One Network Enterprises™

COLD CHAIN is HOT

With vaccines front-and-center, the Cold Chain will take on new importance for every human on the planet in the coming year. Supply chain management is hard enough, but keeping the entire chain continuously temperature controlled is much more challenging. Yet that's exactly what's required for temperature-sensitive products like vaccines, medicines, foods, and some chemical products. Companies need full monitoring, track-and-trace, chain of custody, and point of origin information across all sites and parties to ensure integrity of supply. This includes maintaining product quality with security measures and tracking to combat the problem of counterfeit products entering the supply network. This paper explains how.

Ensuring Integrity in the Supply of Vaccines, Medicines, and Food Products with a Control Tower Strategy

CHALLENGES OF THE VACCINE COLD CHAIN

As with temperature-sensitive products like seafood and steak, vaccines are perishable and require a low temperature environment to maintain quality. The majority of COVID-19 vaccines currently under development, including the Moderna and Pfizer vaccines, are RNA-based and will require constant refrigeration at very low temperatures so they stay effective. And like these fresh foods, they can spoil.

Stray outside the prescribed temperature limits, and the result will be a lot of discarded vaccine. A 2019 study estimated that 25% of vaccines are degraded by the time they arrive at their destination. This is largely due to mishandling and poor shipping procedures, which costs companies US $34.1 billion annually. Compared to these direct costs, the cost of shutdowns to economies worldwide in response to COVID-19 is immeasurably greater. And these numbers do not even take into account the human cost – physically as well as financially – of illness that could have been prevented by timely delivery of high-quality vaccines.

The need for a trusted, secure cold chain will be large, as experts estimate that somewhere between 12 billion and 15 billion COVID-19 vaccines are needed globally. Given these facts, what are the cold chain implications?

Expect a need to handle diverse cold chain product requirements. With multiple vaccine developments in play, there is uncertainty about which COVID-19 vaccine will be approved first and in which countries. The most likely scenario is that multiple treatments will exist. In that case, different vaccines may require different temperatures and different handling procedures. Hence, supply chains would need the facilities to handle such situations, and staff throughout the cold chain would need appropriate training on how to handle each vaccine properly.

With more than 30 vaccines in the testing pipeline worldwide, it's not yet possible to tell at which temperatures an approved vaccine will need to be stored. Certain candidates will require ultra-low temperature storage (-80°C storage), while others may only require -50°C to -40°C and some may allow storage at normal refrigeration temperatures. The smart move is to plan for these now, and be ready when vaccine approval arrives.

Capacity constrained last mile deliveries. Another question is how frequently deliveries will need to be made to points of care. This will depend on the refrigeration capacity of health care organizations and hospitals, staffing resources, and the locations where vaccines will be given and many other factors, including the shelf life of the vaccine itself and timing of follow-up dosing, if required.

WHAT IS THE VACCINE COLD CHAIN?

Today it's vital. According to the United States CDC, "The cold chain is a temperature-controlled supply chain that includes all vaccine-related equipment and procedures. The cold chain begins with the cold storage unit at the manufacturing plant, extends to the transport and delivery of the vaccine and proper storage at the provider facility, and ends with administration of the vaccine to the patient.

