One Network Enterprises™

Product Traceability Across Your Supply Network:

A Natural Evolution

When fielding product quality issues, whether it leads to recalls, warranty claims, or unit level repairs, we will need to regain the trust of the consumer by having the ability to address and communicate our course of action proactively - and thus limit the impact. Business network technology enables us to do this, as it tracks the full chain-of-custody for every item from start to finish, providing visibility across final products, intermediates, and raw materials in real time from their source, across trading partners and to the end consumer.

By Joe Bellini, COO One Network Enterprises

Supply Networks operate based on the trading relationships between brands, consumers, retailers, distributors, and suppliers. These trading relationships are structured as many-to-many, where a brand can interact with all consumers and a consumer can interact with all brands. This extends upstream in the supply chain network where a distributor can trade with all suppliers and a supplier can trade with all distributors. And with a business network architecture, as a participant in the network you only need to define yourself once to open trading relationships with all parties. That's in stark contrast to the old ERP monolith days, where every supplier had to support a point-to-point connection with every distributor, and every distributor had to support a point-to-point contact with every supplier.

Agility and real-time collaboration in your business network are high priorities, given that end consumers can make or break products with ever increasing speed. Layer in the omni-channel requirements for both outbound sales as well as product returns, and you've added scale and complexity to your business network requirements. With product safety top of mind for many consumers, they will give preference to brands that can ensure quality through the ability to provide full traceability across the network. The good news is that a key advantage in your natural evolution toward the digitization of your supply network is providing greater traceability - up, down and across the network.

CONSUMER SAFETY & PRODUCT QUALITY: NOW SERVED THROUGH TRACEABILITY

Earlier in my career, I was the President at Brooks Automation where we provided robotics and software to the high-tech electronics industry. One of our key offerings was a manufacturing execution system (MES) where we were able to provide full track and trace capabilities for products like cardiac pacemakers. Measurement was key at all levels, given the insights it provided that could be applied to product quality and patient safety.

What if we could extend that concept from a manufacturing site to a complete supply network, where consumer safety is now served through traceability across the network, and could be measured in meaningful ways to improve quality for the consumer? The network platform would need to be very robust, given the track and trace functions would need to understand the product lineage across the network including serialization, lots, batch, sub assembly, assembly, fill & pack and more. Many industries like Healthcare have formalized requirements in these areas, as with initiatives such as Chain of Custody.

Legacy Technologies Fall Short. While most supply network hubs have certified their suppliers from a quality perspective, there is always a chance for variance due to material issues, substitution, contamination, formulation, or human error. Many of us have tried to leverage EDI across our network to address some of these issues. However, as a technology EDI is woefully inadequate in addressing today's supply network requirements. Remember, EDI was originally developed during the time of batch business processing, and even with some of the newer XML B2B formats we are still are not capable of processing much of the product quality related data we are consuming through the various IoT sensors deployed throughout the network. So, while EDI itself will still remain in the picture for years to come, we need a supply network platform that will enable continuous digital business processes in order to provide full traceability and the assurance of consumer product quality and safety.

Identify the Root Cause of Quality Issues. When an issue does arise, traceability requires that we have the capability to do a root cause analysis at the process level, which means we need network level master data management (MDM) which is extensible across multiple data types and geographic regions. Just like we need a Single Version of the Truth (SVOT) from a demand signal perspective across the network, we also need a SVOT at the process level from a product quality and safety perspective. In this way, traceability becomes another foundational element of your quality culture. Over time, your network platform will become the backbone for your digital twin, including a multi-party ledger (i.e. a blockchain at the network level) which also provides permission-based security between trading partners. Although we are focusing on traceability in this paper, such an architecture also opens up the potential to add artificial intelligence (AI) into the mix. A multi-party intelligent agent can operate across the network targeted at improving key metrics like on-time in-full (OTIF).

