

Blue Yonder for Pharmaceuticals/ Life Sciences

High-performance, secure supply chains
for strategic advantage



The pharmaceuticals and life sciences industry faces many opportunities and significant challenges. Blue Yonder for Pharmaceuticals / Life Sciences provides an integrated business planning and logistics solution to support revenue growth, cost reduction and strategic competitive advantage.

Blue Yonder for Pharmaceuticals/Life Sciences

With aging populations in the Western world and significant growth in emerging markets, the pharmaceuticals / life sciences industry has tremendous opportunities for growth. Yet, the industry faces significant challenges as well. The growth of biologics, and the rising costs of R&D, manufacturing and distribution, those companies that do not properly balance revenue growth and cost containment will be at a major disadvantage to those companies that do. In this dynamic environment, supply chain management excellence can create a strategic advantage if you have the right technology support.

Today's complex, global demand and supply networks require advanced, integrated supply chain planning and logistics solutions capable of leveraging the many marketplace opportunities while containing costs and minimizing the abundant risks. Blue Yonder for Pharmaceuticals / Life Sciences was built in collaboration with the world's industry leaders to provide the advanced, integrated solutions required to create strategic advantage. That is why 8 of the top 10 global pharmaceutical companies use Blue Yonder for category management and supply chain planning and execution.

In this brochure we will look at some of the key challenges facing the industry, the strategies pharmaceutical / life sciences companies are using to overcome those challenges, and the Blue Yonder solutions that are supporting those strategies. Specifically, we will discuss how the industry must:

- Develop detailed strategies and plans to counter the threats to top-line growth from looming patent cliffs, the intrusion of generics, and the rise of biologics
- Free up capital to support the rising costs of R&D
- Contain costs and minimize margin erosion from rising manufacturing and distribution expense

- Prepare for changes to traditional pharmaceutical production in the post COVID-19 era
- Minimize the risks from counterfeiting and supply disruptions while maintaining compliance with expanding governmental regulations

In addition, we will examine the unique challenges of the medical devices segment of the industry caused by the tremendous complexity of their supply chains, and the strategies and solutions they are deploying in response.

Customers who have deployed Blue Yonder for Pharmaceuticals / Life Sciences solutions to support these challenges have achieved the following benefits:

- Increased sales by 5-10%
- Reduced cash-to-cash cycles by 20%
- Reductions of 10-25% in work-in-process and finished goods inventories
- Improvements of 10-20% in on-time deliveries
- Reduced order cycle times by 10-25%
- Increased labor productivity and reduced labor cost by 10-35%
- Improvements in quality of 3-11%
- Reduced expediting and freight expense by 5-30%
- Improved asset utilization by 5-20%

The manufacturing imperative

To be successful in today's complex global marketplace, all manufacturers, perhaps especially those in the pharmaceuticals / life sciences industry, must embrace five core tenets of supply chain excellence.

- **Customer-centricity** – the consumer is in control and manufacturers must respond with demand-driven, all-channel strategies
- **Dynamic Segmentation** – supply chain strategies must be segmented by region, market sector and customer profile to offer differentiated products and services across segments
- **Synchronization** – supply chain operations must be synchronized across increasingly complex networks of multi-tiered suppliers to drive efficiencies, prevent supply gaps and improve velocity
- **Optimization** – LEAN principles, best practices and more sophisticated technology are necessary to optimize supply chain and manufacturing operations to improve efficiency, cost and throughput
- **Business agility** – pharmaceutical and life sciences manufacturers must be able to quickly and easily realign their supply chains to rapidly changing business conditions

Challenge: Patent cliffs, generics and biologics

Pharmaceutical and life sciences companies have tremendous pressure to maintain top-line revenue. With the increased intrusion of generics, and the rapid rise in biologic technologies, competition is more intense than ever. At the same time, consolidation across the customer base from large hospital and managed care corporations is putting constant pressure on pricing, as is the huge power of government spending on Medicare and Medicaid. Pharmaceutical and life sciences companies must formulate effective strategies and plans for countering these challenges to maintain and grow revenue while mitigating risks.