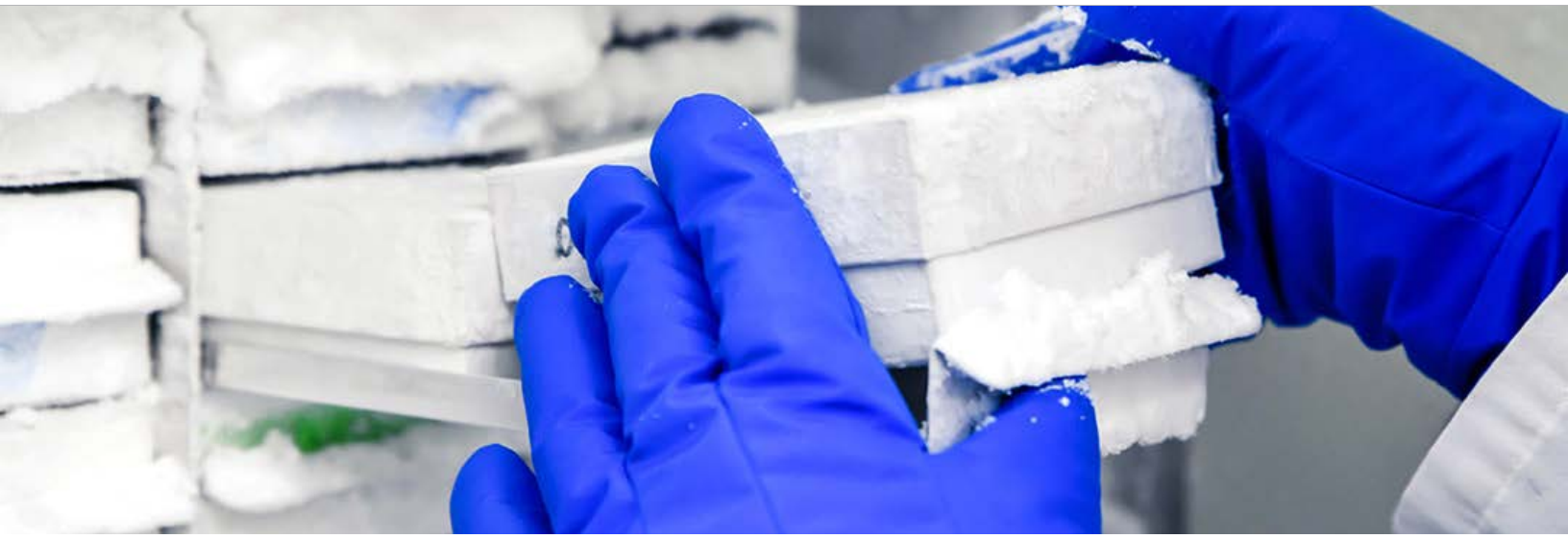
Manufacturers, distributors, public health staff, and health care providers share responsibility to ensure the vaccine cold chain is maintained from the time vaccines are manufactured until they are administered."

Prepare for the initial demand and dependent demand. In all likelihood, certain vaccines will require booster shots, where the booster shot will need to be delivered weeks or months after the initial dose and will need to be the same vaccine type as the first shot. The interval between first and second doses will likely vary for different vaccines. So, demand planning will need to take this into account, as well as the fact that people tend to be unreliable when it comes to scheduling follow ups on time. This forecast inaccuracy means that dynamic supply chain reallocations are likely needed to match supply with actual demand in near real time to minimize waste/spoilage due to under or over supply at delivery points.

Expect substantial cold chain investment. Expansion will likely be needed in shipping and storage capacity - planes, trucks and cold storage warehouses, but also cars, vessels, and any local mode of transportation to the far reaches. This is a global problem impacting every global community. In the end, the determining factor regarding investment will be how the infrastructure is connected and utilized between the vaccine production location and the points of consumption for each vaccine type.

Supply chain scale is also required to handle other supplies for production and treatment services. Short supplies are already a concern for vials and bioreactors in production lines. Further, immunization programs will require the vaccine dose and all essential related supplies be at each site at the right time -- syringes, needles, swabs and more.