TRACEABILITY: THE BASIS FOR CRISP EXECUTION

From restaurants and pharmaceuticals to retail grocery and children's products, it doesn't take much to ignite a crisis when there's a problem, as many have learned. Firms have also learned that any mis-steps in handling a crisis are costly in a social-media driven world where brand damage can happen quickly. It's a very real concern for nearly every consumer-facing business, given that over the last 20 months alone, the FDA is reporting and tracking nearly 1000 product recalls across sectors (see the attached table).

Enabling Agility in Crisis Management. Today global enterprises know that when it comes to a product problem and a necessary product recall, they need to:

- Act immediately with great transparency
- Rapidly identify the scope of the problem
- Exactly locate the specific product lots and impacted locations and consumers
- Initiate the recall and execute the recall logistics
- Identify the source of the problem and fix it.
- Instill confidence in their marketplace and consumers

To do this all this effectively, we need more control over our supply network, with network-based technology that tracks the full chain-of-custody for every item from start to finish, providing visibility into our supply chains with a way to effectively track products, intermediates, and raw materials in real time, from their source, across trading partners, and to the end consumer.

By rapidly extracting only the affected product in a recall, and only at the precise locations in the supply chain, companies can minimize the impact on consumers, preserve their reputations, and minimize costs. Companies also need know exactly what and how much product needs to be replaced in order to resupply affected locations more quickly for minimum business impact.

NEARLY 1000 FDA RECALLS: JAN 2018 TO OCT 2019

Animal & Veterinary	93
Cosmetics	5
Dietary Supplements	35
Drugs	194
Food & Beverages	613
Medical Devices	35
Tobacco	3
TOTAL	**978**

TRACEABILITY: ESSENTIAL FOR BRAND QUALITY

We started by discussing the importance of brand quality in the eyes of the consumer. When fielding product quality issues, whether it leads to recalls, warranty claims, or unit level repair, we need to regain the trust of the consumer by having the ability to address and communicate our course of action proactively - and thus limit impact. Over time, traceability data will enable our process improvement and product quality initiatives. Plus, with AI in the mix we can also relate changes in process variables to potential outcomes, with probabilities measured against acceptable thresholds. But there's more. What's interesting is that today, brand quality extends well beyond product quality.

Understanding & Verifying Sources and Origins. Today's consumer is more informed than ever. They want to know what they are buying, that it's authentic, where it came from, and who made it - and they will want us to prove it. As we've seen, Chain-of-Custody for items, shipments, and origins can be completely tracked, so that all approved sources of raw materials, intermediates and finished products, as well as all their paths through the supply chain network, are 100% verifiable and auditable. This is important to many consumers in understanding environmental impacts or addressing child labor concerns, for example, but takes on life-saving significance where counterfeit pharmaceuticals are a concern. This is particularly true in places like Africa, where medical products or foods must be maintained at safe temperatures to prevent spoilage or degradation during their journey through the supply network.

Business Network Platforms Exist to Support Traceability & Chain-of-Custody. Given the implications traceability has in relation to product quality and safety, along with the numerous and stringent government regulations in this area, there really is no choice but to move forward with a technology investment to enable this capability. With this technology now available at the network level across your trading partners through One Network Enterprises, why limit yourself to manufacturing-level MES and ERP-level EDI? If you are going to invest in something as important as consumer and product safety, why not do it with the best technology available today?

MANDATED TRACEABILITY IN PHARMACEUTICALS

In FDA Commissioner Scott Gottlieb's opening address at an FDA public hearing in February 2018 he said:

"Ensuring reliable patient access to safe and effective medicines requires maintaining a closed, secure U.S. drug supply chain for the distribution and delivery of finished drug products. Every link in that chain must be secure: From the moment finished drug products leave manufacturing facilities to final delivery to pharmacies or providers' offices where medicines are ultimately dispensed to patients.

That's why FDA and stakeholders have been working collaboratively toward full implementation of the Drug Supply Chain Security Act (DSCSA) in 2023. Reaching that milestone, on time, is a high priority for us.

