



# Diagnosing the impact of trends on the supply chain

*Understanding the 7 factors for treatment*

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Delivering on diverse customer expectations while managing an extended supply chain in a constantly changing environment presents formidable challenges in the life sciences industry. Explore the key drivers of supply chain complexity and seven processes that need an integrated approach to overcome the challenges.

Life Sciences companies are faced with a fragmented demand chain with varying regulatory requirements across markets (and several channels within each market), as well as an aging product portfolio which has led to reduced margins. Increasingly, Life Sciences companies are turning to third party operators at all levels of the supply chain to reduce costs, satisfy local demand, and enhance capacity flexibility. Needing to deliver to diverse customer expectations while coordinating an extended supply chain in an environment of constant change is the current reality for Life Sciences industry companies. And there is growing evidence that existing technology architectures are not satisfying the capability needs for this new, complex world.

## Five drivers of complexity

### Exceedingly distinct markets

Through accidents of history and industrial capabilities, the Life Sciences industry has developed to satisfy principally the diseases of the affluent West, such as cardiovascular disease, diabetes, respiratory disease, and obesity, while paying less attention to the diseases prevalent in the developing world, such as malnutrition, malaria, HIV/AIDS, and TB. This has led to a drug market segmented by geography and demographics, with companies in the emerging markets focused on satisfying the 'local' diseases. But in recent years, with the rapid expansion of the middle class in many emerging economies, many of the 'Western' diseases are increasing rapidly in the middle classes of the emerging markets – for example diabetes in India – stretching local healthcare provision while opening opportunities for expansion into these countries. While at the same time innovations by companies in emerging markets are challenging the market leadership of well-established Life Sciences companies in the West.

### Increased outsourcing

With tremendous opportunities for growth in emerging markets, many manufacturers have executed aggressive globalization and outsourcing strategies, while relying increasingly on Third Party Operators (TPOs) in India and China for Active Pharmaceutical Ingredient (API) supply and subcomponents, or even the manufacturing of complete devices. Coming along with these shifts is an increase in business complexity and supply chain risks given the varying regulations across global supply chains and longer and riskier supply chains.

### New regulations

With this rapid increase in the use of TPOs has come added risks to quality and of counterfeiting, leading the US Food and Drug Administration (FDA) to push for the passage of the Safety and Innovation Act (FDASIA), which focuses on the risks inherent in an increasingly global Life Sciences supply chain. Much of the public comment has been on the two user fee reauthorizations, as well as two new user fee programs, and the reauthorization for pediatric research. But buried deep in the text are provisions for supply chain validation – in both domestic and off-shore plants – and drug shortages that will have a profound impact on outsourced and global supply chains.

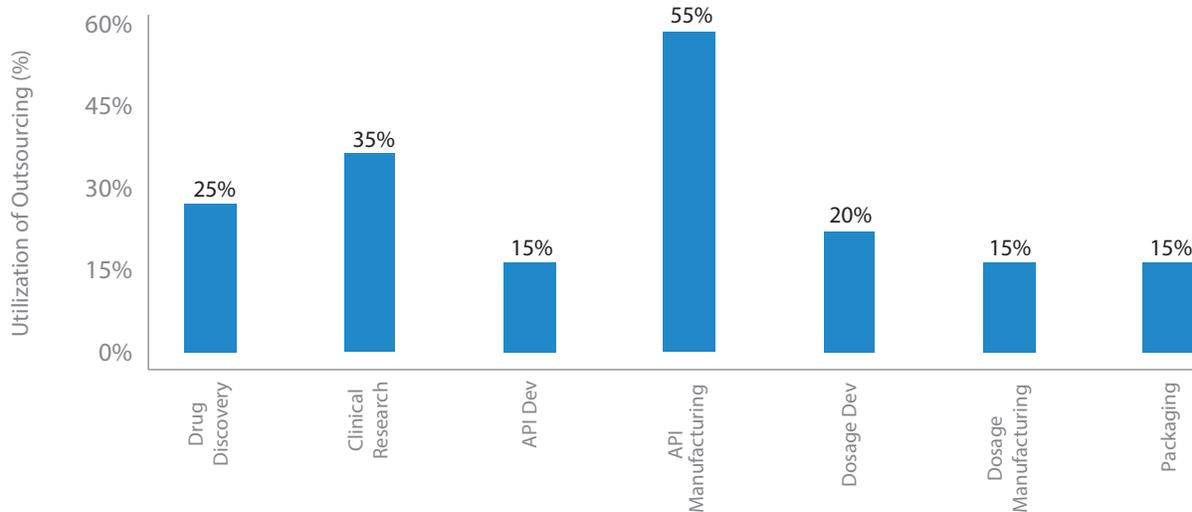
Stefanie Johns, Ph.D., Program Manager, Xavier Health Initiatives, [commenting on conference sessions at Xavier University](#), states that,