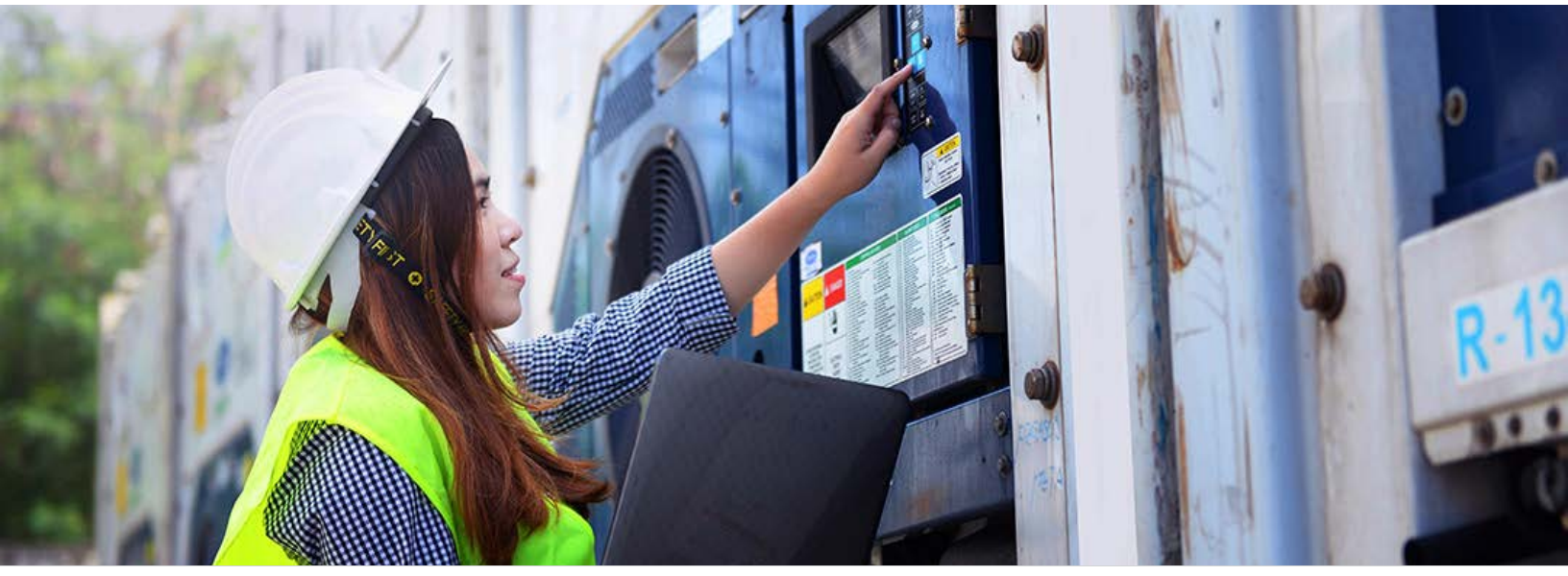
Plan beyond year one. Of course, the world hopes this first round of vaccine development will be enormously successful, yet this is not likely to be a "one-and-done" situation. As with the annual recurrence of the flu, the expanded need for cold chain capabilities is likely to persist as a multi-year effort.



ONE NETWORK'S EXPERIENCE IN HEALTHCARE CONTROL TOWERS

One Network has years of experience in healthcare supply networks that provide medicines and vaccines to hundreds of millions of people in Africa and around the globe. For example, the One Network platform for supply chain planning and execution is used by the Ministries of Health in Nigeria, Ghana, and Rwanda, providing comprehensive inventory visibility across all health facilities for real-time demand-supply matching and collaborative decision making. Major global pharmaceutical & biotech manufacturers, carriers, and distributors connect into the Network to collaborate in delivering contracted services to ensure patient access to medicines, laboratory test kits and other medical devices. With over 16,000 care facilities in Nigeria and over 600,000 SKU orders per year, One Network's platform handles supply chain forecasting, sourcing, planning and execution (with routing and logistics optimization) for one of the largest national Supply Chain Control Tower deployments in the world.

One Network's platform capabilities include GPS and telematics tracking of shipments, vessels, vehicles, and packages on a global basis, including IoT devices with temperature sensors for temperature exception tracking of assets, including smart refrigerators and temperature-controlled storage devices. That's along with complete end-to-end planning and execution capabilities – from inbound supply to outbound order fulfillment and logistics.



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Pfizer's Vaccine Has Super Cold Storage Requirements: A Logistical Obstacle

"The responsibility for determining how many deep-freeze machines exist at healthcare facilities has fallen on states because there is no central inventory," FreightWaves' Eric Kulisch writes. He notes that uncertainty about the cold-chain capabilities of transportation providers and vaccine administration facilities has resulted in Pfizer developing a special cooler, or "thermal shipper," with real-time GPS and thermal monitoring that can maintain deep-freeze vaccine storage for 10 days if left unopened. Kulisch reports that the shipping container is "about the size of a small suitcase" and uses dry ice to maintain recommended storage temperatures.

The Pfizer vaccine's complex and super-cold storage requirements present an obstacle for even the most sophisticated hospitals in the United States and may impact when and where it is available in rural areas or poor countries where resources are tight. The main issue is that the vaccine, which is based on a novel technology that uses synthetic mRNA to activate the immune system against the virus, needs to be kept at minus 70 degrees Celsius (-94 F) or below.