I know this work is technically challenging. I know that reaching true interoperability for systems and processes that can produce ***full information for each transaction going back to the manufacturer – down to the individual package level, in near real time*** *– is challenging.*

We see a world where the risk from counterfeit drugs is increasing rapidly. Where the means to produce counterfeits and distribute them through sophisticated, illegal networks is increasing. And the volume is also rising sharply. The nature of global supply and distribution chains means that illegitimate products can cascade throughout the supply chain and reach patients if they're not caught quickly.

Seamless state-of-the-art security throughout the supply chain must be our shared goal. Full implementation of the DSCSA will create a safe; secure pharmaceutical supply chain that will pay dividends for decades to come, including enhanced patient confidence. But it can also do far more than that.

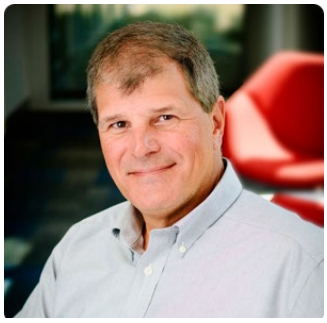
A fully digitized supply chain *can also help develop predictive analytics to reduce health care fraud, waste, and abuse. It can allow regulated industry and regulators to more easily manage or avoid costly or dangerous supply disruptions. It can help support innovative manufacturing and distribution technologies at a time when the drugs being developed are becoming increasingly tailored to specific patient populations."*

TRACEABILITY ECONOMICS IN THE FOOD INDUSTRY

The CDC estimates 48 million people fall sick, 128,000 are hospitalized and 3,000 die annually in the United States due to foodborne illness. That results in an annual cost of $93.2 billion and a cost per outbreak per restaurant up to $2.6 million across fast food, fast-casual, casual dining and fine dining restaurants. According to FDA Commissioner Frank Yiannas, “Today’s food system is amazing, but it does have one major Achilles heel: A lack of traceability and transparency.”

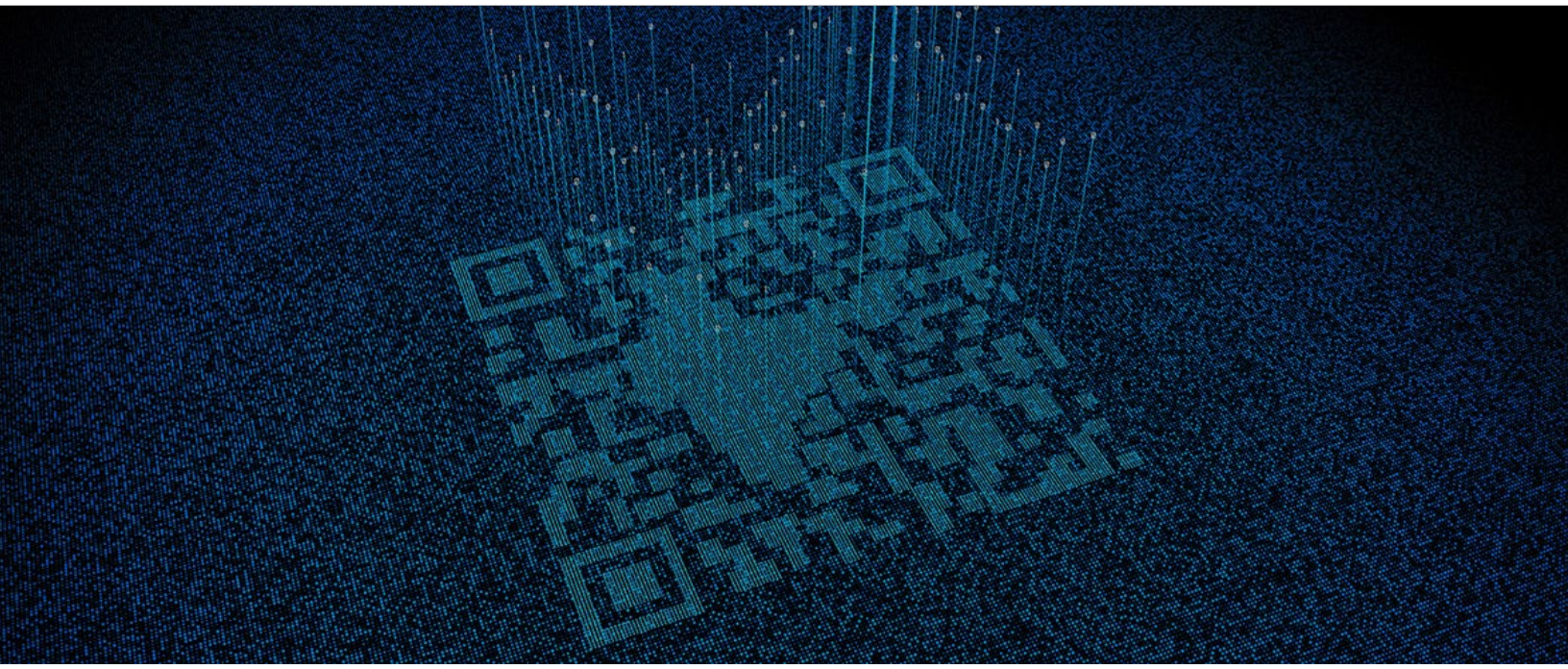
The cost of not adopting systems for tracking chain of custody is easy to see, whether it’s the E. coli outbreak in 2018 (tied to the consumption of romaine lettuce), or the 66% increase in meat and poultry recalls from 2013 to 2018 reported U.S. Public Interest Research Group (PIRG). The inability to proactively stop problems as they arise has caused a lack of trust across U.S. consumers. Trust is breaking down faster than it can be rebuilt, according the FDA at “A New Era of Smarter Food Safety” public meeting held on October 21st 2019. The romaine outbreak resulted in 2018 sales plummeting by more than $136 billion versus 2017 sales of the lettuce – and the implications are still being felt in 2019.

