Digital Transformation of the Cold Chain

Introducing Interoperability While Protecting Life Sciences Product-Release Data

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SUPPLY CHAIN VISIBILITY

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The Life Sciences cold chain is a seamless and interconnected global network of people, equipment, data and processes that helps to ensure the safety and integrity of our medicines and vaccines. Cold chain logistics spending totaled $13 billion in 2017, an investment designed to protect some $283 billion in Life Sciences cold chain products, growing at 19% annually.[1] Sensitech Inc., a part of UTC Climate, Controls & Security, a unit of United Technology Corp., has played an essential part in the Life Sciences cold chain since 1990, providing a comprehensive set of solutions for manufacturers of biologics, prescription pharmaceuticals, clinical trial materials, and over-the-counter drugs. These solutions help to ensure product quality, patient safety, and regulatory compliance while helping to prevent theft and optimizing cold chain performance.

The world's leading industrial and manufacturing companies are now engaged in the process of digital transformation. In the Life Sciences industry, inexpensive sensors and the Internet of Things have created new sources of data that can be combined in novel ways to enable growth and improve margins. Digital transformation presents both opportunity and risk for Life Science customers who have spent decades establishing their critical cold chain processes.

As part of a comprehensive, global initiative called United Technologies Digital (https://digital.utc.com/#designing-the-future), Sensitech is working with customers to ensure that their digital transformation efforts drive business process excellence while safeguarding cold chain best practices. This white paper, the first in a series, responds to recent questions regarding datalogger interoperability and its potential impact on validated product-release data.

In Brief

- Cold chain monitoring companies have recently begun offering "interoperability," defined as the capacity to accept input from any third-party sensor or datalogger into a single database. Interoperability presents an opportunity to reduce costs, enhance data flows, and improve business decision-making across the perishable supply chain.
- The decision to introduce interoperability in a Life Sciences cold chain must be done deliberately, however, as it may pose a risk if Life Sciences' customers must segregate and protect their validated cold chain data used for product-release decisions and regulatory compliance.
- Sensitech has modeled a simple scheme based on ColdStream®, the company's hosted data-management solution, which balances the desire to optimize supply chain performance against the need to ensure the integrity of a validated cold chain database. We do not assume this to be the only solution, but it does help to frame the issues involved in the introduction of interoperability.
- Sensitech sees interoperability as being most effective when the industry agrees on specific formats and standards. These might be established by an industry trade group or organization and have the blessing of regulators. Until such standards are established, customers engaging in interoperability put their validated data at significant risk.

What Is Digital Transformation?

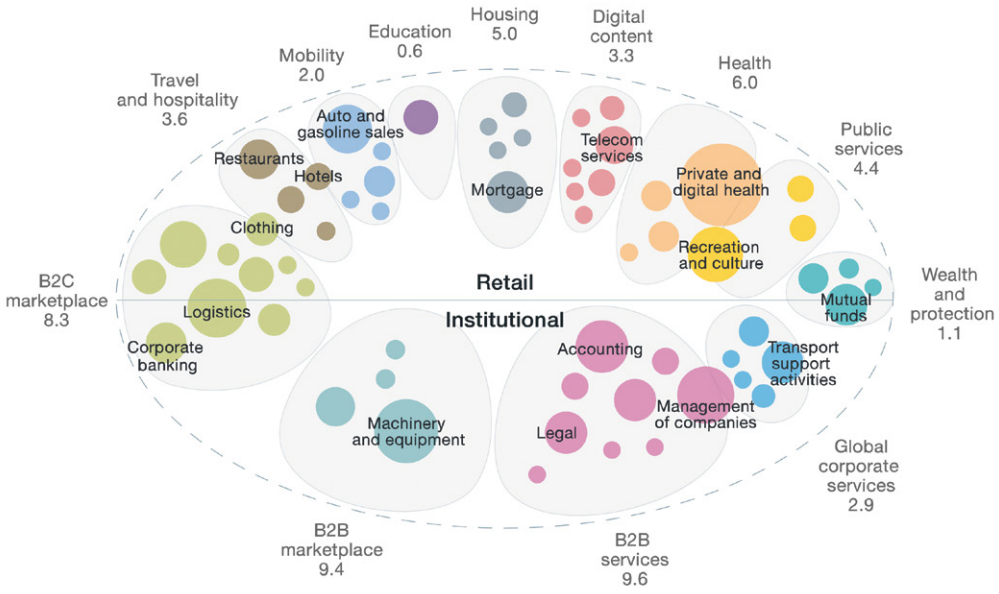
Digital transformation describes the application of digital technologies to reduce costs, improve efficiencies, enhance customer value, manage risk, and better connect with suppliers, partners and customers. For many of Sensitech's cold chain customers, this phenomenon is a half-century old; when companies purchased their first mainframe computer, or connected employees to the web, they were engaging in digital transformation. When Sensitech introduced the first, single use in-transit, electronic monitor in 1990, it began "digitizing" the paper output of strip chart recorders and helping Life Sciences customers create their first cold chain databases.