"The cold chain is going to be one of the most challenging aspects of delivery of this vaccination," said Amesh Adalja, senior scholar at Johns Hopkins Center for Health Security. "This will be a challenge in all settings because hospitals even in big cities do not have storage facilities for a vaccine at that ultra-low temperature."

In fact, the Mayo Clinic has said it does not currently have that capability. "We're talking about a vaccine that needs storage at minus 70 or 80. That's a tremendous logistical issue not only in the U.S. but outside the Western world," said Dr Gregory Poland, a virologist and vaccine researcher with the Mayo Clinic. "We're a major medical center and we don't have storage capacity like this. That will be true for everybody. This is a logistical obstacle."

Pfizer has been working closely with the U.S. government and state officials on how to ship the vaccine from its distribution centers in the United States, Germany, and Belgium around the globe. The plan includes using dry ice to transport frozen vaccine vials by both air and land at their recommended temperatures for up to 10 days. They can be kept in an ultra-low temperature freezer for up to six months, or for five days at 2-8 degrees C – a type of refrigeration commonly available at hospitals. But shots will spoil in around five days at normal refrigeration temperatures of slightly above freezing.

The vaccine of Moderna Inc. is based on similar technology, but does not need to be stored at such low temperatures. Other vaccines including ones from Johnson & Johnson and Novavax Inc. can be stored at 2-8 degrees C, the temperature of a standard refrigerator.

Source: Why Pfizer's Ultra Cold Covid-19 Vaccine Will Not Be at the Local Pharmacy Any Time Soon (Reuters)

ESSENTIAL CONTROL TOWER CAPABILITIES TO OPTIMIZE THE COLD CHAIN

Ensure Product Quality: Traceability Across the Supply Network

To ensure product quality we need a system that enables us to track unit-level items, spot problems, find an optimized solution, communicate our action plan, and orchestrate a response. Business network technology enables us to do this. **Business network platforms, like One Network, enable full traceability 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.

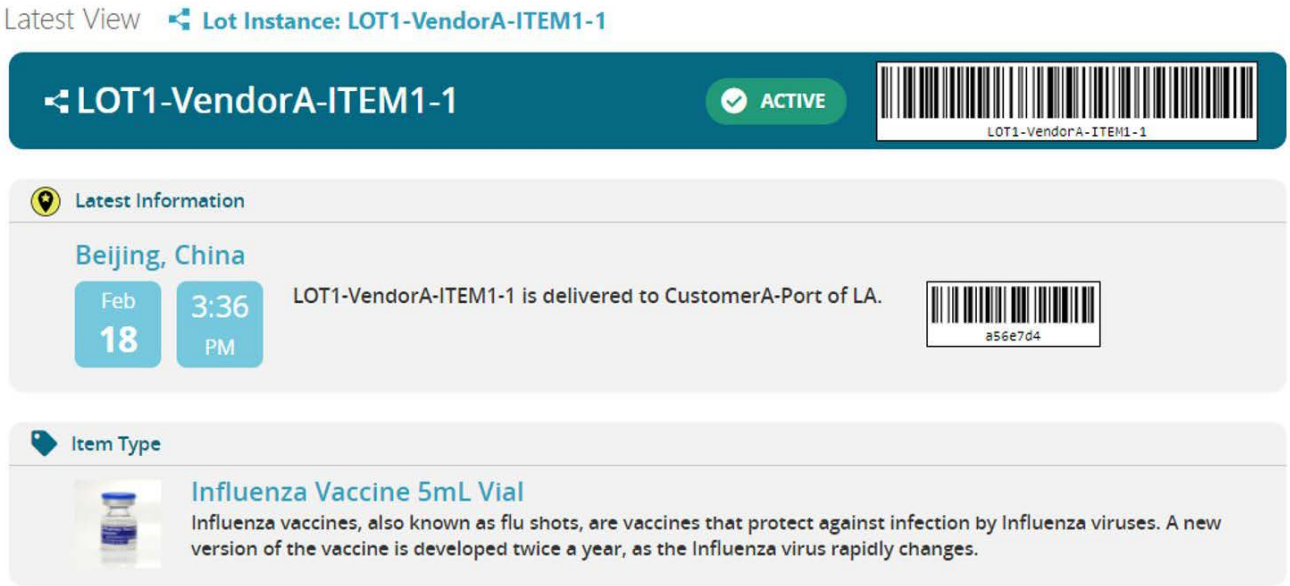
Supply Networks operate based on the trading relationships between producers, manufacturers, consumers, retailers, distributors, and suppliers. These trading relationships are structured as many-to-many, where a brand can interact with all consumers and a consumer can interact with all brands. This extends 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.

