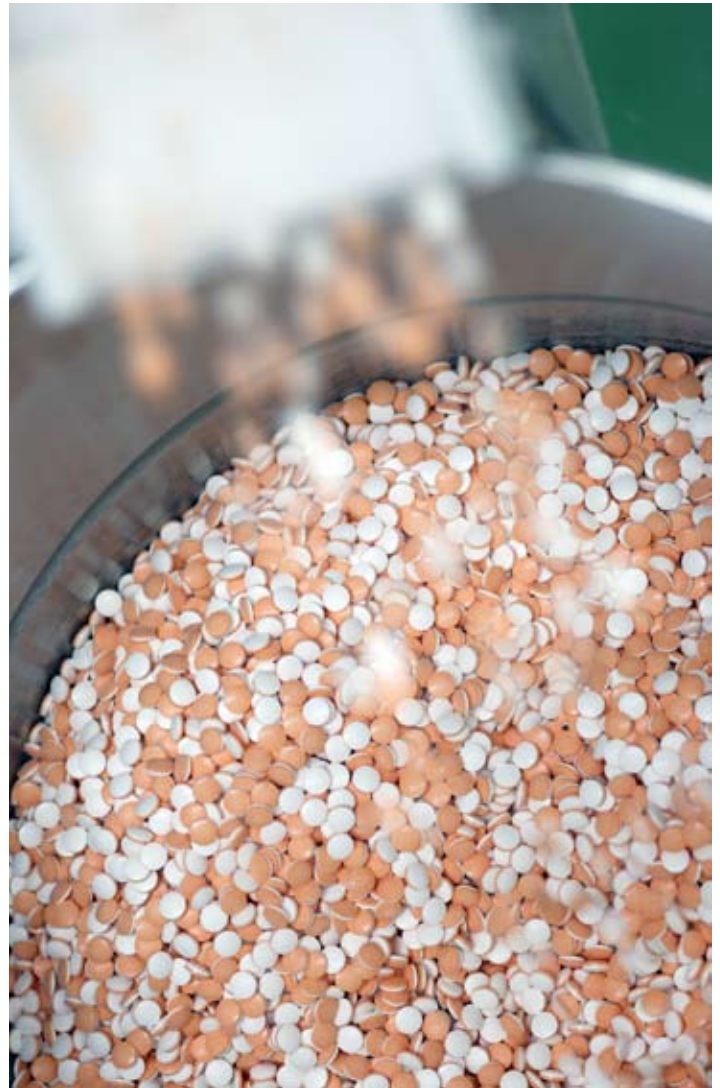
Advanced Planning & Scheduling module has the ability to take an unlimited number of constraints into account and automatically alert planners to any violation. The Microsoft.Net architecture allows for easy addition of custom constraints unique to your business for production of schedules that respect your real-world requirements. The result is maximum production output, reduced time lost to cleanouts, and a planning process that is easy to manage.

EDI

O2 Life Sciences ERP offers more than just EDI integration software or network services. A modular approach enables O2 Life Sciences ERP to provide a comprehensive yet flexible EDI solution that delivers unparalleled scalability.

Forecasting

O2 Life Sciences ERP brings forecasting technology together with dynamic inventory policy simulations. O2 Life Sciences ERP makes it easy to experiment with alternative supply strategies and see the effect on service and projected inventories immediately.





“Our consulting staff receives a certification through a pharmaceutical industry training program, focusing on FDA 21 CFR Part 11 requirements. From my personal experience of managing sensitive IT operations for one of the world’s largest pharmaceutical companies, I understand the stresses and duties associated with strict federal regulatory guidelines. I’ve brought my experiences with me to EVS and have helped to implement process and structure to support strict compliance for this industry.”

*- Scott Kameron, Director of Operations
Escape Velocity Systems*

Landed Costs

The Landed Costs Module allows you to combine actual shipping, handling, and import fees costs into the total cost of goods helping you manage profitability. You’ll also be able to more effectively record actual costs incurred in acquiring goods by including duty, freight, and insurance (many times entered after the fact) as well as capture additional costs incurred later, such as destination fees and freight (often used in the valuation of inventory).

Streamline your procedures and correctly update inventory values by using multiple allocation methods including; by weight, volume, per unit, extended amount, and equal pars per line. Landed costs are automatically allocated to inventory goods received and then posted according to a specific project, avoiding duplicate, manual entries. Landed costs not known at the time of receiving can be entered later and allocated across multiple purchase orders, helping improve accountability.