“The new powers from FDASIA will level the playing field between foreign and domestic sites, enhance transparency and collaboration with foreign regulators, and shift focus “away from the border to a global safety net.” FDASIA also provides the FDA with new tools to destroy counterfeit products, misbrand products on the basis of inspection refusal, and deliver criminal penalties for intentional adulteration. In order to streamline resources, the FDA will be moving towards a risk-based inspection system and will work with foreign regulatory counterparts.”

In summary, the impact of FDASIA on the Life Sciences supply chain will come from provisions for

- ▶ Reporting of drug shortage issues, and the penalties associated with not informing the FDA; and
- ▶ More active inspections of production facilities, including sites in other countries, including those belonging to Third Party Operators

## Outsourcing in the pharmaceutical industry



Source: Frost and Sullivan, Global Bio-Pharma CMO Market Report, May 2010

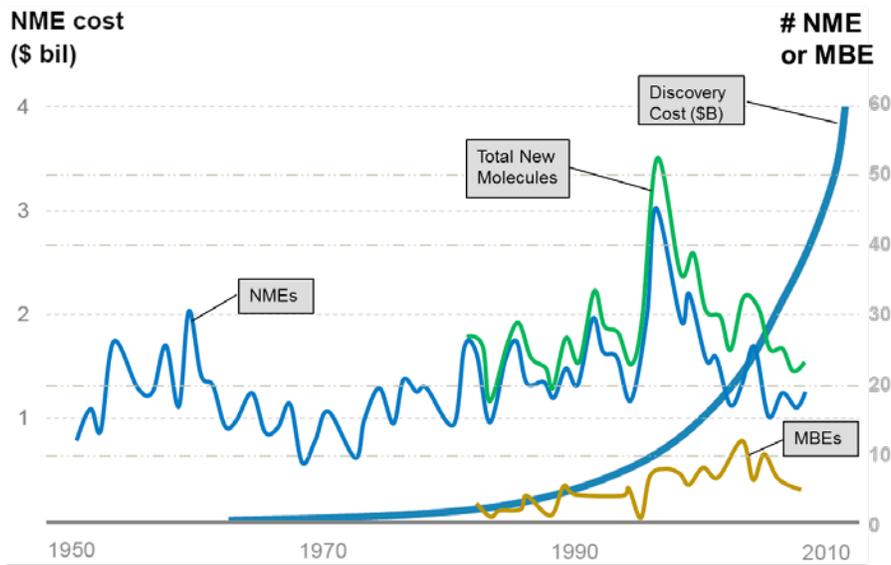
## Shift in treatment focus

One side effect of FDASIA is the fast-tracking of approval for treatments that address an ever narrower spectrum of diseases. Of particular importance to rare disease patients, and likely to help encourage further investment, is the Breakthrough Therapies Act addressing the need to provide expedited development and evaluation of potential therapies that show promise early in the research process; and the Therapeutics for Rare and Neglected Diseases which aims to encourage and speed up the development of new drugs for rare and neglected diseases.

Included in the Breakthrough Therapies Act is a voucher system that allows companies developing for rare pediatric diseases to obtain a transferable voucher which they can use for the expedited approval of another treatment, whether that treatment satisfies the requirements for priority review or not.