Today, engaging in digital transformation is an imperative for Sensitech's customers. The Center for Global Enterprise reports that a digital supply chain can lower procurement costs by 20 percent, reduce supply chain process costs by 50 percent, and increase revenue by 10 percent.[2]

This current chapter of digital transformation is unique. The volume of information being created is doubling every three years as data "pours in from digital platforms, wireless sensors, and billions of mobile phones. Data-storage capacity has increased," McKinsey reports, "while its cost has plummeted. Data scientists now have unprecedented computing power at their disposal, and they are devising algorithms that are ever more sophisticated."[3]

New ecosystems are likely to emerge in place of many traditional industries by 2025.

Ecosystem illustration, estimated total sales in 2025,[1] $ trillion



[1]Circle sizes show approximate revenue pool sizes. Additional ecosystems are expected to emerge in addition to the those depicted; not all industries or subcategories are shown.

Source: IHS World Industry Service; Panorama by McKinsey; McKinsey analysis

McKinsey&Company

Source: "McKinsey Quarterly," July 2017,
https://www.mckinsey.com/business-functions/mckinsey-analytics/our-insights/competing-in-a-world-of-sectors-without-borders.

In the case of cold chain analytics, this has allowed the measurement of temperature to be combined with new environmental inputs, location data, other transportation and logistics information, and powerful algorithms to yield fresh insights into cold chain performance. The ability of organizations to exchange data in all directions throughout a commercial landscape has also led to the emergence of digital ecosystems.

"Removing friction from combining and recombining of software and data (not just a business' proprietary assets, but also those of partners and even competitors) creates the conditions for an ecosystem to emerge," writes Bran Kirschner, director of the Apigee Institute. "Sharing the value generated among its participants creates the conditions for ecosystems to thrive."[4]

This "combining and recombining of software and data" across partners and competitors in a digital ecosystem can create extraordinary value across a range of traditional supply chain decisions, from asset optimization and route selection to facility planning and employee performance. However, mixing data sets can also raise red flags in a Life Sciences environment. What might be a gain in new insights for a supply chain analytics professional may require new ways of accessing and protecting data for the quality associate charged with maintaining the integrity of a validated system used to make product-release decisions.

Life Sciences professionals need to wade carefully through the promise of digital transformation, beginning with the understanding that not all data is created equal.

There Is No Data Like Validated Data

Leaders involved in cold chain monitoring and analytics rely on the Food and Drug Administration's (FDA) rule on Electronic Records/Signatures (21 CFR Part 11) and the European Medicine Agency's Guidelines to Good Manufacturing Practice—Annex 11. Using these guidelines, Sensitech creates proprietary databases that are fully validated and designed to meet the regulatory requirements for product-release decisions.

The Parenteral Drug Association's Pharmaceutical Cold Chain Interest Group defines validation as "a documented testing, performed under highly controlled conditions, which demonstrates a process that consistently produces a result meeting predetermined acceptance criteria."[5] Validation is "for intended use"—applied to a specific system design and specific set of user requirements—and therefore can vary considerably from company to company. In the case of cold chain monitoring sensors, software and databases, any lack of consistency—measurement precision or time-zone calculation differences between monitors, for example—complicates the sharing and mixing of data. In turn, this can disrupt the processes designed to promote transparency and ensure validation.

Sensitech's cold chain solution is, in effect, an end-to-end, sensor-based, risk mitigation system. Customers value this system because it provides consistency, reliability, accuracy, traceability, and validation of their cold chain data. The introduction of new practices such as interoperability must conform to the requirements for data integrity. Sensitech and its cold chain customers recognize that, while many supply chain planning decisions can be enhanced by the mixing and matching of various third-party sensors, there is no data like validated data, and there is no decision like a product-release decision.

Interoperability: Hype and Risk

Several cold chain monitoring companies have recently begun offering "interoperability," defined as the ability to accept input from any third-party sensor or datalogger into a single database.

While generally a straightforward technical proposition, interoperability is not always a straightforward business proposition. For example, each monitoring company uses its own proprietary source code to program its electronic datalogger; there is no simple way to validate that every third-party monitor used in a common database works as intended, or that the transfer of data and subsequent reporting will comply with regulatory requirements.

Even customers willing to facilitate a technical discussion between competitors, who are then willing to share source code, face a number of important questions:

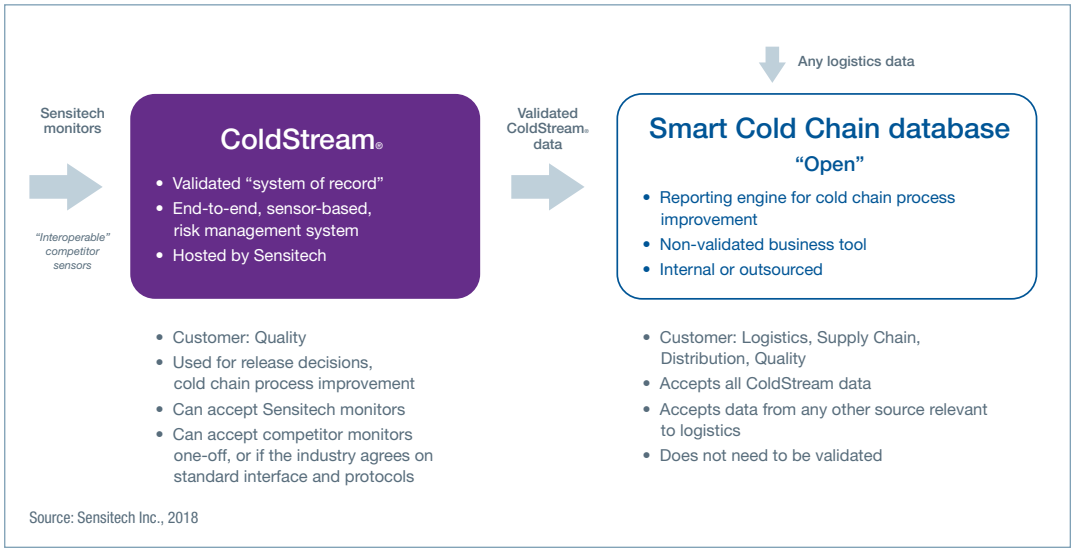
- Who ensures that third-party devices remain validated?
- Who ensures that all validation documentation and artifacts are maintained?
- Who is responsible for validating new sensors?
- Will advanced notification be required for any and all changes to sensors and software, even those that do not constitute a new product introduction? How might changes in advanced notification impact the underlying costs to provide a monitoring program, and the ability to adapt to changing conditions?
- If a company alters or improves its monitor, how will validation be assured?
- How are product-release decisions made with inconsistent or incompatible data from two or more suppliers?
- How will differences in measurement precision, time-zone calculations, rounding, conversion from Fahrenheit to Celsius, or other differences in monitor specifications be reconciled?
- How will regulators view interoperability?

These are questions that Sensitech believes should be answered by the industry, with specific formats and standards agreed upon, perhaps established by an independent third party. These formats and standards should have the blessing of regulators before the interoperability of validated databases is offered. Industry players must find ways to enhance features of their product in ways that benefit customers and maintain competition but protect the integrity of interoperable cold chain databases. Until such standards are established, customers engaging in interoperability put their validated data at risk.

Framing the Issue: One Customer, Two Requirements

Some of the confusion around interoperability stems from the fact that there are two distinct customers with two different needs within Life Sciences companies. As the industry seeks to control costs and improve efficiencies, focus is on supply chain analytics and optimization—work that can be accomplished with a variety of third-party data flows. This emphasis on costs and efficiencies must be balanced, however, with the need to meet regulations protecting validated databases.

We have modeled below a simple scheme, using Sensitech's ColdStream solution, for balancing the need to optimize supply chain performance against protecting the integrity of a validated cold chain database.



The existence of two separate but complementary databases meets the needs of both Quality and Logistics, creating an "open" database ideal for process improvement, and a closed and validated database designed to manage regulatory compliance risk. This scheme does not eliminate the need for industrywide standards for dataloggers and sensors if interoperability is desired, but maintains the integrity of validated data while providing all of the inputs needed to optimize supply chain performance.

Common Sense

The Life Sciences industry is undergoing a profound digital transformation. New data, along with new ways to combine and share this data, creates both opportunity and risk. Customers are being "offered endless promises of business transformation and operational efficiency improvements" in the wake of Big Data, a paper prepared by researchers at Cranfield University, concludes. Instead, the authors write, many supply chain organizations are already burdened with more data "than they know what to do with,"[6] and struggle to unlock its value.

Perhaps the first question the Life Sciences industry needs to answer, before diving into interoperability, is whether they are making the best use of the information they already generate. For decades, Sensitech customers have used their cold chain data to make both product-release and broader supply chain decisions. We continue to enhance this capability, but in a careful, common-sense approach that incorporates new technologies only when they are ready, remaining in sync with regulatory bodies and protecting validated data and processes critical to product integrity, patient safety and the broader success of the Life Sciences industry.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SUPPLY CHAIN VISIBILITY
Multi-Alarm Position in Trip
Alarm 1
Alarm 2
Alarm 3
Alarm 4
Alarm 5
Alarm 6
Start
End
Month/Year
All
Origin
All
Carrier
All
Destination
All

About Sensitech

Headquartered in Beverly, Mass., Sensitech offers a robust portfolio of products and services designed to help monitor and manage the cold chain of the world's most temperature-sensitive, perishable products: food, pharmaceuticals, biologics, and industrial chemicals. Sensitech is a part of UTC Climate, Controls & Security, a unit of United Technologies Corp.

For more information, visit www.sensitech.com or follow @Sensitech on Twitter.

Sources

[1] 19.3% annually, 2015-2021. See "2017 Cold Chain Outlook," Pharmaceutical Commerce, September 7, 2017, Web October 24, 2017, http://pharmaceuticalcommerce.com/supply-chain-logistics/pharmaceutical-cold-chain-logistics-13-4-billion-global-industry/.

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