End-to-End and Real-Time Logistics

To successfully represent the complete logistics lifecycle across a network of supply chain participants (warehouses, plants, DC's, carriers, LSP, customers, contract manufacturers, and suppliers), the One Network platform serves as a system of engagement, integrating and harmonizing data across internal and external players. It also operates with the capability to embrace many systems and to assume control of any point in the shipment execution lifecycle as needed, even serving to replace legacy or redundant systems. By integrating transaction information across all parties, the solution enables real time visibility of the entire logistics lifecycle from purchase order to shipment order, shipment execution, track and trace, and to financial settlement.

Real-Time Information with IoT and Telematics

One Network is a unified platform that combines the power of telematics with planning and execution to provide global visibility, quality tracking, and optimized decision making. One Network's Telematics Solution captures, analyzes, and consumes real-time streaming data from GPS, IoT devices, sensors, and electronic data logging devices (ELD) embedded in containers and vehicles, across vessels, trucks, airplanes, and warehouses. It provides real-time status and locations of orders and shipments, predicted future locations, and accurate arrival times. It also provides advanced monitoring for temperature of the product and container, and logistics parameters such as door openings. In addition, the platform's intelligent NEO agents consider factors, such as speed, traffic, storage capacity, and delivery times to optimize logistics and the supply chain. The platform also alerts users to potential problems with predictive analytics and proposes optimal solutions using prescriptive analytics as well.



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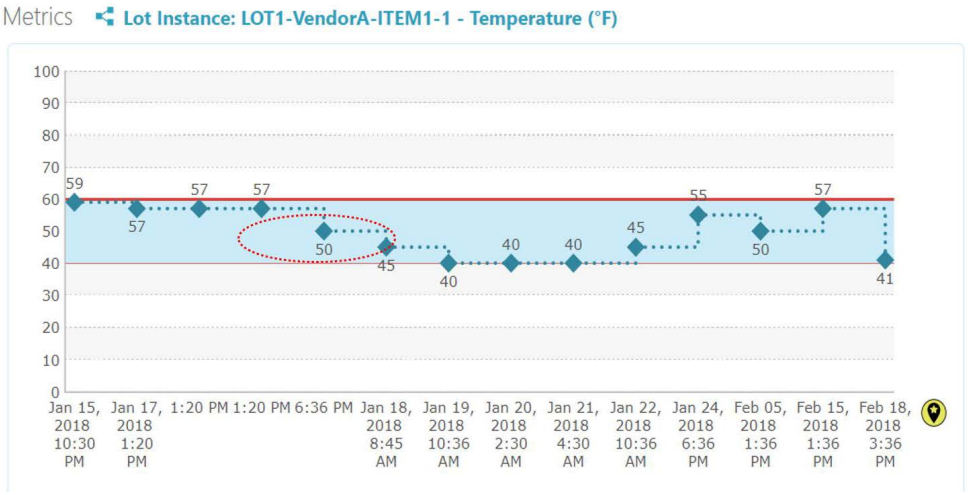
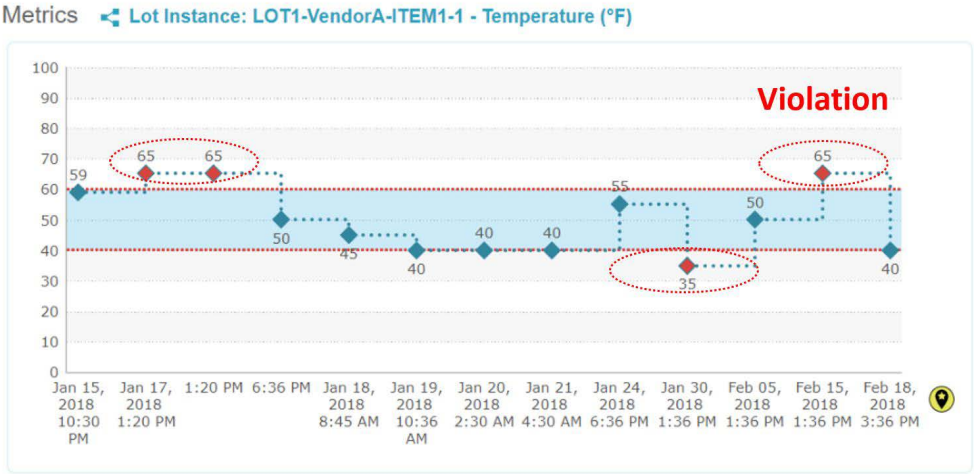
A SYSTEM OF RECORD FOR TRACKING COMPLIANCE AND IDENTIFYING/REPORTING VIOLATIONS

