

Streamlining pharmaceutical manufacturing and distribution while preparing for a more complex future

Increase throughput and enhance regulatory compliance using Radio Frequency Identification technology



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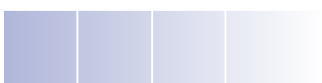
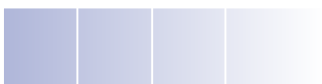
Executive Brief

Executive overview

In recent years, pharmaceutical manufacturers have struggled with responding quickly to market demand and overcoming supply-side inefficiencies. An increase in the number and complexity of products, coupled with the demands of regulatory compliance in a time of growing market pressure, has made it a challenge to maintain a foothold in the marketplace. To continue to compete—and survive—pharmaceutical manufacturers must become more lean and agile in their approaches to streamlining operations and create a step-change in quality, process and compliance management.

Though historically supply chain management has not received much management attention, this situation is changing with a new focus on driving revenue and increasing profit margins. Currently the number one issue for products not launching on time is supply chain readiness; yet supply chain operations can cost companies more than a third of revenues—including cost of goods (COGS), inventory and assets—while consuming about half of total headcount. As a result, pharmaceutical manufacturers are looking for new ways to improve efficiency and supply chain responsiveness.

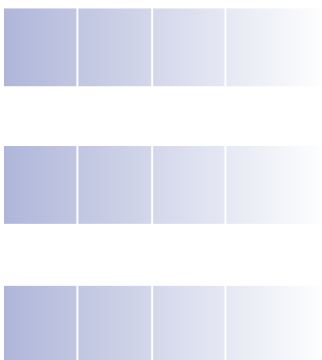
IBM solutions for Radio Frequency Identification (RFID) can help you eliminate typically slow and inefficient manufacturing processes, helping you prepare for a future with more complex products produced in smaller quantities. This executive brief explains the benefits of an RFID solution for pharmaceutical manufacturing and how IBM Business Consulting Services can help you take advantage of technologies that transform your supply chain—all to help you more rapidly respond to market demand and heightened regulatory scrutiny.



Addressing the pressures pharmaceutical manufacturers face

Currently, six major forces affect the global supply chain:

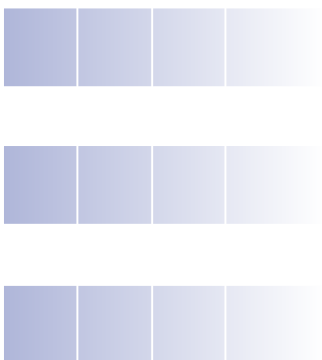
- Regulatory compliance has become the primary driver for prompt change in pharmaceutical manufacturing, calling for a science-based correlation between manufacturing processes and requirements critical to patient care and quality.
- The increase of new product types—high-density and targeted treatment solutions—combined with significant manufacturing complexities could create a worldwide biologics manufacturing-capacity constraint.
- A new threshold of pharmaceutical innovation enables manufacturing of increasingly complex products to small but highly lucrative markets. Yet these products require high-speed manufacturing to support rapid market availability, and higher quality and increased frequency mandated by shorter shelf lives.
- As the value of high-density and targeted treatment solutions increases, so does the threat of theft and counterfeiting. Consequently, the supply chain must be modified to verify drug safety at an individual level, while allowing you to monitor patient compliance and results.
- The supply chain continues to be squeezed for greater productivity while asset utilization drops and volumes become static or decline. Typically, standard manufacturing processes are slow and inefficient, and with an increase in complex drugs, even greater demands will be placed on cycle times. It is anticipated that lengthier production processes and complex quality and control requirements will become the norm, along with better traceability and less waste.
- As part of new compliance and reporting requirements, the Sarbanes-Oxley Act forces increased cross-company and border transparency, along with traceability across the entire supply chain.



Meeting changing industry dynamics head-on

The issues noted previously generate other issues, creating a ripple effect throughout your supply chain. As more treatments become targeted to subpopulations, an increase in the number of products occurs, necessitating lower-volume manufacturing with high changeover requirements. Your business cannot afford to carry inventory and manage the inefficiencies that characterize traditional manufacturing processes. Further, prices are continuously driven down by competition from generic drug sales, an increase in the negotiating power of managed-care providers, as well as the creation of government-subsidized prescription drug benefits.