Strategy: Beat them at their own game

Many large pharmaceutical companies are choosing to compete with generic and biologics companies by joining them. That is, they are building or acquiring their own generic and biologics businesses— leveraging their scale to outperform the competition and secure the revenue lost from their own patented drugs. But this approach also brings a whole new set of challenges and supply chain complexities they may not have faced before.

Other pharmaceutical companies are reducing prices once their drugs lose patent protection or are using distributors to increase sales. But while these strategies may increase volume, they further squeeze margins.

Another strategy many companies are deploying or considering is expansion in emerging markets. This has huge potential for growth, but also brings a new set of supply chain and logistics challenges. All of these strategies require an increased focus on supply chain management as the foundation for success, especially in the post COVID-19 era.



Merck Serono is the division for innovative prescription pharmaceuticals of Merck, a global pharmaceutical and chemical group. Merck Serono discovers, develops, manufactures and markets innovative biopharmaceuticals to help patients with unmet medical needs. Merck Serono's biggest challenge was the integration of two very different supply chains for traditional pharmaceuticals and biotechnology-based pharmaceuticals.

Merck Serono decided to create one centrally managed supply chain, based on the push principle and driven by Blue Yonder's advanced supply chain management solutions. "The flexibility that the Blue Yonder solutions offer as an integration platform was one of the main reasons they were deployed for the entire Merck Serono network," said Didier Dayen, head of supply chain process at Merck Serono.

Blue Yonder's forecasting enabled Merck Serono to leverage forecasting methodologies across the enterprise while Blue Yonder's supply planning allowed the company to position the right inventory in the right places at the right time, ensuring that inventory is available across the entire company.

With the help of Blue Yonder's solutions, Merck Serono accelerated the integration of two very different supply chains. It improved the efficiency of its supply chain network and overall business operations. Merck Serono continues to strengthen its core therapeutic areas, while also improving its demand practices and key supply chain metrics.

"Implementing Blue Yonder solutions provides Merck Serono with one synchronized view of demand. Having only one tool as a demand data repository in the entire company worldwide allows us to easily follow an aligned process across the organization." — Head of Supply Chain Process, Merck Serono





Solution: Forecasting

What all of the strategies for maintaining and growing top line revenue have in common is the expansion of operations beyond traditional norms. Whether it is adding generics or biologics, working with distributors, or expanding into emerging markets, there are more entities and new variables to be considered in the planning process. There may also be thousands of new SKUs for which demand is uncertain. Coordination of plans across these diverse operations is crucial to leverage the scale they bring to the business. Blue Yonder for Pharmaceuticals / Life Sciences provides industry-leading planning tools to create consensus demand plans across all of these operations. The tools include:

- **Demand planning** – Advanced statistical forecasting techniques support bottom-up demand forecasting from internal sales and distributed sales affiliates to better understand true end-point demand. This is coupled with top-down revenue forecasting with automated reconciliation across hierarchies to balance demand and constraints. The forecasting algorithms support lifecycle forecasting and new product introductions, and incorporate third-party data for causal forecasting. The result is a more accurate picture of demand across all operations.
- **Sales and operations planning (S&OP)** – Given the variability in supply and demand in pharmaceutical supply chains, it is critical that key organizational functions, including sales, marketing, finance and operations, together with executive management, stay aligned on corporate business objectives. The sales and operations

planning component of Blue Yonder's integrated business planning solution enables companies to aggregate demand across all functions and locations, with the ability to view demand at any level, drill down to underlying details, perform supply and demand balancing, create what-if scenarios, and do plan-to-plan comparisons.

