



## Addressing Pharmaceutical Supply Chain Challenges with a Pharma ERP Solution

## Pharma industry overview:

---

Despite a few challenges such as global healthcare reforms, growing market demands and stringent regulatory pressures threatening to peg the industry back, the pharmaceutical industry has been one of the best-performing industries in the recent years. During last decade or so, pharma companies across the globe have made significant progress and breakthrough achievements in many areas, such as R&D, manufacturing, sales and marketing, etc. The companies have increasingly strived to maintain the highest safety and quality standards, which has resulted in higher sales and increased profits, much more than most other industries.

This growth notwithstanding, the companies can't overlook the challenges, which can take a bigger shape going forward. They can't ignore the demands of the patients and regulators, who expect higher quality of care with reduced costs while ensuring enhanced transparency. To meet all such complex business challenges, it has become imperative for the pharmaceutical industry to take a proactive approach towards compliance and product safety while responding to the market demand. In addition, it has also become important for the industry players to address the pharma supply chain challenges. There are, in fact, many issues which threaten to cripple the supply chain, thus underlining the importance of supply chain management in pharma industry.

The pharma industry is multi-layered with a complex outbound supply chain that comprises of various stakeholders such as Carrying & Forwarding agents (C&F), super stockists, dealers, distributors, sub-stockists, etc. The distributors can be further distinguished as trade distributors, hospital stockists, generic pharma distributors, medical device suppliers, consignment agents etc. To complicate this further, there are inter-state transfer pricing challenges, CST, Octroi, etc. If you thought the intricacies would end here, you are wrong, for there is more to add to the industry's woes!

There are hundreds of thousands of brands present in the market and numerous new brands get introduced almost every day! Then there are the sales targets, incentives, procurement managers, etc., which define the supply chain dynamics. The resulting adverse implications are reverse logistics, high expiry rate as well as employee turnover ratios. This differentiates pharma supply chain to a large extent and hence, makes it one of the most complicated ones. With changing times, the industry hasn't quite opened up to the changing supply chain requirements, operating at the same old paradigms. But considering the way technology and digitalization has had an impact on every industry, pharma supply chain will not be left far behind.

In this White Paper, we will take a look at the current state of pharma supply chain, importance of supply chain management in pharma industry, in-depth view of the pharma supply chain challenges, how a pharma ERP can help deal with those challenges, why pharma supply chain needs it, and what future technologies will have an impact on the pharma supply chain. Continue reading:

## Present scenario of Pharma supply chain:

---

In the wake of increasing competition, pharma manufacturers have taken bold steps to diversify their portfolios and bring down the costs. Some such steps include developing capabilities to manufacture complex generics, investing in capacity to manufacture biosimilars, and improving overall operational efficiency. For the same, the companies are looking to review their supply chain. The state of the pharma supply chain can in fact be assessed by evaluating the three key performance indicators, which are customer service, inventory levels, and supply chain costs:

**Customer service:** Pharmaceutical companies of all sizes strive to ensure their products' availability across the supply chain. The companies also aim at maintaining the quality of their products, which also ensures good service levels. The integration of the pharma supply chain, in fact, is essential to achieve the desired service levels.

**Inventory levels:** Fragmentation has resulted in a large number of stocking locations. A country like India has a multi-tiered distribution network through C&F agents and stockists. Because of long manufacturing lead times and regulatory requirements, pharma companies usually maintain higher stock levels than other industries, even at the cost of writing off expired inventory. This has created the need for better supply chain planning and inventory management.

**Supply chain costs:** Supply chain costs depend mostly on the type of product. For example, specialized cold chain requirements for vaccine and other complex formulations can significantly increase the supply chain cost. Higher transportation costs, and issues with storage, specifically for high-risk and conditional products, are other factor involved in the supply chain costs.



## Significance of Pharma supply chain:

---

Supply chain in pharmaceutical industry is predominantly important for two reasons - product sensitivity and on-time delivery. The pharma firms thrive to seamlessly provide affordable and good quality drugs to millions of people - and the supply chain plays a crucial role in this process. In fact, managing the supply chain efficiently is the most important aspect when it comes to transportation of pharmaceutical products. A well designed supply chain takes care of the various lead times that can help achieve speed to market.