The trend to ever more targeted products is widespread across most industries whether Life Sciences, High-Tech/Electronics, or Consumer Goods. In the past, the limited markets coupled with the fact that many of the patients were in less affluent areas of the world, were a disincentive to major Life Sciences companies that were addressing a large set of diseases with broad spectrum therapeutics. However, with many of the major disease categories covered effectively by existing treatments, combined with the fact that a) many treatments are reaching the end of their patent protection period, b) growing competition from generics, and c) increasing scrutiny from regulatory bodies have all led to a rapid shift in focus of research, as well as mergers and acquisition activity toward rare diseases. (While there isn't a universally accepted definition of a rare disease, the US government defines a rare disease as one afflicting fewer than 200,000 Americans, while the European Union defines a rare disease as one afflicting fewer than 1 in 2,000 people.)

## Innovation versus cost

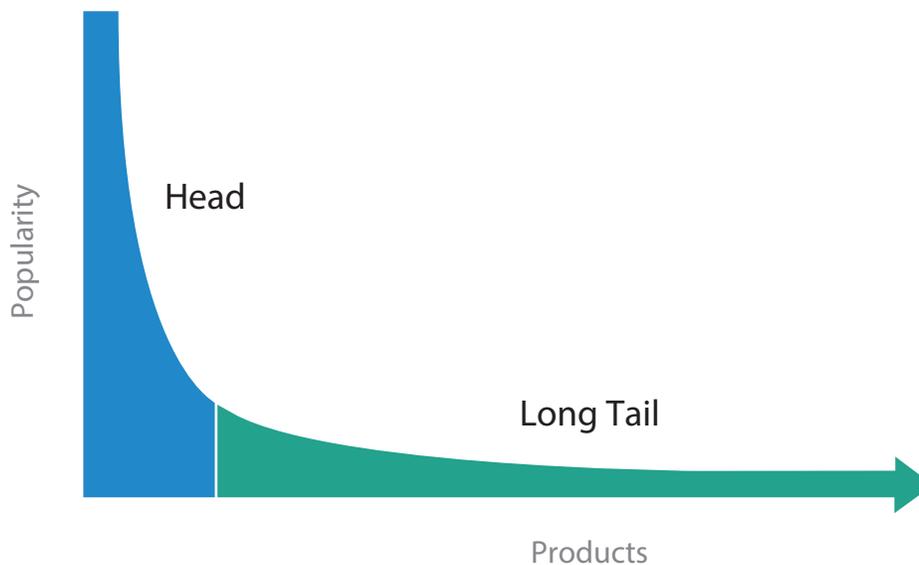


Source: Morgan Stanley, The US Healthcare Formula Cost Control and True Innovation, June 16, 2011

A report released by the Pharmaceutical Research and Manufacturers of America (PhRMA) in 2011 emphasized the extent of this shift away from broad spectrum drug research focused on diseases with large patient bodies to narrow spectrum drugs focused on rare diseases. According to the PhRMA report there were a record 460 medicines for rare diseases either in clinical trials or awaiting FDA review at the time the report was published.

To overcome the economic barriers associated with the discovery and development of diagnostic equipment, drugs and devices to treat rare disease, big Life Sciences companies have been pursuing collaborations, acquisitions, and joint ventures, often with companies in India and China.

This search for 'long tail' drugs will mean that Life Sciences must also deal with increasingly complex demand patterns. They have to simultaneously deal with predictable patterns for mid-life cycle products and highly unpredictable patterns for new introductions. They typically have to manage both low volume, high mix products that require quick response for clinical trials and high volume products that require ramped production and global delivery capabilities.



## Shorter patent protection

An aging product portfolio, along with a future of shorter patent periods in general, with limited opportunities for patent extensions (as demonstrated by the recent challenge by the Indian government of patent extensions based upon reformulation), only serves to reinforce the critical requirement for supply chain efficiency and effectiveness, in order to capitalize fully on the opportunities while they exist.