To keep pace, your company will inevitably need to shift to a more flexible, demand-driven supply chain, requiring an increased level of control over process efficiency and faster, more frequent input replenishment. This shift will entail not only reducing COGS and inventory levels, but also shrinking the entire order-to-cash cycle, from materials management through facilitating new distribution channels. Staying ahead in the marketplace also requires that you successfully address critical but currently inefficient and time-consuming regulatory compliance processes.

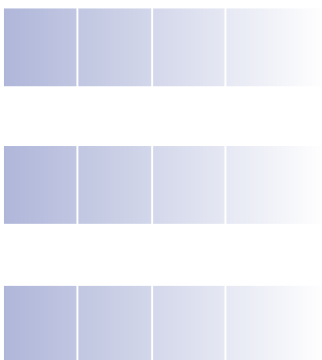


Achieving manufacturing goals with technology

To stay competitive and remain in compliance, you're driving toward lean, high-performance operational standards. Consider the current state of pharmaceutical manufacturing in comparison to an ideal yet achievable outcome. (See Table 1.)

Table 1: Challenges faced by today's pharmaceutical manufacturers can be catalysts for change.

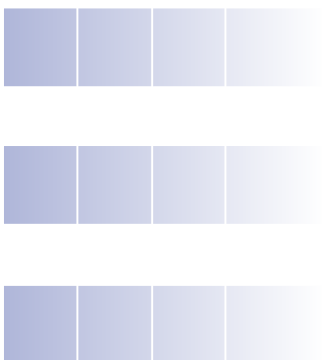
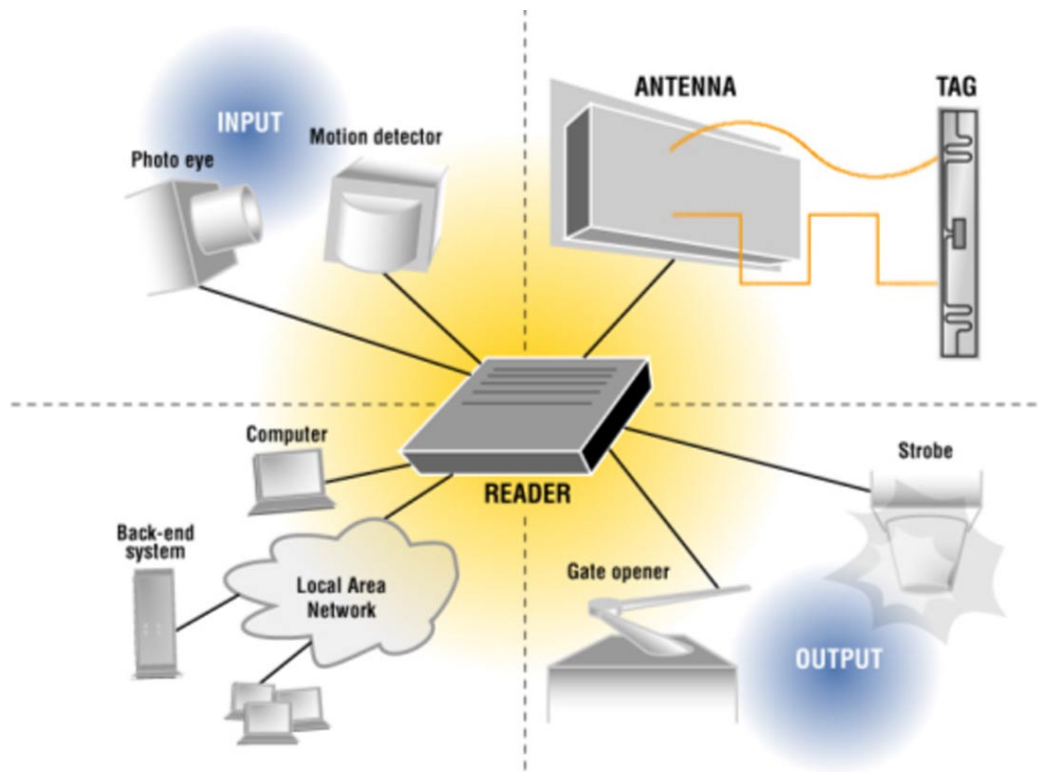
	Current	Ideal
Customer service	Accomplished by inventory development	Accomplished by improved supply chain responsiveness and agility
Inventories	Necessary to hide poor capabilities and inefficiencies	Reduced with synchronization of supply with actual demand
Process efficiency	Expected failure and high variability result in excess resources	Reduced variability and waste as a result of real-time performance at high quality levels
Cost performance	Driven by volume and traditional cost-cutting approaches	Driven by productive use of resources, only when customer need requires
Asset base	Sized to take account of historical inefficiency and unreliability	Determined from lean production-run strategy and enhanced flexibility
Quality	Inspected and measured in batches	Corrected in realtime with regulatory use of process analytical technologies



