

Pharmaceutical Supply Chain Solution for EU Compliance, Serialization and Track and Track to Prevent Counterfeiting



Shabbir Dahod
President & CEO
TraceLink Inc.

CEOCFO: *Mr. Dahod, would you tell us about TraceLink?*

Mr. Dahod: TraceLink provides solutions that integrate the end-to-end pharmaceutical supply chain into a digital network. Our network is being used predominantly for the track and trace of pharmaceutical drugs and to prevent counterfeiting, which is killing anywhere from 100,000 to 1,000,000 people a year. As a result, governments have established laws that require track and trace of pharmaceutical drugs to prevent counterfeiting from entering the legal supply chain, and TraceLink provides the end-to-end solution to ensure that all pharmaceutical suppliers can comply with these regulations anywhere in the world.

CEOCFO: *Is that pretty much worldwide these days as far as regulatory issues?*

Mr. Dahod: Yes it is. Laws have been passed in the US that require all pharmaceutical products to be identified with a unique serial number on a per package basis, and this has to be completed by November by 2017. The EU has passed a similar law that will have the same requirement by the end of 2018 or early 2019. China has a law that already requires serialized products today. South Korea, India, Brazil, and Saudi Arabia all have laws as well. We estimate that 75% of the end-to-end pharmaceutical supply chain will require serialization by the 2018-2019 timeframe.

CEOCFO: *How are you able to help a company with all of the steps?*

Mr. Dahod: We provide a SaaS solution in the cloud called the Life Sciences Cloud. Pharmaceutical manufacturers are able to leverage complete application packages from TraceLink to create serial numbers and connect with line systems so they can manufacture products, and then connect to warehouse management systems as well as all of their different partners. In many cases pharmaceutical companies, wholesalers and hospitals need to exchange information with each other. Our Life Sciences Cloud is a network platform that enables a single company to integrate once into our network and then interoperate with all of their trading partners across the entire supply chain. It is a solution that requires the least amount of cost, time and risk.

CEOCFO: *Would several entities along the way need to be connected with TraceLink?*

Mr. Dahod: The Life Sciences Cloud works end-to-end. We have customers that are some of the largest pharmaceutical companies and contract manufacturers in the world as well as wholesalers in the US, very large hospital systems, and even independent "mom-and-pop" pharmacies. We have over 195,000 independent companies on our network. Not all of them are customers but all of them are buying or selling from one of our customers, so they are able to join our network on that basis for the purposes of exchanging compliance data with their trading partners.

CEOCFO: *When a company is using your service, is it one solution where they can access all the components they need or might a company pick and choose?*

Mr. Dahod: We offer a modular architecture. If you are a contract manufacturer you may only need to use a few of our modules and services. If you are a pharma company, you may need to use most of the applications. A wholesaler may only need to use a subset of the modules, and a pharmacy may only need to use a subset of that. We have specific modules for specific use cases that are applicable across the entire supply chain depending on the customer's need.

CEOCFO: *How do you keep up with regulatory matters; do they change much?*

Mr. Dahod: The laws, regulations and standards are highly evolving and changing at a rapid rate. Countries establish them on a basis that is not necessarily predictable and we monitor all of them. One aspect of our value proposition is that

we have a single network running on a network tenant platform, which means we are able to quickly adopt any regulatory changes introduced for a particular country and instantly make those changes available throughout our entire network to offer the least amount of disruption to customers. We rapidly incorporate these changes into our solution and ensure that our customers are compliant. That is the beauty of a network-tenant, cloud-based architecture. We have a staff of people that constantly monitor and track these laws, regulations and standards, and we also leverage our community of customers to work with us in a collaborative manner, so in effect, we collaboratively source requirements for all of our solutions with them, which is how we are able to get to a quick convergence within the industry on exactly how to implement a specific law or regulation.

CEO CFO: What is the competitive landscape?

Mr. Dahod: This is a unique situation in the sense that this market opportunity requires a lot of depth in both expertise and technical acumen. We have been in this marketplace for over a decade so we have accumulated a wealth of strong technology and expertise. We do not have competitors that possess the same level of expertise or technical capabilities to meet these industry challenges from a complex regulatory perspective or highly demanding technology perspective. There are companies out there but none of them have approached the marketplace with a network model, a comprehensive solution, or the technical expertise to scale to the tens of billions of transactions, hundreds of billions of serials numbers, and trillions of objects that need to be managed and tracked across the entire supply network.

"Our Life Sciences Cloud is a network platform that enables a single company to integrate once into our network and then interoperate with all of their trading partners across the entire supply chain. It is a solution that requires the least amount of cost, time and risk." - Shabbir Dahod

CEO CFO: Do many companies still not realize they need a system such as TraceLink?

