What to look for when selecting a real-time cold chain visibility solution

— Real-time Insights

Controlant

As supply chain demand increases and new technologies enter new markets, it is time to evaluate and challenge current temperature monitoring devices and processes. Savvy manufacturers and suppliers understand the need to identify a digital solution that can help them operate with more agility, and improve lean operations, efficiency, productivity, performance, and customer service orientation. Moreover, as track and trace regulations go into effect—the EU's Directive Against Falsified Medicines and the US's Drug Supply Chain Security Act—traceability, security, counterfeit and cargo theft prevention are top of mind for pharmaceutical manufacturers. They must maintain full chain of custody and control over their products as they move through the supply chain. End-to-end cold chain visibility and traceability technology are now mission-critical. Although Pharma manufacturers and logistics provide reliable and stable services, inefficiencies may exist:

- Solutions that monitor ambient temperature and cold chain products in transit and distribution often do not provide full visibility during transport. Rather, such data is available only after the shipment arrived and is not linked with logistics data.
- When real-time or near real-time visibility data is available, lack of internal resources and expertise may make it difficult to respond.
- Manual, often paper-based, processes require either downloading PDF files or data loading into a software application.
- Enterprises often must rely on external data dependencies and do not own or control their own supply chain data.
- Inconsistencies exist with third-party data, such as arrival dates and time-stamps.
- Lack of real-time supply chain data that connects temperature, location, time, date, light events, and potential tampering data, makes identifying security issues and improvement opportunities difficult.
- Shipment investigations for excursions and discrepancies follow a manual process before acceptance or rejection of products.
- Integrating data points with internal business systems, such as enterprise resource planning (ERP) systems and Quality Management Systems, is difficult to achieve.

Digitalization, smart sensors, connected technology, and services can now enable businesses to:

- Gain end-to-end supply chain integration and efficiency
- Decrease the resources spent on shipment review and release processes
- Facilitate an efficient change control to a single, integrated solution
- Maintain compliance with FAA, EASA, IATA, GMP, and GDP rules and regulations, as well as validation requirements
- Drive millions of dollars in cost savings annually due to fewer excursions, reductions in product loss, and less investigation time needed
- Drive sustainability initiatives and carbon footprint reduction across the supply chain

Leading factors for switching to a real-time visibility solution typically include cost savings, temperature control, patient safety, increased compliance, efficiency, agility, and sustainability. With the right technology and services, enterprises gain an automated solution for packaging and lane validation, risk assessment, operational qualification, product integrity, and supply chain efficiency. Life sciences and logistics companies should consider several key factors when looking to deploy a real-time visibility solution for their temperature-controlled supply chain.

Visibility

Reliance on manually retrieved cold chain data at the end of a shipment slows the shipment and review process, and can lead to downstream stock outages in critical markets. Today, a cloud-enabled software dashboard can provide Pharma enterprises, shippers, and freight forwarders a single source of truth over the entire supply chain in real-time. This proactive visibility eliminates friction by alerting stakeholders of a temperature deviation. Shipment review can begin immediately and well in advance of receipt of products, which allows for implementation of corrective action to prevent an excursion. IoT data loggers can remain with products as they travel throughout the supply chain, providing critical supply chain information to all relevant stakeholders.

Key questions:

- Is supply chain data accessible on demand for a single shipment and for global supply chain operations?
- Does the customer own all shipment data registered within the system?
- Can stakeholders access supply chain data through a user-permissioned, cloud software dashboard?
- Does the solution provide high-level and granular insights across all lanes—air, road, rail, and sea?
- Does the platform identify the geo-location of a deviation to assist with root cause investigation?
- Is it possible to see temperature history from start to end of process?

IoT devices

Today's IoT monitoring devices support the storage, retrieval, and sharing of time-sensitive and routine shipment information continuously through the cloud. In real-time they can collect time, temperature, location, light events, and tampering information. The devices can immediately transmit sensitive and alert information including shipment duration. At regular intervals routine information is collected. Data collection via the IoT loggers can be manually or automatically started and stopped. Visual alerts automatically display on the device and in the cloud software platform, and notify designated stakeholders of issues requiring escalated attention.

Key questions:

- Does the IoT device include easily understandable status indicators?
- Is the IoT data logger durable? Can it operate under extreme ambient conditions while complying with 21 CFR Part 11? Does the data logger qualify as a non-dangerous good?
- Is the hardware user-friendly? (e.g. form, factor, display)
- Can the device support different travel modes: air, road, rail, and sea? Is the device approved for use on major airlines?
- Can the device record for up to 90 days without charge, depending on the upload frequency?
- Are the devices individually calibrated and documented to NIST standards?
- Can technology monitor temperature ranges between -20C to +50C / -4F to +122F for refrigerated shipments, frozen shipments, and ambient shipments?