Pharma industry has also benefited from the technological evolutions, as IT has played a significant role by providing visibility of inventory across various supply chain nodes as well as for inventory in transit. Availability of the inventory data online holds the key for the success of the supply chain, and use of IT tools makes it possible. As the companies aim to provide cost-effective and innovative medicines, importance of supply chain management in pharma industry gains major attention. In fact, supply chain management plays an important role in making these medicines available, thus playing a significant role in the pharmaceutical industry.



## Challenges faced by Pharma supply chain:

---

- **Supply chain fragmentation:** The pharma supply chain is highly fragmented, comprising of contract manufacturers and thousands of suppliers. There are many geographical areas which are operating with larger numbers of SKUs, while there are areas where the essential medicines are not available on time. This makes the whole process of supply chain management complex and poses concerns about the safety and quality of the products. In addition, decentralized R&D centers, and a complex distribution network with thousands of distributors result in poor supply chain visibility and service levels.
- **Contract/Third party manufacturing:** Realizing the benefit of R&D and to get mileage out of their brands, more and more global pharma companies have shunned their vertically integrated business models and have resorted to outsource many of their operations. But they are looking for partners that focus not just on production but all aspects of drug manufacturing, as this saves them for dealing and coordinating with multiple contractors. This has posed a challenge in front of contract manufacturers to have sufficient resources and right tools in place to provide everything and not just cost-efficiency, labor and machinery. They are forced to re-invent themselves to provide deeper visibility, better quality, class-A service, security of formulation and complete documentation to the contract givers. Read more on the challenges of contract manufacturing in pharma industry [here](#).
- **Infrastructural challenges:** The demand variability in the supply chain increases as the stock moves from manufacturer to patient. Also as the products move from the manufacturer to the end consumer, they face infrastructural challenges, such as transportation, power supply, storage, etc., thanks to inadequate road, rail and air network. This results in higher cost, impacts every stakeholder negatively on performances and more.
- **Non-visibility of inventory:** The presence of large number of vendors and the lack of integration across the network also leaves an impact on the visibility and traceability of the products. The non-visibility of inventory causes serious threats of counterfeits, loss of sale, challenges to trace products and unpredictable demand scenarios.
- **New product development:** Leading pharma players in India are expanding their product portfolio and launching around 30 products a year. Many manufacturers are looking at bringing complex and innovative products, and resorting to new technologies to support production, thus adding significant complexity to the supply chain network.
- **Reverse logistics:** Just the product expiries result in over 300 USD loss in India! Reverse logistics does take a toll on costs, thus posing a serious financial threat to the pharma manufacturers.

- **GST woes:** GST has had an impact on the lives of pharma manufacturers, affecting their pricing, working capital requirements, contracts with vendors and customers, change in processes, etc.
- **Temperature control:** During their production, the pharmaceutical products can be exposed to a diverse range of temperatures. The causes for the same could be natural calamities, unexpected changes in climate, etc. The ability to maintain a constant temperature is crucial to ensure the effectiveness and quality of the drugs, which actually is a challenge for the pharma manufacturers.
- **cGMP compliance:** Complete adherence to regulations worldwide is an absolute must within the pharmaceutical supply chain. With enhanced global regulations and stricter regulatory framework for the movement of medicines coming into effect over the next few years, meeting all compliance requirements is essential. In such times, the pharma manufacturers need to adopt current Good Manufacturing Practices (cGMP). These practices help them ensure that the products they offer are absolutely safe and adhere to all the safety & quality standards – something an extremely-aware consumer demands these days.

cGMP are nothing but a contemporary as well as standard set of principles, preventive measures and hygiene practices enforced by the FDA, which ensure that the pharma products are consistently produced, handled and controlled in accordance to the quality and safety standards. They are designed to minimize the risks involved in pharma manufacturing. The cGMP guidelines provide guidance for manufacturing, testing, and quality assurance in order to ensure that the drugs and other pharma products are safe for human consumption.



## Why GMP is important for Pharma manufacturers?

---

It is pretty simple. cGMP are important for pharma manufacturers in order to produce safe drugs. It is the legal and moral responsibility of a pharma manufacturer to produce products that are not hazardous for the consumers. Not implementing the cGMP can in fact prove costly to the pharma businesses, as failure to meet the cGMP requirements results in situations like recall, seizure, penalty & even prosecution. Hence, it is a massive challenge for the pharma manufacturers to meet the cGMP requirements.