Whether verifying compliance or spotting and reporting an exception, a reliable network-based global system of record creates enormous efficiencies when compared with the alternative - which is fragmented, partial, and maybe manual systems and processes. When the system of record is a multiparty business network platform like One Network, then all stakeholders – manufacturers, distributors, carriers, customers and hospitals can be sure they are looking at the same real-time, accurate information. Best of all, these capabilities are an integral part of the platform, which is your TMS, planning, and execution system. So once an exception is spotted, it can be resolved and a solution implemented immediately in the same platform.



Verify Compliance Over Time and Across Geographies

Identify Violations with Real-Time Alerting



Quickly Get to the Root Cause of Quality Issues

When an issue does arise, traceability enables you to quickly pinpoint the source, whether it's a manufacturing or packaging issue, or the violation of a temperature specification for a vaccine. Rather than relying on a patchwork of systems or manual processes, a network platform enables rapid root cause analysis based on accurate, up-to-date information that is visible and consistent for all involved parties.

Respond Quickly and Optimally to Spikes in Demand or Disruptions in Supply

Reality will certainly differ from your plans, so when you experience demand spikes or supply upsets, companies will need to have a rapid, optimized response in the near term. A real-time network platform offers your best solution with Global Demand-Supply Matching and process orchestration across business partners with dynamic reallocation. When problems happen, One Network enables you to identify supply chain exceptions in real time and resolve them optimally at the network level with intelligent algorithms and the latest in artificial intelligence and machine learning technology, to provide automated decision-making and prescriptive analytics.

With One Network, shipment visibility goes much deeper than basic transportation visibility and includes visibility into every order that makes up the shipment. And the inventory that makes up the shipment (even in the container) can be used for dynamic decision-making in real time and is available for dynamic reallocation to orders – just like any other inventory quantity in your warehouses, plants, or healthcare provider locations. This explains why One Network helps optimize business performance with automation and prescriptive analytics in ways that others can't – to drive extraordinary service levels and value.

Crisis Management: Handle Recalls Quickly, Accurately, Efficiently, and Specifically

Over the last 20 months alone, the U.S. FDA is reporting and tracking nearly 1000 product recalls across sectors. With the stringent temperature requirements of the vaccines in development, and the record-shattering volumes to doses to be delivered worldwide, there's a good chance that manufacturers will need to face the reality of a recall at some point. 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.

Accurate, real time inventory visibility is essential - in warehouses, DCs, intransit and at every node in the cold chain. 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.

Understand and Verify Sources and Origins

Today government regulators, vaccine providers, and the public in general will want to have confidence in the origins of the vaccines and medicines they are receiving, 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. For general consumer products, 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, as for some regions in Africa. And of course, in the case of medical products like vaccines or foods that must be maintained at safe temperatures to prevent spoilage or degradation during their journey thru the supply network.

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WHAT MAKES ONE NETWORK DIFFERENT?

One Network's Cold Chain Solution is powered by the NEO Platform, the patented real-time, multiparty technology that supports the Real Time Value Network with tens of thousands of companies worldwide. Here are some of the unique features:

Truly One Network, One Solution: One Network has been a technology leader for more than 15 years, and the advance that has provided the greatest performance benefit for customers is the sharing of applications, data, and transactions on one common business network. Here the entire supply chain can be viewed, managed and optimized as one unified system, as opposed to many small, disparate parts. The platform's end-to-end capabilities have been conceived and built entirely by One Network to be network-based, using a single database, a single UI, for a single one integrated and intelligent set of network services. They are not a collection separately acquired, stitched-together systems. This unified network solution is unique in the industry.