Automation

Through sensors and geofencing, technology now automatically captures time, temperature, location data, and light events in real-time, sending critical quality and compliance data to a centralized software platform that is accessible on-demand. A single solution can travel with products from manufacture through last-mile delivery, providing end-to-end visibility, for greater quality and control. Custom, pre-configured shipment templates, alarm boundaries and settings accurately measure reporting on temperatures of products, lanes, packaging, and other variables. Data is available earlier in the shipment process, making it possible to manage by exception and segment problem shipments only for further investigation and review. Root case suggestions facilitate the shipment review process, substantially reducing operational costs.

Key questions:

- Is shipment data automatically uploaded through a hosted cloud software platform, without the need for manual intervention or upload?
- Is it possible to retrieve data manually via USB in case there is an issue with the communications?
- Is data accessible in real-time through a computer and mobile user interface?
- Is the temperature, geo-tracking location, and duration data accurate and reliable?
- Can shipment data help expedite the quality review and release process?
- If an alarm is triggered, will the system immediately notify designated personnel, along with details of the alarm/event?

Security and privacy in the cloud

Security and data privacy requirements are paramount for Pharma IT teams. Data storage, backup, and retrieval must be maintained in a secure data center or system. A cloud-enabled system must be validated and compliant for Pharma applications according to regulation.

Key questions:

- Can the solution track and trace critical data, including temperature, location, and light events, and immediately notify stakeholders if an issue arises?

- Has the solution provider validated the process of data uploading from the IoT device to their cloud platform? Can they confirm that data cannot be changed from the device to the software platform?
- Are Rest APIs available for systems integrations?
- Can user-permission access to shipment data be granted to partners and other stakeholders as needed?

Compliance

Global logistics teams often maintain limited visibility during transportation, as shipment data is often available retrospectively after shipment and after manual efforts, which can yield inconsistent data. Historically, improvements are driven by Corrective and Preventive Actions (CAPA's) after an issue has arisen. Temperature deviations are often discovered late, and not proactively detected, which can lead to shipment and quality release delays, and other discrepancies where investigation/root cause analysis takes several days and late initiation of a CAPA occurs. A lack of supply chain visibility makes quality management and supplier qualification difficult as well as ensuring that effective remediation actions are implemented in a timely manner, if at all. Today, technology can deliver real-time alerts if a deviation occurs, release notifications, and complete and accurate release reports, triggered immediately at the end of a shipment.

Key questions:

- Is the technology compliant with 21 CFR Part 11 automation and data storage requirements?
- Do electronic temperature records include a timestamp and an audit trail?
- Is the technology compliant with FAA/IATA/GMP/GDP rules and regulations as well as fulfilling validation requirements?
- Is the system manufactured in accordance with ISO 9001:2000?

Data integration and output

Relevant, timely data and analytics are paramount for supply chain optimization and efficiency. Today's real-time technology allows for the centralized data collection, shareable with relevant stakeholders. Seamless integration with other business systems including ERP systems such as SAP, is possible through REST API's. Data can be

exported in PDF and Excel format, and custom reporting provides data analytics and insights on supply chain performance, including excursions and saved product loads, lanes and packaging, points of interest, root cause suggestions, and total cost savings.

Key questions:

- Can the software platform easily integrate with other business solutions, such as SAP and Transportation Management Systems?
- Does the software provide near real-time shipment tracking during transport, predictive insights to trend and analyze data, and provide metric trending for Business Intelligence?

Cost

Traditionally, temperature data loggers were purchased up front. For a Pharma enterprise, this would translate to tens of thousands of data loggers annually, a cumbersome CAPEX cost. Today, real-time cold chain solutions are offered as a cost-effective alternative and provide a single source of truth. IoT hardware, software, and services are included as an all-in-one, leased solution. This provides economy at scale; the solution can be used for all shipments, both high-value products, as well as smaller and less valuable goods. IoT loggers and reverse logistics are managed as an included service, and 24/7 monitoring and response services provide around the clock, control tower visibility, eliminating the need to hire internal resources to manage reusable data loggers and respond to real-time alerts.

Key questions:

- Is the total cost to serve competitive with traditional, USB-based data loggers?
- Is the solution cost-effective and scalable, including for smaller parcels and less valuable goods?
- Can the solution provider share actual use cases demonstrating business success and ROI, including direct savings of tens of millions of dollars?

Sustainability

Sustainability and environmental concerns are top concerns in today's supply chain. Preventing replacement shipments, exploring new shipment methods, such as sea freight and LCLs (Less than Container Load), and implementing systems that provide real-time visibility and the ability to proactively protect product quality and integrity will enable enterprises to reduce waste and decrease their carbon footprint.

Key questions:

- Are the IoT data loggers reusable?
- Is the technology validated for ocean freight, LCL shipments, and other methods of shipment?
- Can the solution substantially reduce product and operational waste and drive down carbon emissions?

Services

Today's efficient temperature-controlled supply chains are partner- and services-focused. Pharma enterprises no longer need simply temperature monitoring data loggers. Rather, a partnership model that includes IoT hardware, access to real-time shipment data via a software dashboard, and a variety of services that automate, streamline, and operationalize the supply chain will increase efficiency, flexibility, and agility going forward.