- **Collaboration** – The collaboration capabilities from Blue Yonder enables multiple business units and outside distributors and suppliers to collaborate on forecasting to create a true consensus demand plan. It extends the capabilities of demand planning and S&OP to partner organizations to arrive at a consensus view of supply and demand.
- **In-Line analytics** – Blue Yonder's integrated business planning solution incorporates in-line analytics to enable the analysis of all forecast and demand data simultaneously to support what-if scenario planning, evaluate planning alternatives, and display results on graphical, easy-to-understand dashboards.

The above combination of planning and analysis components of Blue Yonder for Pharmaceuticals / Life Sciences enables manufacturers and distributors to better plan for looming patent cliffs, better compete with generics and biologics alternatives, and rise to a new level of service for their ever-larger customers.

Challenge: Rising R&D costs

The rising cost of research and development for pharmaceuticals is squeezing margins and putting intense pressure on the bottom line. One of the reasons for the rising cost is the increasingly long, complicated and uncertain clinical trial process. It can now take 10-15 years to develop a new drug. Yet with cost containment initiatives by governments and insurers, pharmaceutical companies cannot always recoup these costs with higher prices. They must therefore look for other ways to generate cash flow to cover R&D expense.

Strategy: Leveraging other sources

Many pharmaceutical companies are attempting to reduce R&D costs and time by obtaining research in other ways, such as purchasing it from research specialists and universities, acquiring companies that have already developed, or are well along the way in developing, promising drugs, or by collaborating with other companies for joint development of new drugs. While these initiatives can speed up the process, it is questionable whether they actually reduce costs or just move the cost to other parts of the ledger, such as for M&A. New means must be found for improving cash flow to cover R&D costs regardless of how the research is obtained.

Solution: Generating cash flow from supply chain operations

The pharmaceutical industry's focus on high production asset utilization has led to unusually high inventory levels compared to other industries. Total inventory and safety stock levels are significantly higher than parallel industries. Therefore, optimizing inventory levels based on actual needs can free up capital and cash flow to cover rising R&D costs. Blue Yonder for Pharmaceuticals / Life Sciences helps free up cash flow in two ways: by reducing inventory levels to match needs and through segmentation of customers to right-size service levels. This analysis will be particularly critical as companies launch or acquire generic and biologic operations and as they develop new drugs, all of which have less understood demand patterns.

- **Inventory and order optimization** – Advanced algorithms determine optimal inventory levels at each node of the supply chain based on mining customer order history to discern average order lead times. The system supports what-if analysis to plan inventory for new product introductions and other variations to demand and supply patterns. By right-sizing inventory levels, safety stock can be reduced resulting in lower capital requirements and improved cash flow which can be used for R&D.
- **Dynamic segmentation** – By segmenting products and customers based on flexible criteria such as order history, total revenue, volumes, etc., service levels can be set based on customer value contribution. This enables inventory to be reduced in some segments while service levels are increased for key customers. This improves cash flow and customer satisfaction. Blue Yonder's in-line analytics can be especially helpful in analyzing customer value to aid segmentation.

While the prospects for reducing R&D costs are slim, segmenting customer service levels and optimizing inventory levels can free up capital and cash flow to help cover R&D costs.



Challenge: The high cost of manufacturing and distribution

Manufacturing pharmaceuticals is a complex, capital-intensive process. To maximize utilization of expensive production assets and improve efficiency, companies tend to run large fixed batches. The objectives are to “keep the machines running” and reduce the time and expense for clean-outs, sterilization and change-overs. There is also the question of how to manage the co-products from production. However, these long production runs risk creating costly demand-supply imbalances.

Manufacturing supply chains are also becoming more global and complicated. Often active product ingredients (APIs) are being outsourced to lower cost countries such as India and China. However, this increases transportation time and costs and impacts both shelf-life constraints and patient safety concerns. Thus, modeling distribution across API production, formulation, packaging, internal distribution and customer distribution can be very complicated. To be cost effective, companies must do a better job of planning and managing production and distribution.