The Network Effect: Any new company joining the One Network community has immediate access to this established business network of manufacturers, suppliers, customers, and logistics partners. This is the "Network Effect", which is particularly advantageous in many industries because of the massive numbers of parties involved in the collective group of manufacturers, suppliers, logistics providers, distributors, and contract manufacturers. Companies only need to on-board once, and chances are good that many of your customers, suppliers, and logistics providers are already on the network, greatly accelerating projects and time-to-value.

A Single Version of the Truth: Having all business partners on one backbone lets information flow throughout the network seamlessly and in near real time. This means uncertainty and variability are minimized, reducing the "bullwhip effect," where order quantities are distorted and amplified upstream in the supply chain. It also means a problem anywhere in the network is quickly recognized and can be dealt with in a fraction of the time of former approaches. Squelching small problems before they become large problems requires quick notice and action – one of the many benefits of the Network approach.

A Complete Set of End-to-End Capabilities: One Network is the only solution that offers a seamless, integrated and comprehensive suite of solutions across all supply chain functions. These enable planning, execution and optimization across all supply chain functions, to maximize results. This lets companies maximize efficiencies by coordinating their replenishment process with the logistics planning and execution process, thus optimizing service levels, inventories and operational costs concurrently. As Gartner recently stated (May 2020), "One Network's solutions cover processes across supply chain planning as well as supply chain execution with a single transaction backbone and master data management system. **Its ability to offer this supply chain convergence is leading among providers**."

Rapid On-Boarding Services: The scope of vaccine deployment will likely bring thousands of new players into your supply network, so onboarding speed will be essential. One Network uses a rapid onboarding and automatic quality assurance testing process, which enables hundreds or thousands of suppliers, carriers, customers, and partners to be onboarded in weeks instead of months. It also enables a service model for onboarding new partners, as well as facilitating the elimination of those no longer required.

Global Demand-Supply Matching Across Tiers: With continuous and incremental demand-supply matching in real time, your business can ensure that inbound supply is truly demand-driven and matches the needs of your end customer at the other end of the value chain. While other solution providers may claim this at a high level, One Network enables this in real time at every level of granularity and time horizon – even at the item level.

Truly Integrated Inventory, Logistics and Order Management: With One Network, system lead-times can approach zero. With a real-time view into inbounds, inventories, and shifting demands you'll find information lags are minimized or eliminated, enabling you to increase service levels even as you dramatically reduce inventories. You'll eliminate excess inventory buffers and the costs that go along with them, as well as the problems of having too much of the wrong product at the wrong location. These include markdowns, spoilage, waste, and otherwise outdated products.

With One Network, shipment visibility goes much deeper than in basic transportation systems, and includes visibility into every order that makes up the shipment. And the inventory that makes up the shipment (even in the container) can be used for dynamic decision-making in real time and is available for dynamic reallocation to orders when disruptions occur – which will be important to the cold chain.

Prescriptive Analytics and Multiparty Collaboration: With Global Demand-Supply Matching and process orchestration across business partners, One Network enables you to identify supply chain exceptions in real time and resolve them optimally at the network level through multiparty collaborative workbenches. The workbenches use intelligent algorithms and the latest in artificial intelligence and machine learning technology, to provide automated decision-making and prescriptive analytics. What's unique here is that rather than "one-issue-at-a-time" problem solving, the NEO algorithms are designed to solve problems in a multiparty fashion, optimizing the network as a whole.