**Validation:** It is one of those challenges which the pharma manufacturers face after they make the decision to go for an ERP software implementation. As the system is used for cGMP-critical operations, its third-party testing and subsequent validation is a must and a critical element of the implementation process. The validation testifies that the product is in-line with FDA and global regulatory guidelines and meets all the FDA and cGMP standards. Finding the right ERP software which meets their business needs and at the same time comes with requisite validation is a challenge.

It is imperative to know that there are various kinds of business models that exist in this industry and hence, the degree and types of challenges would vary as per the model.



## Pharmaceutical ERP software:

---

A Pharma ERP solution is a comprehensive software solution designed specifically for the pharmaceutical industry. In addition to providing simple and cost-efficient process model, the pharmaceutical software also helps manufacturers to be in full compliance to the cGMP requirements. Pharma being a formula/recipe-based industry, the software understands formulation management requirements and integrates with your operations to provide real-time information, which in turn helps manufacturers streamline their entire operations and take proactive as well as informed decisions to outlast the competition.

## Why Pharma Supply Chain Needs a Pharma ERP software?

---

The pharma supply chain directly or indirectly affects the well-being and lives of millions. This makes it important for all the businesses that operate throughout the healthcare industry to have complete control and traceability of their supply chains. Also for all such businesses, quality control is the key, as they have to meet the compliance criteria set by the regulatory authorities. Demand planning, inventory control, stock management, order processing, customer service, production scheduling, and manufacturing control, are other key functionalities pharma manufacturing businesses require. Hence, it's crucial that the pharma manufacturers and distributors are equipped with the tools that help them achieve the highest levels of efficiency, traceability, quality and delivery. Few tools are as important to achieving this as an Enterprise Resource Planning (ERP) software.

A Pharma ERP Business software can ensure that the pharma supply chain challenges are dealt with, and the supply chains are performing efficiently, accurately and transparently. By improving the flow of information and control throughout the organization, ERP can help to drive cost out of the supply chain, reduce lead times and ensure greater customer service. Many businesses have disparate IT systems, or manually labor intensive tasks, which can be managed for a while, but not in the long run. A Pharma ERP solution provides a single, scalable solution to help pharma manufacturers gain greater control, complete traceability, transparency and visibility of their entire supply chain operations. By keeping records, meeting compliance requirements associated with clinical trials, as well as the cGMP requirements, research and product manufacture, an ERP for pharma leaves no room for error, and places supply chain control and visibility at the top of the pharma manufacturer's agenda.

## How an ERP can address the Pharma supply chain challenges:

---

- **Connect and collaborate:** Pharma companies need to connect all outside supply chain partners and bring them together on one single platform, thus consolidating the fragmented supply chain and allowing all the supply chain partners to work in sync with 'one version of the truth' being shared across all of them. This enables both end-to-end visibility and the collaboration needed to support business interactions among all the stakeholders. A comprehensive Pharma ERP software makes it possible.
- **End-to-end visibility:** Lack of visibility into the inventory creates the problem of understock or overstock inventory and results in poor delivery of goods and services to the customers. With an efficient Pharma ERP solution, the pharma companies can have end-to-end visibility into the inventory, knowing where it is presently and where is it headed. The companies can thus quickly identify and resolve problems. This also addresses the issue of inventory loss, which causes heavy monetary losses to the pharma manufacturers every year.
- **End to infrastructural woes:** We read earlier how infrastructural challenges result in higher costs and impact the performance of every stakeholder in the supply chain. A Pharma ERP loaded with modern digital capabilities and supply chain solutions such as predictive analysis can help companies get rid of the infrastructural challenges.
- **Robust quality and compliance system:** A highly efficient Pharma ERP software builds a robust quality and compliance system for the pharma companies, taking care of their regulatory as well as other statutory requirements. It works within the global pharma regulatory framework, thus ensuring manufacturing of high quality pharma drugs meeting compliance needs set by FDA and other regulatory bodies. Besides, it is also fully compliant to GST rules and other mandatory legal requirements.
- **Cold chain management:** Cold chain is the process of moving temperature-sensitive products through the supply chain. Many a time such temperature-sensitive products lose their efficacy while in transit due to unplanned and unexpected events. Proper cold chain management helps ensure that medications reach patients retaining their effectiveness and quality. An ERP software, loaded with supply chain and cold chain management capabilities, ensures real-time temperature monitoring utilizing latest technologies to keep your pharma products effective, safe and secure for the consumers.