“Since the Order Optimization implementation, we have reduced our days of supply for safety stock on many of our items. We were running well over our service level goal in aggregate, and we were able to take out one day of supply from about two-thirds of the items. We are now meeting our service level goal with less inventory. I think that’s one of the objective proofs of the value of the system.”

— Director, Supply Chain Inventory,
Owens & Minor



Strategies: Plan, plan, plan

With pharmaceutical companies outsourcing API production for cost containment, thus complicating manufacturing and distribution processes, the importance of planning is raised to a new level. The step-by-step process of API production, formulation, packaging and multi-tiered distribution must be carefully modeled and planned to streamline processes, reduce costs, and ensure patient safety. This cannot be adequately accomplished using standalone planning processes and systems. It requires an integrated approach to manufacturing and distribution planning that optimizes the entire process, not just disjointed silos and functions. This becomes even more critical with expansion into emerging markets, where imbalances between supply and demand are both more frequent and more costly.

Solution: Full-spectrum planning and execution

Blue Yonder for Pharmaceuticals / Life Sciences plans and optimizes the full spectrum of manufacturing to distribution processes. It optimizes production and fulfillment across all sites and stages in each product's lifecycle. It addresses the production bottlenecks and simultaneous constraints found in multi-stage, outsourced manufacturing processes to improve cycle times and reduce costs. It also manages the flow of orders and inventory across emerging markets. Specific components include:

- **Master planning and capacity planning** – Blue Yonder's master planning, capacity planning and production scheduling capabilities work together to plan and schedule multi-stage manufacturing across extended supply networks. Using forecasting capabilities from Blue Yonder, the system employs order-by-order planning and linear optimization to align supply and demand throughout the production process. It intelligently handles alternate routes, components and resources and addresses bottlenecks and simultaneous constraints. The system plans shipments based on demand type and priority and provides exception-based alerts when demand and production imbalances occur.
- **Distribution planning** – Blue Yonder supply planning and order optimization model distribution across multistage API production, formulation, packaging, and internal and customer distribution. The systems:
 - Generate distribution plans that respect shelflife constraints and alternate sourcing rules by market
 - Track and manage date-sensitive inventory
 - Consume forecasts based on actual orders
 - Enable visibility and management of safety stock by local affiliates
 - Understand bulk requirements from bottom-up replenishment
 - Support new distribution models such as direct-to-pharmacy and direct-to-hospital
- **Warehouse management** – Blue Yonder's warehouse management manages the flow of raw materials, work-in-process and finished goods inventory across internal distribution networks. The system makes warehouse and distribution center operations more efficient by computer-directed management of all tasks. Each worker is automatically assigned the most productive next task based on order priorities, proximity to the inventory, and the equipment used by, and certifications of, each worker. This efficiency can be further enhanced through the use of RF or RFID devices, voice and pick-to-light automation, and integration with material handling systems.
- Warehouse management also supports new strategies for distribution operations such as put-to-store for direct-to-pharmacy or direct-to-hospital models, flow-through and crossdocking, as well as work order processing for special handling and value-added services. These strategies reduce handling and storage requirements resulting in reduced inventory levels and lower distribution costs.
- **Labor productivity** – While improved distribution operations and strategies reduce the need for labor, the labor that is required must be made as productive as possible. Blue Yonder's labor

management improves labor scheduling to better match labor resources to demand, and improves productivity by ensuring all tasks are performed in the most efficient, safe and error-free method possible. Blue Yonder industrial engineers help develop the most efficient work methods and engineered standards for each task. The system monitors adherence to these standards and keeps supervisors apprised in real-time when productivity drops or work falls behind schedule so they can take immediate corrective action.

- **Transportation management** – The volatility of fuel costs has impacted all modes of transportation, causing companies to rethink transportation strategies. This is particularly important with pharmaceutical companies' extended global supply networks. Blue Yonder's comprehensive transportation solution optimizes all modes of transportation to ensure lowest cost modes, routes and carriers are used that meet delivery commitments. The system optimizes everything from global multi-leg, multi-modal shipments to local multi-stop fleet routing. And transportation is fully integrated with warehouse and labor management to synchronize operations based on priorities and constraints. As a result, all supply chain operations are more coordinated and efficient, reducing costs and the impact of demand and fuel volatility.