Mr. Dahod: That's correct. Education is a large part of our effort, which is how we have become experts in the marketplace for all the different segments. You would think that once a law is passed that everyone should be aware of it, especially if it affects their business. We find that a lot of companies are not fully aware, and the reality is, few recognize the magnitude of challenge that they have to overcome to be successful. Sometimes they do not start soon enough. So we are very focused on education of the requirements and the kind of solution that is required to meet the regulatory requirements.

CEO CFO: How do you reach out to potential clients?

Mr. Dahod: We typically work on a one-to-one basis with each customer so that we have a unique understanding of their needs and requirements. Our initial customers may have other suppliers, or customers of their wholesalers and contract manufacturers, so many of these partners get exposed to TraceLink through supply chain business partnerships and see the benefit, value and importance of our solution. It's what we call "the network effect." Through the network value that we provide to our customer base, many prospects come to us just because they are already on the TraceLink network, working with one of our customers.

CEO CFO: Do you work through associations, manufacturers or hospitals?

Mr. Dahod: Yes. We work closely with organizations like the HDMA for wholesalers and GPhA for pharmaceutical companies, as well as other groups like InterPharma in Brazil. We are members of NCPA and NACDS for pharmacies, and PBOA for contract manufacturers that produce drugs for pharmaceutical and biotech companies. We also work with GPOs like Novation, which is the largest GPO in the US. Novation has about 100,000 independent pharmacies and hospitals as part of their GPO group. We work through multiple channels to provide access and the appropriate contractual pricing for our solution.

CEO CFO: In September you introduced Version 6.1 of the Life Sciences Cloud. What can you do today that you could not do three or four months ago?

Mr. Dahod: A lot of the new functionality in version 6.1 was driven by international regulations. For example, we addressed Brazil requirements, as well as EU requirements to help companies get compliant with the False Medicines Directive. 6.1 was also a major performance release so we made significant architectural enhancements to the core capabilities.

CEO CFO: What surprised you as TraceLink has grown and evolved as a company?

Mr. Dahod: I think what has been the most surprising for us is the lack of knowledge within the marketplace about the laws and the actual requirements to achieve compliance. There is a small pool of people that understand the challenges

and that pool is generally within the TraceLink community. What we are trying to do is leverage all of our employees and customers that have this expertise, and to share that knowledge with the marketplace to help the tens of thousands of companies that need to get educated about this specific challenge.

CEO CFO: What is your business model?

Mr. Dahod: TraceLink has a standard subscription business model. Depending on the specific subscription, there can be a variable component, for example, if you are a pharmaceutical company that is producing serial numbers. But we are a software company and our software does not require any customization so our business is less than 10% services from a revenue perspective. It is a pure software subscription model.

CEO CFO: How do you address security issues?

Mr. Dahod: We have a 360 degree view on security, from our office infrastructure to our IT infrastructure, and all the way through our relationship with Amazon Web Services. One of the key advantages we have is leveraging Amazon's security infrastructure, which is used by governments and many leading security agencies themselves. We also have a board-level security committee that is constantly looking at security and compliance, and we also have a chief information security officer on staff who oversees all of our security initiatives.

CEO CFO: How would someone find TraceLink in an internet search?

Mr. Dahod: People often search for their main requirements, which may include terms like "DSCSA compliance," "pharmaceutical track and trace," and similar terms like these. TraceLink will usually be one of the top organic hits for these types of searches.

CEO CFO: How is business these days?

Mr. Dahod: Business is fantastic. We have been growing at over 100% year over year for the past three years in a row and we anticipate growing at greater than 100% over the next two years. A year and a half ago we were just 35 people, and today we are more than 165 and intend to be over 350 by the end of 2016. We are also growing our sales, services and marketing at a global level and now have offices in India, London, and Singapore, and a sales and services partnership in Brazil.

CEO CFO: What is the key to managing a global company when people are scattered and growing at a rapid rate?

Mr. Dahod: There are three things that I attribute to managing a high growth global company. First, you have to have a fantastic management team, which we have been able to assemble. They understand how to manage aggressive growth. The second is a strong interviewing model to ensure that you are properly screening and getting the best and brightest talent into the company. The third is really about training. We focus heavily on training and spend 10% of our time training all of our employees in many different ways. So, it is about a great management team, hiring great people and getting them trained as quickly as possible.

CEO CFO: Why pay attention to TraceLink today?

Mr. Dahod: TraceLink is doing something very important in this world. We are protecting patients by making all the medications that people take safer and more secure. Pharmaceutical companies need to be compliant in order to buy and sell products in the marketplace and we are the prominent solution that helps them to save the most money, implement in the shortest amount of time, and minimize any risk to their business. And from an investor point of view, we are a fantastic business model.

Interview conducted by: Lynn Fosse, Senior Editor, CEO CFO Magazine



TraceLink Inc.

For more information visit:
www.tracelink.com

Contact:
Carter Holland, Chief Marketing Officer
781-914-4952
cholland@tracelink.com