

An Epicor® White Paper

## Four Essential Things To Know About Pharmaceutical Traceability





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## Introduction

Pharmaceutical manufacturers are scrambling to comply with impending global legislation that will mandate sweeping changes to packaged drug coding and marking operations. With major upheaval in the industry—pressure on patents, counterfeit products, greater complexity in releasing new medications, and a spotlight on manufacturing efficiency—drug companies face more challenges today than at any other point in history.

For companies that produce medications, track and trace capability is no longer a valiant goal—it's a critical requirement. Even if there was no compliance issue at stake, no one wants to put a single person at risk, let alone tens, hundreds or thousands. Yet, incidents of medication-related illnesses show up in the news every day. Amid demands for more stringent legislation for end-to-end traceability," pharmaceutical manufacturers struggle to adequately track and trace their products.

The "trace" part of the formula is visibility into where a product has been, looking backwards at the inbound supply chain of ingredients and materials. "Track" refers to understanding product location as it moves forward through the distribution chain. While some believe that "track" and "trace" are independent of each other, experts indicate they are interdependent.

## What you need to know

Consider this: if a toxic product turns up on a retail shelf, it's imperative to have a thorough understanding of every stop along the way, not just from your door to the retailer's hands, but also inventory handling, inbound supply shipments, your suppliers' handling and production, their suppliers' harvesting and production, and so on.

To meet rigorous traceability requirements, manufacturers must arm themselves with the right tools, processes, and insight to uncover and report every element along the supply chain—from origin, all the way to the shelf or provider. And, the cost of all this insight can't be a barrier to enterprise financial success.

If you're ready to take traceability to the next level, there are a few things you'll need to know:

### 1. Not all ERP is created equal

If you're using an industry-agnostic ERP system, you probably have some insight, but likely not enough. Since most manufacturers don't need end-to-end traceability—that is from absolute origin to final dispensing point—the average ERP system generally provides only one level of trace in each direction. With this scenario, a drug maker's system would only provide detail about their direct ingredient distributors.

But, what about the facilities that produced the binders or capsules? What if any one of them had a problem along the way? Moving even further back in the supply chain, it's anybody's guess about the plant growers or chemical formulators. Without the ability to trace an unlimited number of points along the supply chain, it could take weeks or months to pinpoint problems. Meanwhile, your business could face massive financial devastation due to complete recalls, lost inventory and liable actions.

### **2. Effective materials management reduces cost and risk**

When you're thinking about traceability, materials management doesn't usually come to mind. Consider some of the things that cause problems—not just for you, but for your inbound supply chain, and outbound distribution. While some materials, like packaging, have a long or indefinite shelf-life, other critical ingredients can spoil or cause production problems if not used at their peak.

The ability to accurately forecast and report production, consumption, and fulfillment translates to a capacity to adjust inventories and material orders to optimal levels. For example, carrying less inventory, and placing more frequent chemical orders can mean significantly less carrying cost. With accurate materials planning, ingredient throughput improves and often increases end-product shelf-life. Ultimately, more rapid turnover of raw ingredients and product helps to reduce the likelihood of spoilage and helps you deliver higher quality to your customers.

### **3. Medications begin with formulations, so should your ERP system**

Most ERP systems have been built for discrete manufacturing of engineered products. But, pharmaceutical manufacturers have distinct needs, and face risks that are unique to their business. Formulation-based materials management helps process-oriented manufacturers stay on target for “day one for day one” order and delivery processing. For example, when you have the ability to plan appropriately for multiple product attributes and grades, and retailer-specific packing and labeling, you can boost customer service levels while giving a shot to item-specific traceability. Formulation-based materials management improves quality by streamlining planning and production activities, especially when data capture extends all the way back to the field or compound lab. Consider for a moment a bill of materials that's optimized for formulations, and multiple units of measure. Setting up products and production processes becomes easier, and even difficult formulations can be accurately represented and traced.

### **4. Making traceability a priority naturally improves utilization and capacity**

Businesses that focus on traceability generally increase operations performance. When planning, scheduling, production, and inventories align with orders, line utilization improves. Drug companies that look to Lean, Six Sigma or other improvement methodologies find that having the right tools and processes to manage traceability improve throughput, experience less waste, and reduce downtime due to unavailable ingredients. These dimensional improvements translate to cost savings or more capacity, and ultimately contribute to bottom-line performance.

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## Conclusion

Pharmaceutical manufacturers that successfully navigate the traceability maze will ultimately win the game. While they might not ever be free of drug-illness hazards, they will significantly reduce the risk and cost associated with mass recalls and useless inventory.

Furthermore, these leaders will position themselves ahead of the compliance curve, and improve their competitive advantage. Origin-to-shelf traceability doesn't have to be an IT nightmare when you arm yourself with the right ERP system. Look for one that addresses your specific needs and risks as a pharmaceutical manufacturer:

- ▶ Uncovers and reports every element along the supply chain—from origin, all the way to the dispensing point
- ▶ Offers unlimited layers of trace in both directions—inbound and outbound supply chain
- ▶ Delivers robust, formulation-based, day-to-day materials management
- ▶ Forecasts and reports production, consumption and fulfillment
- ▶ Processes orders and delivery on a "day one for day one" basis
- ▶ Captures multiple product attributes and grades, retailer-specific packing and labeling
- ▶ Streamlines planning and production activities
- ▶ Optimizes BOMs for formulations and multiple units of measure

## About Epicor

Epicor Software Corporation drives business growth. We provide flexible, industry-specific software that is designed around the needs of our manufacturing, distribution, retail, and service industry customers. More than 40 years of experience with our customers' unique business processes and operational requirements is built into every solution—in the cloud, hosted, or on premises. With a deep understanding of your industry, Epicor solutions spur growth while managing complexity. The result is powerful solutions that free your resources so you can grow your business. For more information, [connect with Epicor](#) or visit [www.epicor.com](http://www.epicor.com).



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