Challenge: Counterfeiting and traceability

The expansion of pharmaceutical production to lower cost countries has had the unfortunate side effect of increasing the production and distribution of counterfeit drugs. In fact, the FDA estimates that counterfeiting increased 800 percent between 2000 and 2006. This has cost pharmaceutical companies billions of dollars in lost revenue and put patients at risk. In response, governments have initiated new traceability and ePedigree regulations that put significant burden on pharmaceutical companies for compliance. With extended, multitiered supply chains, this is a major challenge for the pharmaceutical industry.

Strategy: Advanced technologies

Pharmaceutical and life sciences companies understand that traditional distribution systems are inadequate for the task of tracing inventory from raw materials to finished goods and on into the hands of consumers. They are looking to more advanced technologies such as RFID and cloud-based tracking to help address this challenge. However, the cost for equipment and tags to put an RFID label on each package of drugs has rendered this strategy cost-prohibitive for most companies. Therefore, cloud-based alternatives are looking more attractive.

“With greater than seven million SKUs in the master files, the positive impact that the Blue Yonder solutions have had on our business is remarkable. We have truly set the standard for the pharmaceutical industry in our country and we believe one of the reasons we have been able to capture 70 percent of the Danish retail pharmacy market is because of this successful VMI program.” — **Logistics Director, Nomeco**



Solution: Brand protection

Track & trace is a cloud-based solution providing continuous visibility and control over the pharmaceutical and life sciences supply network from raw ingredients to the end customer. It enables all supply chain partners to enter detailed product, lot and shipment information in real-time to create a “glass pipeline” providing visibility to everything in their supply network. It also provides tools to simultaneously interact with all network partners when actions are necessary. Blue Yonder’s track and trace is comprised of several capabilities, including:

- **Global inventory visibility** – Through the cloud network, companies have real-time access to product, lot and shipment information from all supply chain partners simultaneously. Not only is this important for traceability and brand protection, it allows the network to reduce inventory levels because visibility to what is happening throughout the network means less safety stock is needed at each node. Operations are streamlined across the network resulting in lower costs and increased shelf life.
- **EDI support** – You may have EDI networks in place with large suppliers and customers. Track & trace can accept EDI transactions from these networks while receiving cloud-based EDI-syntax transactions from other suppliers and customers. The system accepts, translates and normalizes transactions from all sources to create a single picture of network inventory and activity.
- **QA/Recall** – Quality assurance testing of pharmaceutical and life science products, components and ingredients is becoming more critical, especially as more APIs are sourced internationally. But holding lots until QA testing is complete slows the supply chain and decreases shelf life. Blue Yonder’s track & trace has QA/hold capabilities that allow inventory to be put on multi-level virtual holds anywhere in the network without physically detaining in-network shipments. This speeds movement of inventory through the network while ensuring no items on hold will be delivered to customers.

In case of a recall, the multi-level hold capability can lock down suspected lots while the traceability functionality enables rapid detection of the source. In collaboration with customers, holds on suspected products can be extended to pharmacy POS systems and hospital inventory systems so tainted goods are not sold or dispensed to consumers.

Medical device manufacturing and distribution

The medical device manufacturing and distribution segments of the Life Sciences industry deserve special mention due to the unique challenges they face. In addition to negotiating the same challenges as the pharmaceuticals / life sciences industry, as discussed above, they must continually drive incredible amounts of product innovation, deal with long and costly R&D clinical trials to get those innovations approved for sale, and manage extremely complex supply chains to bring innovative products to market.

The downside to innovation is that demand is intermittent and hard to predict, and product life cycles are short. Medical device companies must carefully balance demand and supply to avoid getting into negative inventory positions where sales don’t cover costs. This requires a high level of demand planning and inventory optimization integration.