Key questions:

- Does the vendor provide access to 24/7 support?
- Does the solution provider offer packaging and lane validation as a service?
- Are 24/7 monitoring and response services offered optionally to respond to real-time alerts?
- Can the solution provider manage the reusable IoT data logger pool?
- Does the solution provider offer customer success services to train and support internal and external stakeholders?
- Does the solution provider offer program management services to review business intelligence, identify performance trends, and suggest areas of improvement and cost savings?

Building an agile and sustainable supply chain requires the right technology and services that can monitor, measure, and optimize processes and efficiencies while reducing costs and carbon footprint. For Controlant, the answer to each of the above key questions is: **yes.**
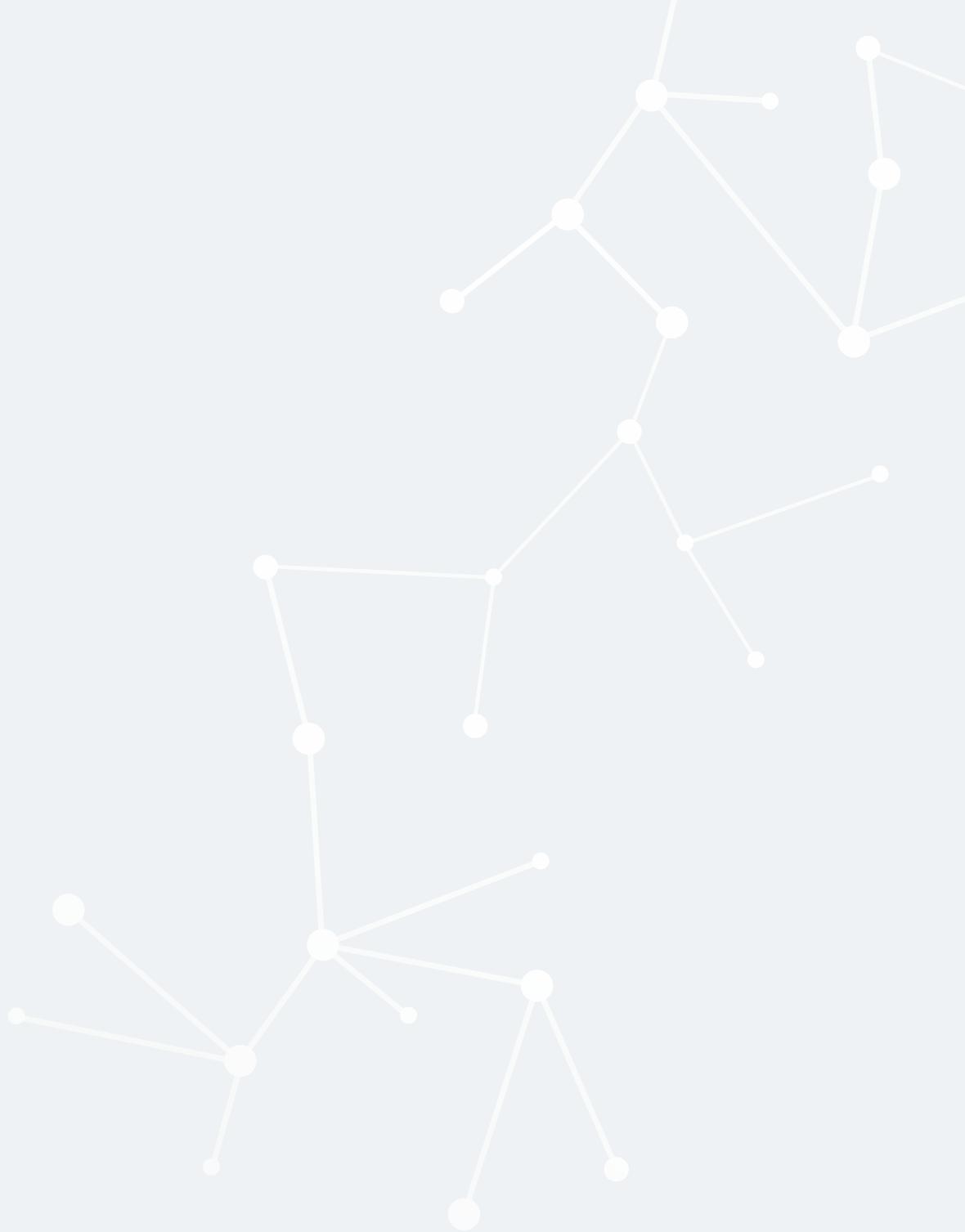
About Controlant

Controlant is an ISO 9001:2015 company, headquartered in Reykjavik, Iceland with operations in the U.S., Ireland, and Denmark. We deliver product quality, compliance, sustainability, and enhanced cold chain performance through our unique services-based partnership.

To learn more or get started with a pilot, please visit controlant.com or contact us at contact@controlant.com.

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