When the urgency for food traceability is high, time is of the essence in quickly determining the source of an outbreak. In 2018, because of the uncertainty in extent and location, a great deal of food went to waste unnecessarily, as essentially all romaine lettuce was thrown out. Similarly, 12.1 million pounds of beef were recalled by the USDA, as well as 206 million eggs over salmonella concerns. In 2018, the US food system took reactive actions rather than proactive ones that would be possible with platforms and systems in place to enable traceability and transparency. Regrettably, there are many stakeholders in the supply chain today who remain stuck in the past – where keeping track of food is still mostly done on paper. Today’s business network technology is here to challenge the status quo and change all that.



About the Author

Joe Bellini is Chief Operating Officer at One Network Enterprises. Joe’s experience extends across some of today’s leading technology companies, including General Electric, HP/EDS, Brooks Automation, IRI, R1 and Oracle. Joe was granted patents in Supply Chain Planning and is the co-author of the business strategy book, “The Real-Time Enterprise.” Joe holds degrees in Mechanical Engineering, Applied Mathematics and Statistics, is an alumnus of Harvard Business School, and is certified in Artificial Intelligence and Machine Learning from the MIT Sloan School.



ABOUT ONE NETWORK

One Network is the intelligent business platform for autonomous supply chain management. Powered by NEO, One Network's machine learning and intelligent agent technology, this multi-party digital platform delivers rapid results at a fraction of the cost of legacy solutions. The platform includes modular, adaptable industry solutions for multi-party business that help companies lower costs, improve service levels and run more efficiently, with less waste. This SaaS and aPaaS platform enables leading global organizations to achieve dramatic supply chain network benefits and efficiencies across their ecosystem of business partners. One Network offers developer tools that allow organizations to design, build and run multi-party applications. Leading global organizations have joined One Network, helping to transform industries like Retail, Food Service, Consumer Goods, Automotive, Healthcare, Public Sector, Defense and Logistics. To date, more than 75,000 companies have joined One Network's Real Time Value Network™ (RTVN™). Headquartered in Dallas, One Network also has offices in Japan, Europe, and India. For more information, please visit www.onenetwork.com.

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