Leveraging RFID for manufacturing success

While these challenges do present obstacles, they can also serve as catalysts for improvement. Through the use of RFID solutions—a relatively untapped technology in pharmaceutical manufacturing—you can begin to address strategic manufacturing goals and lay the foundation for handling future complexity.

By using radio waves to identify materials and products to an item level, RFID technology improves upon the 25-year standard of product identification and compliance-tracking through the use of bar codes. Since radio waves don't require line-of-sight visibility, an entire pallet of product can be identified and tracked, for example, just by passing through a reader mounted on a warehouse door. The capacity of RFID tags to contain enough data for the identification of unique items, combined with the ability to layer encryption and additional features, is designed to let you increase operating efficiencies and decrease labor costs while simultaneously increasing throughput. While RFID cannot independently solve the problems raised by the key forces described above, it can serve as a consistent and critical component of a layered solution approach that addresses these issues.



Using RFID to transform your supply chain

The most common means of identifying products using RFID technology is to store the product information, including its unique identifying serial number, on a microchip attached to an antenna, together known as the RFID tag. When interrogated by a reader, the tag transmits that identification information to the reader, which converts the radio waves returned from the RFID tag into language a computer can understand and use.

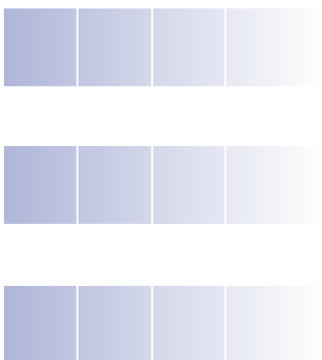
With RFID technology, each unit has a unique electronic product code (EPC) that allows authentication at any point in the supply chain (from the lot or product level). By providing data in realtime, the EPC enables more flexible processes, moving you closer to creating a pull-based supply chain in an on demand environment—one that is designed to let you respond in realtime to process controls, compliance requirements, product diversions, recall management and customer demand levels.

RFID technology makes use of unique identifiers that can be directly associated with production runs. Depending on the type and capability of the tag, information about the product and associated processes can be written to an RFID tag attached to the product container or to a security-enhanced database identified by the tag. This information, along with increased data integrity and reduced process variability, helps ensure new levels of product quality across the entire supply chain.

Applications of RFID in pharmaceutical manufacturing include:

Asset and product tracking to increase efficiency and reduce labor costs

- Track equipment and reusable assets, along with raw materials and work-in-process, throughout the manufacturing system.
- Verify correct materials inputs and rotate components for first-expiration/first-out use to support proper use of expensive raw materials.



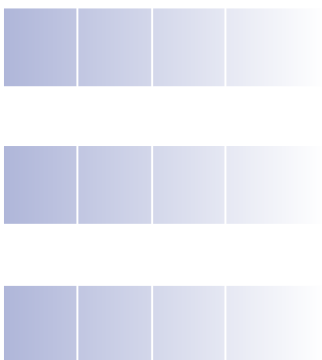
Manufacturing process improvement and compliance tracking

- Monitor environmental conditions of components.
- Increase automation of documentation (e.g., batch records, lot data, product location and test data) to help improve regulatory compliance.
- Obtain proactive alerts to process problems and their sources.
- Identify batches affected by problems—before they enter the distribution chain.
- Verify line clearance between batches and proper product labeling.
- Support introduction of process analytical technologies (PAT) by tracking product quality and validating compliance in the production process, rather than upon manufacturing completion, to optimize product consistency.