Since demand for these products is often driven by medical emergencies such as accidents or quick onset medical episodes, lead times are short. But when you consider that these devices are often SKU-intensive, for example, with many fittings for the human body, and that many components may be outsourced to China, Mexico or Ireland, you begin to sense the special challenges medical device manufacturers and distributors face.

Solution: Integrated planning and execution

Although the entire pharmaceuticals / life sciences industry will benefit from the integration of supply chain planning and execution, the needs and rewards of integration are more intense for medical devices. Medical device manufacturers and distributors need advanced planning and execution technology to enable accurate demand forecasting and planning and highly efficient supply chain execution. But the short order lead times and short product life cycles require planning and execution to be closely integrated so that sense and response are virtually instantaneous. Blue Yonder for Pharmaceuticals / Life Sciences offers both best-of-breed functionality and the tightly integrated processing so critical to the medical devices industry. And with in-line analytics and in-memory processing, analysis of events and exception handling are rapid, fact-based, and flexible. Only Blue Yonder offers this combination of capabilities that is so critical to medical device company success.

SaaS: A perfect fit for the pharmaceuticals / life Sciences industry

Because large pharmaceutical and life sciences companies usually have complex global operations and markets they serve, they are excellent candidates for SaaS deployment of supply chain planning and execution solutions. SaaS deployment allows all operations to be instantly visible, which is important for traceability and brand protection, as discussed above. But it also helps align and standardize operations: everyone has access and visibility to the same data (depending on secure access permission), everyone is using the same versions of the systems, and there is no time delay between actions or events in one part of the world being known by those in other parts of the world. Thus, the whole demand and supply network can act as one entity. This greatly speeds up operations, enables significant reductions in safety stock, and facilitates more rapid response to disruptions.

In addition, SaaS deployment helps protect your software investment and increases business agility by having Blue Yonder experts manage, monitor and maintain your Blue Yonder solutions. Blue Yonder's SaaS offerings can reduce your

implementation time and risk while enabling you to quickly and easily deploy new functionality to keep pace with your changing business needs. With your software running in the cloud and upgrades included in your service, you will benefit from solutions that are optimized for your specific business requirements to help ensure that you achieve and sustain a long-term return on your investment.

Summary

The pharmaceuticals / life sciences industry faces many unique challenges not common to other industries. With truly global operations, intense pressure on revenues, long product development cycles, rising costs for R&D, manufacturing and distribution, and a strong focus on counterfeiting and patient safety, this industry needs expert advice and technology support for supply chain management excellence. Eight of the top ten global pharmaceutical companies have turned to Blue Yonder and Blue Yonder for Pharmaceuticals / Life Sciences for this strategic advantage. Can you afford not to do the same?

Deploy Blue Yonder for Pharmaceuticals / Life Sciences via Blue Yonder's SaaS offerings

Protect your Blue Yonder investment and increase business agility by having Blue Yonder experts manage, monitor and maintain your Blue Yonder solutions. Change to Blue Yonder's SaaS offerings reduces your implementation time and risk while enabling you to quickly and easily deploy new functionality to keep pace with your changing business needs. With your software running in the cloud and upgrades included in your service, you will benefit from solutions that are optimized for your specific business requirements to help ensure that you achieve and sustain a long-term return on your investment.

About Blue Yonder, Inc.

Blue Yonder, Inc. (formerly JDA Software, Inc.) provides seamless, friction-free commerce, empowering every organization and person on the planet to fulfill their potential. Blue Yonder's machine learning-driven digital fulfillment platform enables clients to deliver to their customers when, how and where they want it. Applying over 35 years of domain expertise, contextual intelligence and data science, Blue Yonder is helping more than 3,300 of the world's leading manufacturers, retailers and logistics companies create more autonomous, sustainable and profitable operations.

[Learn more at blueyonder.com](https://blueyonder.com)



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