



Supply Chain Solutions for Life Sciences





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The Life Sciences Supply Chain

Today's life sciences supply chain is increasingly complex and involves many players. Competing priorities, changing regulatory expectations, cost pressures, sustainability initiatives, emerging markets - these are some of the challenges faced by supply chain executives every day. Life sciences leaders need practical solutions that deliver value in their supply chains by enhancing the speed in their product development cycles, offering flexibility across multiple clinical trials around the globe, balancing the trade-offs in manufacturing efficiencies and inventory levels across clinical and commercial supply demands, and ensuring regulatory compliance, product quality and safety.

Today, supply chain professionals in the life sciences industry face economic pressures, elevated regulatory expectations, accelerating costs, technology changes and the need to constantly adapt business models. The advent of more widely distributed supply chains demand greater investment in tools, expertise and most importantly, the human capital needed to succeed despite the toughest challenges.

enVista Life Sciences Solutions

Supply chain planning and execution is at the center of your product development, manufacturing planning and inventory management activities, and your operational decisions, both strategic and tactical. Together, these planning and execution tasks form the basis for success. enVista stands alone in that we are not a management consulting firm that merely provides process maps and recommendations. Our experienced team of consultants and systems and industrial engineers analyze your operations requirements and develop process improvements to support your long-term goals.

enVista develops a roadmap for your physical process as well as your IT platform and software to provide specific life science solutions to your supply chain challenges. With strong regulatory

compliance understanding, best-in-class supply chain modeling capabilities and a proven track record of selecting, configuring and implementing supply chain IT solutions, enVista can design the path forward and also implement across your extended supply chain and integrate with your partners.

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We work with Life Sciences clients to:

- Assess compliance of people, processes and technology to a myriad of regulatory directives, guidelines and expectations
- Develop inventory planning and execution tools for management of the product lifecycle through development, clinical commercial and transitional stages
- Integrate drug product stability, thermal packaging capabilities and network design into a integrated, time-phased supply chain design
- Balance operational, inventory and transportation costs to deliver lowest total delivered cost
- Validate supply chain processes and qualify packaging designs
- Accommodate drug product presentation and indication changes – planned and unplanned
- Consult, implement and operate distribution operations in a GxP environment

Benefits of enVista's solutions:

- Compliant people, processes and technology able to sustain the rigors of regulatory agency or supply chain partner assessments
- Mitigate drug product and medical device losses by aggressively managing inventory
- Time-phased supply chain design and execution focused on total delivered cost, product quality and regulatory expectations
- Validate supply chain processes and qualified packaging designs
- Optimize inventory and maximize space utilization
- Turnkey solutions for your supply chain operational and IT infrastructure

enVista's Life Sciences Solutions include:

Enterprise Consulting Services

- Corporate Strategic Planning
- Operations and Facilities Planning
- Lean Materials/Process Flow Analysis
- Inventory Optimization
- Computer Simulation Modeling
- Third Party Logistics Pricing, Selection and Contract Negotiations
- Detailed Supply Chain Systems and Application Architecture Engineering
- Freight Management

Supply Chain Integration and Regulatory Compliance

- Integrated Business Applications, including:
 - Manufacturing
 - Materials Management
 - Procurement
 - Order Fulfillment
 - Supply Chain Planning and Execution
 - Quality Systems Management
 - Document Management
- Support for Good Manufacturing Practices (GMP) and Good Distribution Practices (GDP)
- Extensive Assessment and Remediation Capabilities, including:
 - DEA Compliance
 - Batch Recall Requirements
 - Lot Tracing Requirements
- Digital Signatures and Audit Trail
- Complaint Tracking and CAPA Functionality
- PDMA-compliant Sales and Sample Processing
- Full Support for 21 CFR Part 11 Compliance and FDA Validation

Materials Handling, Design and Implementation

- Operations and Materials Handling System Concept Development
- Racking and Warehouse Location Labeling Solutions
- Mechanized and Automated Conveyor Systems
- Serialization and Track and Trace Solutions
- Warehouse Management Solutions

Cold Chain Management Integration

- Thermal Packaging Engineered Solutions
- Process Validation
- Transport Simulation Laboratory Testing
- Cold Chain Logistics – Design, Validation, Implementation and Monitoring
- Clinical Trial Operations