- **Development of new products:** An ERP for Pharma provides complete support in the development of new products (for both in-house as well as contract manufacturing) with enhanced features like specialized costing and quotation and modules such as R&D, formulation, and costing. The pharma ERP system supports innovation, and allows bringing products to the market at a faster rate.
- **Meet the cGMP requirements:** An ERP solution can have a significant impact on ensuring compliance with GMP are met easily, paving way for quality drugs and pharma products being delivered to customers. An ERP solution can effectively handle the following:
  - **Batch tickets:** A perfect ERP solution can provide individual batch tickets, including QC tests for each phase of production ensuring the strictest QC. It also provides archived batch tickets, which come in handy in cases of audit, as they provide a properly documented trail of process control.
  - **Formula management:** ERP software allows tracking revisions to formulas and provides an audit trail throughout the revisions. It can also scale those formulas to meet current demand levels, optimizing ingredient usage, tracking all ingredient costs and ensuring compliance.
  - **Quality Control (QC) testing:** The best-fit ERP solution sets up user-defined QC tests to manage how often QC tests are performed, what is tested, and what amounts are tested. It prevents failed items from entering the manufacturing process.
  - **Document management and regulatory reporting:** An ERP solution allows managing documents from archiving Standard Operating Procedures (SOPs) to providing proper shipping documentation by batch, customer or product.



## Pharma ERP solution & future technologies:

---

Empowered with all the information, which is being readily available at their fingertips, the modern-day consumers have become more demanding than ever. They increasingly demand for high quality drugs at an extremely affordable price. This has put the pressure on pharma manufacturers, who have to deal with these and many other challenges on a daily basis. An efficient pharma ERP software does help them with it. However, in future, things are likely to get more difficult to manage for the manufacturers, with an increase in volume of business as well as change in technology. Dealing with the future pharma supply chain challenges will require companies to incorporate technological innovations to their system.

Here are few future trends that are likely to be incorporated to a Pharma ERP in the years to come:

- 1) Robotics:** We know that the robots can go on repeating the same tasks hour after hour with high quality and precision. They can thus be a very good fit for pharma manufacturing, where exacting precision is often an important requirement. The use of robots can ensure improved quality while at the same time, it can also result in reduced cost of labor. The use of robots in pharma manufacturing is not a distant reality, with few firms working on this idea.
- 2) Blockchain:** Blockchain is 'an ever growing list of records, called blocks, which are linked and secured using cryptography.' In the context of pharma supply chain, this collaborative technology can be used to bring in more transparency and security. In the present pharma supply chain, trading partners usually connect via individual systems for exchanging agreements as well as transactions, which can duplicate work and in some cases, produce varying conclusions. A Blockchain provides a single source of truth for partners to work with and limits the risk of exposing proprietary information. It is definitely going to be a huge thing in the future pharma supply chain.
- 3) Internet of Things (IoT):** With an eye on the future, few pharma companies are looking at opportunities to digitize their supply chain, and creating a supply network with end-to-end visibility not just to the internal stakeholders, but also to the patients. IoT is going to play a major role in it. In fact, it is already playing its part, with devices like commercial telematics, which is being used in trucking fleets to improve logistics efficiency, and smart fabrics, which uses sensors within clothing and industrial fabrics to monitor human health or manufacturing processes, already showing what they are capable of. With time, these capabilities are expected to become mainstream, and allow modern supply chains to deliver more differentiated service to customers more efficiently.