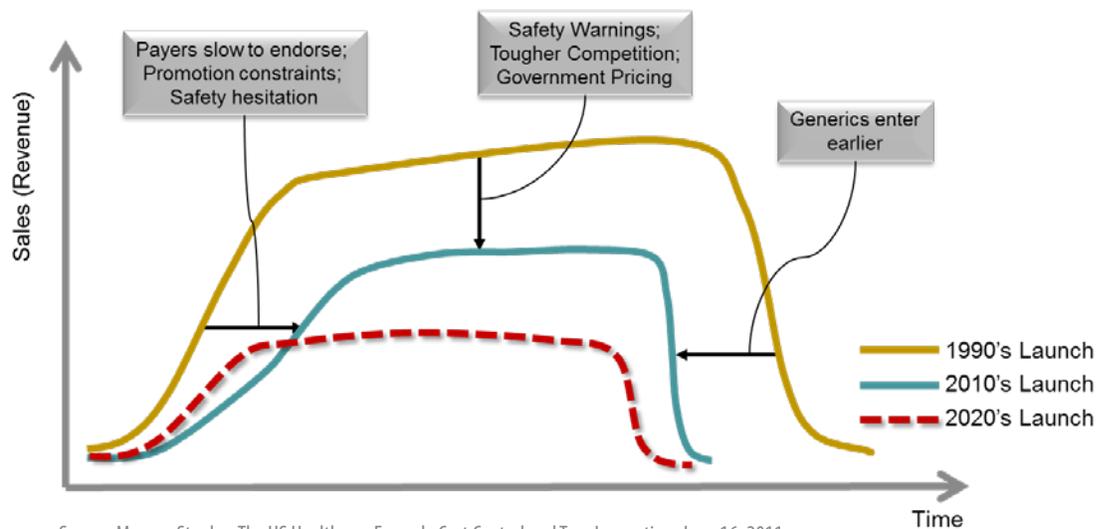
## The 7 processes that need to deliver

With emerging or intensifying industry dynamics, along with significant shifts in strategy, it requires no stretch of the imagination to understand that this has a direct and material impact on the way supply chains must operate. Consider these seven supply chain processes that require an integrated and highly-effective approach.

### Coordinated launches

The effective launch of a new product is critically important in any industry, but it is of particular importance in the Life Sciences industry given the long time it takes to bring a new drug to market from discovery through clinical trials and commercialization, with regulatory oversight and conformance throughout the process. When the 'long tail' trend is coupled with shorter patent protection, the margin and market captured during the early launch period will be crucial to the recovery of the R&D investment, and thus the pressure to streamline and coordinate clinical trials and the regulatory process with the commercial launch has become intense.

### Revenue trends throughout the product life cycle



### Jurisdictional control

In addition, mandates by regulatory bodies require jurisdictional control of demand satisfaction to account for third country sourcing, validation, and shelf life requirements, amongst others. This requires sophisticated attribute based planning to link demand characteristics to supply characteristics while simultaneously analyzing and reducing expiry risk, especially when inventory postponement strategies are used.

### Consensus demand planning

For tax, legal, and regulatory reasons, many Life Sciences companies establish semi-independent sales affiliates or subsidiaries in some jurisdictions or sell through third parties. Creating a consensus demand plan across all the affiliates and subsidiaries is not a trivial task. Often, each demand region will forecast in different units (doses, standard packs, grams of API, etc); almost always in different currencies; at a different cadence (quarterly, monthly, weekly); and over different time horizons. However, manufacturing needs to create a single forecast using a consistent unit of measure so that they can net the demand against available supply and determine future manufacturing capacity needs. To make matters worse, the affiliates are often less than fully transparent about their on-hand inventory.

## **Risk evaluation and recovery (including shortage analysis and reporting)**

Current technical architectures do not provide the capabilities needed to address new requirements under FDASIA - reporting obligations for drug shortage issues and more active inspection of production facilities for instance. Information flow is typically limited to EDI exchanges with little or no ability to understand, for example, the impact of an API supply de-commit on future treatment —drug or device— availability in a regulatory region. To do this, Life Sciences companies will require much greater visibility and what-if scenario capabilities to both inspect and affect the global supply chain across Third Party Operators and into the supply base.