Optimizing opportunities for cost savings and process improvements

When you view manufacturing strategically, RFID technology can help you address many of your goals and achieve measurable—and profitable—business benefits. You can improve regulatory compliance and reduce liability by enabling realtime monitoring of good manufacturing-practices compliance. You can create a traceable path by numerous variables, including raw material batch, manufacturing equipment, time of production and equipment operator. Finally, you can reduce lengthy quality assurance (QA) times by decreasing risk or errors in documentation.

With an integrated RFID system that permits linking environmental and process controls, you can detect and repair sources of line stoppage or out-of-spec processes for in-line rejection in realtime. And with the ability to collect data in realtime, your manufacturing enterprise can support a shift to a pull-based supply chain, letting you become more responsive to changing market demands. Along with improved production efficiency comes improved product availability—helping to eliminate lost revenue due to drug shortages.

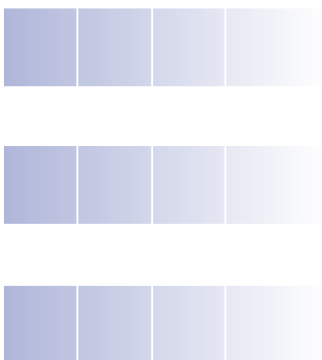


With the use of RFID in the distribution channel, you can:

- Reduce warehouse and distribution center labor costs.
- Manage product recalls much more efficiently by knowing which products to recall, and where they are in the channel.
- Enable direct-to-physician distribution as appropriate.
- Manage inventories more tightly as a result of realtime visibility.
- Reduce rebates paid to wholesalers and distributors by knowing when purchases were made and by whom.
- Reduce levels of overage and shortage through tighter coupling of supply and demand.
- Enhance drug safety and lower liability by reducing counterfeit and diversion.

QA tracking capabilities—from receipt of raw materials through packaging to the customer consumption—decrease the need for manual processes and associated labor, along with rework. With smaller inventories of raw materials, work in progress and finished goods, working capital is reduced. Consequently, fixed assets decrease due to better plant and equipment utilization.

Access to realtime, recorded information of all product data transactions through the lifespan of the product (from process parameters to specific batches and equipment) lets you support PAT. The U.S. Food and Drug Administration most likely will pass legislation making PAT a requirement, ultimately replacing the current standard of audits and reporting. And since QA cycle times are frequently greater than process cycle times, RFID technology that can reduce lengthy QA times can add directly to your bottom line.

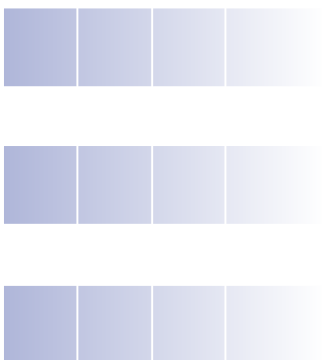


While the FDA is not endorsing any single compliance technology, it has identified RFID as a key technology for tracking products throughout the supply chain.

Extending existing technology with RFID

When compared with existing manufacturing technologies such as bar coding, RFID offers more robust efficiencies. Manual involvement is decreased, because line-of-sight technology is not required for product scanning. Less product waste occurs, since verification of authenticity doesn't require product destruction. And unlike bar codes, EPC codes not only identify individual products, but are themselves unique and cannot be duplicated. They can also be encrypted for additional security. Scalable, usable RFID tags carry substantially more information than bar codes and have faster read times for high throughput. When implemented along with traditional technologies like bar coding, RFID gives you a highly effective means to reduce errors while increasing throughput, enabling you to better meet market demand.

Although RFID enables a broader range of capabilities than bar coding offers—improved drug accountability and product availability, rapid batch identification and recall capability, and accurate product movement data—the technologies will likely coexist. With this in mind, companies including IBM have developed solutions that incorporate both RFID and bar-coding technologies. IBM Track and Trace, for example, is a combination RFID and bar-code-capable solution designed to track goods that move through a multienterprise supply chain. Units can be tagged from an individual level, at the manufacturer's facility or from a bulk level, upon distribution at hospitals, pharmacies and doctor's offices to end customers. The result? You can simultaneously report on goods' movement and status while feeding realtime tracking data to multiple enterprise resource planning, supply chain management and warehouse management systems. Unique IDs support creation of an international pedigree that can be verified at any point in the supply chain, creating a continuous assurance chain.