Material Requirements Planning (MRP)

MRP is integrated with finite scheduling to provide a true closed loop system, which utilizes actual demand and transaction data from sales orders, purchase orders, inventory management, and work orders. It also provides integration with demand forecasts for items based on advanced replenishment rules and formulas, thus enabling more accurate material plans by item. Planners have total control over generation criteria including start and stop dates, planning bucket sizes, and a demand time fence. Multiple MRP versions provide greater flexibility and simulation/comparison capabilities. MRP may be instantly accessed for material data from sales orders, purchase orders, work orders, and inventory.

Enterprise Asset Management

Enterprise Asset Management speeds the information flow between the enterprise business system and the maintenance department to accelerate performance and help you achieve maintenance excellence.



Mobile Warehouse

Purchase Order Receiving

Increase the accuracy, speed and effectiveness of your receiving department with the Mobile Warehouse. By utilizing Smart-Barcode™ technology your employees will learn in minutes, how to perform the receiving function. With a couple scans from a barcode reader, your inventory will be received, compared to the purchase order in O2 Life Sciences ERP, validated against the receiving rules that you have defined and labels printed with any information you wish.



By empowering your receiving personnel to enter inventory receipts at the dock, you will have faster, more accurate inventory information of raw materials, better communication with production planning and scheduling functions and more timely information for material purchase planning.

Warehouse/Bin Movements

Knowing specifically where your inventory is located within your organization is essential to effective inventory management. For companies that manage lot tracked items and/or expiration dates of materials, this information becomes critical. Historically, capturing this information has been prohibited by cost; both human-capital and dollars, slowness by which transactions are updated and the ability of systems to handle the transactions.

With Mobile Warehouse and Smart-Barcode™ technology, bin movements within a location is as simple as scanning a couple barcodes. Warehouse employees will adopt the process change easily because the process doesn't significantly interfere with their normal duties. They will embrace the change the first time they are able to find missing inventory by querying the barcode scanner to get the precise location.

Process Manufacturing

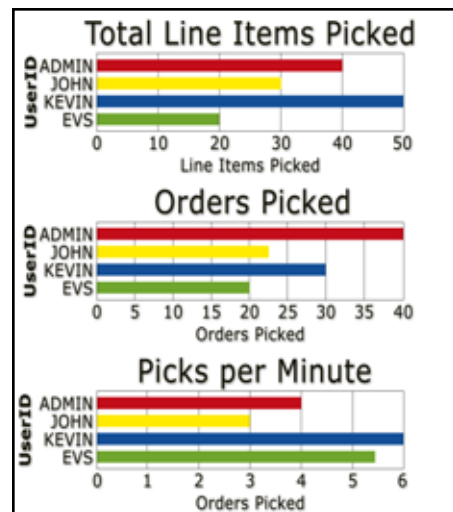
Process manufacturing generally has complex requirements in the warehouse environment. Warehouse personnel may have to manage inventory lots, expiration dates, hazardous materials, quality control release/quarantine, etc. Mobile Warehouse was specifically designed to enable material handlers to effectively and easily manage these inventory complexities.

This module, in conjunction with the Process Manufacturing module of O2 Life Sciences ERP allows your to create production pick tickets based on rules you define, FEFO (first-expire, first out), oldest lot, single lot picking, etc. and either request or require your material handlers to pick these lots. Do you allow your material handlers to determine the material to pick? No problem, Mobile Warehouse can tell your material handlers what item to pick, where the items reside in your plant and allow them to chose the appropriate lots.

As materials are produced and potentially put on pallets or in containers, Mobile Warehouse can allow your material handlers to enter quantities produced for the batch, identify the pallet/container that they are on and track that pallet/container throughout your warehouse.

Sales Order Shipping/Picking

Sales order picking is a powerful and flexible function within Mobile Warehouse and O2 Life Sciences ERP. The warehouse management function of O2 Life Sciences allows complex rules to determine what should be picked, where from, and how much. The Mobile Warehouse will communicate the desired picks to your material handlers who will know exactly where in the warehouse the inventory resides. If you track inventory on



containers or pallets, material handlers can load a pallet, homogeneous item, mixed items, mixed lots, etc. and stage the pallet for shipping. With Mobile Warehouse and Smart-Barcode™ technology, shipping is as simple as a couple scans; shipping documents are printed, and O2 Life Sciences ERP is immediately updated for the shipment.

Physical and Cycle Counts

Increase the speed and accuracy of your physical counts while minimizing the effort and costs to capture the required data with Mobile Warehouse with Smart-Barcode™ technology.





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