

**SAGE MAS 500**

## O2 Life Sciences ERP

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EVS, Inc.  
3005 Sterling Circle, Suite 200  
Boulder, CO 80301

303-494-1765  
[www.evs-sw.com](http://www.evs-sw.com)





## Life Sciences Industry Issues

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 real-time access to information providing visibility across your whole enterprise.

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).

### 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.

**Biotechnology:** O2 Life Sciences ERP provides automation with full validation which can help biotechnology companies manage rapid growth in very short time frames.

**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.

### Inventory Management, Production Efficiency & Managing Costs

#### FEATURES

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

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). O2 Life Sciences provides Business Intelligence tools for powerful, flexible and graphical management reporting.

O2 Life Sciences helps life science manufacturers maximize R&D and production efficiency with multiple unit of measure calculations. O2 Life Sciences also provides finite capacity scheduling to optimize production schedule based capacities and constraints of your plant.

O2 Life Sciences offers real-time cost data to track material costs (including intermediates), labor, packaging and finished goods. In

addition, the "What-if" cost-analysis helps make pricing decisions easier and improves your bottom-line with better visibility.

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.

### Risk Mitigation & Recall Protection

#### FEATURES

- 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. 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 control and minimize risk. 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.

### Regulatory Compliance, Quality Control & Validation

#### FEATURES

- 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. By automating processes such as lot tracking you can significantly lower the time and overhead associated with following your product's life cycle.

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.

## O2 Life Sciences ERP 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.

### Formulas 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.

### 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.

### Sales 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.

*"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 in an ERP system, I recommend your first call be to EVS."*

*- Deb Kastelic, Training Director, ARSO, NAS Medical*