## **Tender analysis and management**

Many manufacturers lack the required process standardization in manufacturing, inventory and expiry management, and other core business disciplines to make the required trade-offs during tender analysis between demand satisfaction, expiry risk, and constrained capacity utilization, ultimately leading to effective supply and capacity planning to balance demand across regions. Collaboration across the players in the supply chain is often insufficient and inefficient to achieve these tradeoffs. Given the harsh penalties imposed for non-conformance, being able to make the trade-offs to maintain profitability span the life cycle of the tender, not simply the tender acquisition phase.

## **Expiry management**

Streamlining manufacturing and distribution processes in order to satisfy demand while reducing unit cost is therefore becoming increasingly important in order to maintain profitability, reduce inventories and enhancing competitiveness within the industry.

This is especially true given the long manufacturing lead times, often as long as 12-18 months in bio-pharmaceuticals, which lead to the need for expiry risk and stop sell analysis capabilities to balance effective demand satisfaction with efficient capacity utilization.

## **Life Sciences companies must satisfy the following business processes in an integrated manner:**

1. Collaborative launch management — Clinical, Regulatory, and Commercial
2. Jurisdictional control to respect regulatory needs during planning
3. Consensus demand planning across affiliates & countries
4. Risk evaluation and recovery to deal with shortages and FDA shutdowns
5. Shortage analysis and reporting for FDASIA compliance
6. Supply and capacity planning to balance demand across regions
7. Expiry management to balance long supply lead times and shifting demand

## **A new technology paradigm for a new world**

Legacy demand planning and supply chain planning systems were not designed for today's complexities, and consequently don't meet the many challenges that have emerged.

As a result, Life Sciences companies are adopting process improvements and new technologies targeted at removing business "silos," improving collaboration, and increasing productivity.

For a true breakthrough, you need an integrated solution. People must be able to leverage a single system with one set of data, supported by comprehensive analysis and decision-making capabilities, no matter what the process or the problem.

To keep a finger on the pulse of the supply chain, today's solutions must:

- ▶ Embrace the reality that today's supply chains are multi-enterprise in nature and, thus, must provide comprehensive visibility into the extended supply chain to regain an understanding of the manufacturing commitments and inventory positions throughout the supply network. Visibility is an essential pre-requisite for effective orchestration of the business.
- ▶ Proactively bring to light major variances to plan, identifying not only specific events, but also identifying and quantifying the consequences to customer service, revenue, margin, and a number of other financial and operations metrics, and thereby flagging those that could do most harm to the business.
- ▶ Arm decision-makers with scenario simulation capabilities for risk trade-off and response, to model and compare situations quickly and appropriately to ensure a profitable response is put into action. And it must facilitate and incorporate human judgment, since many of the decision requirements are extremely difficult, if not impossible, to capture in a mathematical model — the foundation of an optimization system.
- ▶ Foster collaboration for team-based decisions that tap the collective insight of the right people in the organization — those that understand the potential impact of any event and proposed action alternatives.

## The RapidResponse advantage

Large Life Sciences companies with complex supply chain networks and volatile business environments rely on RapidResponse for collaborative planning, continuous performance management, and coordinated response to plan variances across multiple areas of the business.

Core to RapidResponse are comprehensive supply chain planning capabilities that drive effective coordination of internal and outsourced manufacturing operations through rich and fast data analysis and complete supply chain visibility.

RapidResponse allows for:

- ▶ Concurrent planning between functions
- ▶ Active monitoring of current business results
- ▶ Rapid creation of “what-if” scenarios to evaluate and respond to change

RapidResponse delivers **six underlying technology capabilities** that are essential to making demand and supply balancing decisions across the enterprise. These capabilities are interdependent and it is the delivery of the full and unified set of capabilities within one product which sets the RapidResponse architecture apart from other supply chain solutions.

### What-if analysis

- ▶ Anyone can create private simulations to see the projected impact of the decisions they may take. Simply put, no other supply chain solution can simulate supply chain “what-if” analysis scenarios at the speed and detail of RapidResponse.

### High-speed supply chain analytics

- ▶ The “always on” in-memory supply chain analytics combined with a networked, in-memory database allow for sophisticated calculations thousands of times quicker than legacy supply chain solution systems. With RapidResponse, people query for real answers, not just query data.
- ▶ RapidResponse includes specific functionality required by Life Sciences companies - from expiry reporting, to days of forward cover, to stop-sell.