Creating a roadmap for your success

The value of implementing an RFID solution will depend on business-case dynamics exclusive to your company and products. IBM Business Consulting Services professionals can lead your business through the entire process from start to finish. We work with you during three key RFID implementation phases:

Business-case and deployment strategy

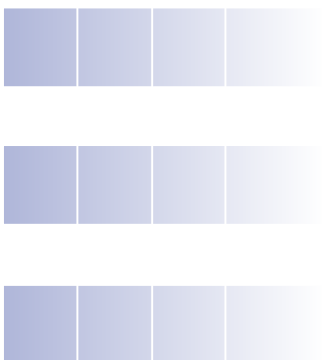
We can identify the tangible business benefits that RFID can offer your company. We discuss implementation designs that can reduce business impact and assess your existing technology infrastructure to determine a more cost-effective, efficient software strategy.

Solution-build and pilot program management

We can develop and implement the pilot installation, including solution architecture and hardware and application integration. Following thorough testing of the pilot implementation, we verify that data is appropriately captured from the tags and transferred into your backend systems quickly and accurately.

Enterprise rollout and integration

During the final implementation phase, we estimate capacity and performance needs, establishing benchmarks for testing your solution once it's deployed. Our professionals plan and manage your enterprisewide deployment, from installing the data warehouse and setting up data management services to integrating new processes with your appropriate supply chain partners.



Putting our experience and solutions to work for you

IBM can design customized, scalable solutions for multiple manufacturing facilities, distribution centers and warehouses—and help ensure a virtually seamless fit with your existing infrastructure. With solutions that integrate RFID tags and multifrequency readers with existing bar code and backend systems, you can implement cost-effective RFID technology across your enterprise.

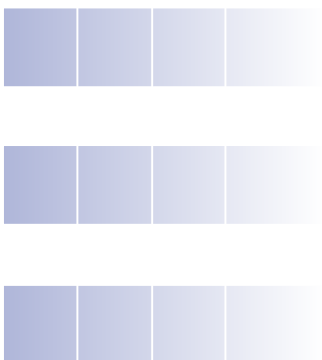
A leader in RFID solutions for over ten years, IBM developed some of the original patents that support the current tag and reader technology and drive today's industry. IBM is itself an RFID-enabled enterprise, using RFID technology as a key technology that enables the full automation of our semiconductor chip fabrication plant in Fishkill, New York.

Since successful RFID implementations require industrywide collaboration and commitment to standards, IBM has been a member of the Auto ID Center and a representative on the Technology Board since 2000 and is an active participant in EPCglobal. Our alliances with leading hardware and software developers in the RFID industry allow us to offer superior solutions backed by best-in-class technology. IBM consultants represent both functional and technical specialists, who have provided support to 75 percent of the top pharmaceutical firms.



Creating the supply chain of tomorrow, today

As a pharmaceutical manufacturer, you face not only top-line pressures but significant challenges unique to your industry: extensive regulatory compliance burdens, increasingly complex products and supply chains, and inefficient manufacturing processes. But with RFID technologies working for you, the advantages are many. The data flowing throughout your supply chain can help you monitor the manufacturing process in compliance with regulatory requirements. It can also help you shift from a reactive build-to-inventory mode to a proactive pull-based approach, creating realtime flexibility in your supply chain. As a result, you can maintain—and even improve customer service levels—and reduce manufacturing costs and liability exposures while continuously improving processes.



For more information

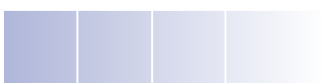
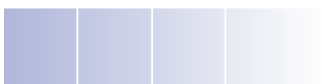
To learn more about IBM Business Consulting Services, contact your IBM sales representative or visit:

ibm.com/bcs

To learn more about IBM Solutions for Radio Frequency Identification visit:

ibm.com/services/bcs/pharma

¹² *Pharmaceutical Supply Chains: Key Issues and Strategies for Optimisation*, Nilay Shah, Centre for Process Systems Engineering, Department of Chemical Engineering, Imperial College of Science, Technology and Medicine.





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