- 4) **Self-driving trucks:** Still not quite being a reality, the self-driving trucks are being developed by multiple teams as a medium to lower the costs and improve the service levels. As of now, few organizations have revealed the plans to use their own self-driving trucks to make freight deliveries as a pilot project. The tests from this project will go a long way in helping the pharma industry develop this capability further. Once ready, these trucks will have the potential to really change the distribution landscape; including the size and location of warehouses, design of the supply chains, to inventory levels and the speed of servicing customers.
- 5) **Continuous manufacturing:** We will see in future the pharmaceutical industry rapidly move from batch processes to continuous manufacturing, which is actually the future of pharma manufacturing. The continuous flow, and end-to-end integration of manufacturing sub-processes, with a significant level of control strategies, will make pharma manufacturing less complex. Other benefits of continuous manufacturing include reduced waste and downtime, increased gross margin and profitability, etc.
- 6) **3D printing:** 3D printing, the technology which allows making three dimensional solid objects from a digital file, is going to change pharma manufacturing forever. Its scope would cover drug dosage forms, supporting delivery, or helping to research cures. It could open up a whole new world of opportunities in personalized medicine, with patients getting an optimal medication dose and medicines in their preferred color or shape.
- 7) **RFID chips:** Pharma manufacturers are constantly looking at how they can improve the ways of monitoring their products in the supply-chain. Radio-Frequency Identification (RFID) is currently being looked at as the possible tool that can help them in this quest. With the capability of capturing and relaying data, RFID is perhaps just the tool pharma manufacturers are looking at in order to improve quality, reduce costs, and most importantly improve patient safety.



## Conclusion:

---

Pharma industry has become a lot more complex these days. Comprising of numerous channels, multiple regions and specific target markets, it poses a serious supply chain challenge for the pharma companies. The need of the hour for the pharma manufacturers is to understand the importance of supply chain management in pharma industry. With the right Pharma ERP system to assist them, they can tackle the pharma supply chain challenges, keeping their businesses agile as well as profitable. A pharma ERP solution makes it possible, as it gives the pharma manufacturers end-to-end visibility into their supply chain, consolidating it from its highly fragmented state. It gives them visibility into the inventory, helps with new product development, regulatory compliance, and deal with the GST and reverse logistics woes.

Once such Pharma ERP is the BatchMaster ERP for Pharmaceuticals and contract manufacturers, which is an integrated, end-to-end platform. It delivers solutions that align with cGMP compliance requirements, a mandatory obligation of this sector to regulatory agencies. BatchMaster ERP for Pharmaceuticals has been tested by a well-known third-party neutral organization 'OnShore Technology Group' against USFDA guidelines. It can fulfill the needs of pharma manufacturers of all sizes and segments. Available on Cloud and on premise, it is tailor-made to meet the manufacturing, distribution, compliance, quality and cost-control needs of Pharmaceutical industry. Be it, API, Bio-technology, Medical Devices, Life Science, Nutraceutical or such, BatchMaster has tailor-made solution for them all.



**Check out BatchMaster ERP for Pharmaceuticals' features below:**

- Raw material planning and procurement
- Supplier / vendor management and qualification
- FDA 21 CFR part 11 compliance, which includes secured master data management
- Quality Control (QC) with sampling plan, stability testing
- Quality Assurance (QA) as per cGMP norms
- Inventory management, including material characteristics such as lot potency, classifications, expiration dates, lot control, and varying units of measure
- Contract manufacturing and third party manufacturing support
- Formulation management: Complete formula security with audit trail and approval workflow. Also includes by-products, co-products, intermediates, variations in expected yields and alternate equipment-specific formula
- Batch monitoring activities by inspection plan
- Electronic execution of SOPs by inspection checklist
- Electronic Batch Ticket, Electronic Weigh Sheet and Manufacturing Batch Record (MBR)
- Non-conformance (NC)
- Corrective and Preventive Action (CAPA)
- Easy material substitutions
- By-product and co-product management
- Multiple packaging of same formulation
- Shelf life / expiration support
- Bi-directional lot traceability and lot recall
- Separate granular costing of formula and packaging material
- 'What-if' analysis and various costing methods for increased margins
- Adverse event / complaint reporting
- Allergen management
- Mobile warehousing: Employment of handheld RF devices to execute material movement and adjustments within one or more facilities
- Dedicated module to handle all complaints, returns and recalls
- Master Production Scheduling (MPS)
- Material Requirement Planning (MRP)



## Who We Are:

BatchMaster Software is one of the market leaders in offering enterprise software solutions for the process manufacturing industries. With an in-depth industry analysis, we clearly understand the unique industry challenges and help them address those challenges through our industry-specific ERP solution.



Don't lose your existing software; Integration available with:



For more information Log on to [www.batchmaster.co.in](http://www.batchmaster.co.in)