### Scenario comparison

- ▶ “What-if” scenarios can be evaluated against the baseline, other scenarios, and against key performance targets to understand the impact on the business. Various supply chain participants can run and compare multiple “what-if” scenarios to identify the best course of action for the organization.

### Responsibility-based supply chain collaboration

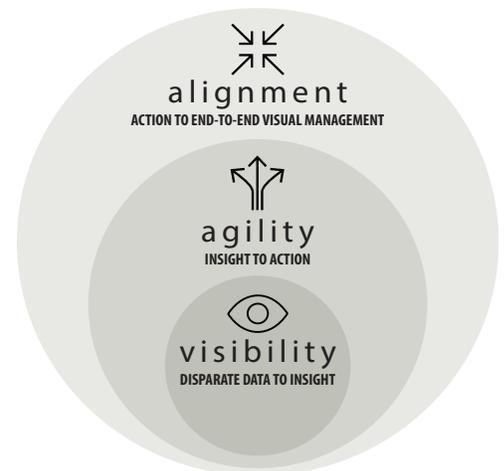
- ▶ Teams of collaborators can be assembled according to their declared responsibility for particular areas, activities, or events. When scenarios are created, RapidResponse can identify others in the organization who are impacted and should be involved in the decision making.

### Consequence evaluation and alerting

- ▶ Exception-based notifications alert on changing demand and supply conditions and their projected impact to the business. It is never enough to simply know that something unexpected has occurred. You need to understand the business context, the impact and the possible next steps.

### Dashboards

- ▶ Self-configurable dashboards, containing a broad collection of chart options, can be created to present role-based information that can be viewed on any device — PC-based or mobile.



## Reaping the benefits

The benefits of managing the Life Sciences supply chain with RapidResponse include improved customer service, improved capacity utilization, and reduced inventory. These types of benefits have been proven in successful deployments, both within the Life Sciences industry, as well as across several other industry verticals.

### RapidResponse customers get results

One Kinaxis pharmaceutical customer needed a responsive planning and simulation tool that would provide immediate and comprehensive feedback on inventory balances against target, while considering network capacity.

The challenges they faced included a monthly planning process that was labor intensive and took 20 days to complete. This was brought down to 7 days with huge gains in personnel productivity, but equally important was the ability to monitor execution of the plan and respond very quickly to any changes. During the implementation, several off-line tools — used to plan and analyze expiry, demand simulation, bulk planning, and shortage notification and response — were replaced.

This customer determined that RapidResponse was the best one-stop solution for demand, supply, and capacity planning, simulation, and reporting.



Research by  TechValidate

### Cutting Down the Planning Cycle

“ RapidResponse put the power of performing scenarios back into our users hands versus our administrators. We reduced the execution time of the planning cycle by 10+ days. ”

Source:  Operations Manager, Global 500 Pharmaceuticals Company

[www.techvalidate.com/product-research/kinaxis-rapid-response](http://www.techvalidate.com/product-research/kinaxis-rapid-response)

TVD: D2E-8A1-7FA



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### Better Inventory Management

“ With RapidResponse we improved event management for supply with non conformance and improved adherence to inventory targets above 95%. We are consistently managing abnormal scrap below budget (20% below budget). ”

Source:  Executive, Global 500 Pharmaceuticals Company

[www.techvalidate.com/product-research/kinaxis-rapid-response](http://www.techvalidate.com/product-research/kinaxis-rapid-response)

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## About Kinaxis Inc.

Offering the industry's only concurrent planning solution, Kinaxis helps organizations around the world revolutionize their supply chain planning. Kinaxis RapidResponse, our cloud-based supply chain management software, connects your data, processes and people into a single harmonious environment. With a consolidated view of the entire supply chain, you can plan expected performance, monitor progress and respond to disconnects when reality hits. RapidResponse lets you know sooner and act faster, leading to reduced decision latency, and improved operational and financial performance. We can prove it. From implementation to expansion, we're here to help our customers with every step of their supply chain journey.

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