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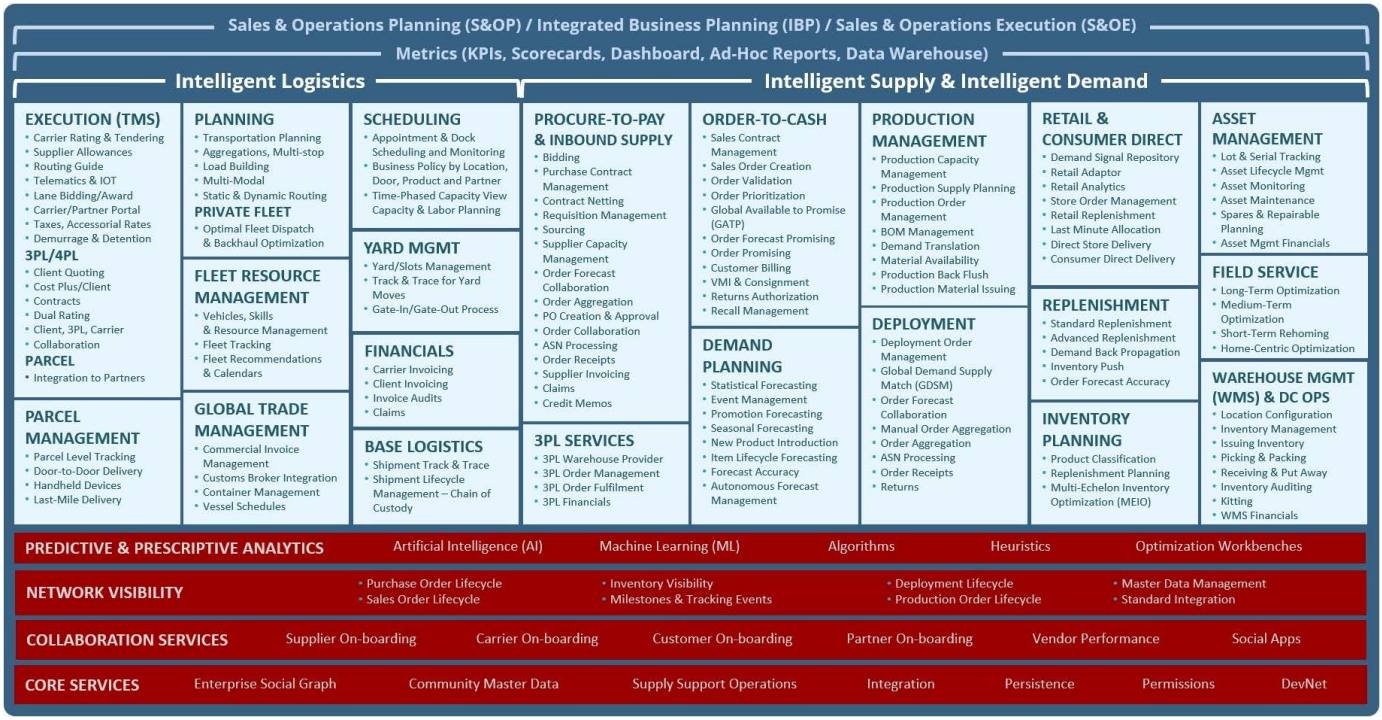
THE CONTROL TOWER PLATFORM TO SUPPORT TRACEABILITY, QUALITY, AND CHAIN-OF-CUSTODY FOR THE COLD CHAIN

One Network's Cold Chain Solution is part of a comprehensive set of tightly integrated end-to-end capabilities that work together intelligently and run in the cloud, serving tens of thousands of companies worldwide. It's a multiparty platform that leverages the latest in business technology, including many-to-many networks, AI, machine learning, social networking, big and fast data, and mobile apps.



These capabilities are unique in the industry. From planning to execution, inbound supply to outbound fulfillment and logistics, the end-to-end capabilities have been developed in-house as a single unified real-time platform with one data model, one user interface, one master data management system, and one global community of suppliers, customers, logistics partners and global brand customers. For this reason, there are no data silos, barriers, or information time lags between any of the planning and execution capabilities – nothing standing in the way of real-time performance, visibility, and a single version of the truth. One Network is not an amalgamation of disparate systems or acquired technologies patched together over time. The solutions have been conceived as one network since inception.

Why is this important? Because it enables a level of optimization and responsiveness in One Network solutions that others simply cannot match. The platform is designed around the fact that supply chain planning and execution are inherently multi-tier and multi-enterprise, whether it be inventory optimization, demand propagation, inbound supply planning, forecasting, order fulfillment, global demand-supply match or global ATP. This perspective forms the foundation that enables One Network's customers to achieve the highest possible service levels with the highest quality product delivered at the lowest possible cost. Even via the Cold Chain.

Contact One Network Enterprises to learn more.

ABOUT ONE NETWORK ENTERPRISES

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, tens of thousands of 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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