White Paper

Mandates, Opportunities and Solutions for Improved In-Transit Medication Management (ITMM)

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Abstract

Transporting medicine from the pharmaceutical factory to pharmacies is a $78.8 billion industry, globally. Traditionally, only the cold-chain (refrigerated) portion of the total biopharma/supply chain — estimated to be a $12.6 billion market — was monitored for temperature and humidity. However, with the introduction of biologic-based drugs, expansion of the international drug trade, and new regulations requiring stricter oversight of drugs during transportation, both the cold-chain portion and the non-cold-chain (ambient) $66.2 billion part of that supply chain will have to be monitored closely in the future. This new reality gives companies great opportunities to provide highly integrated, more carefully controlled drug supply chains. Very effective tracking and environmental regulation systems can be implemented using the electronic technology that enables the Internet of Things (IoT).

In this white paper, tracking and environmental regulation systems that can be implemented using the electronic technology that enables the Internet of Things (IoT) will be discussed, as well as an ITMM solution that enables implementation.

I. Growth in the Global Biopharma Logistics Market

After a pharmaceutical product is produced at a manufacturing plant, it typically goes to wholesale distributors who send it to dispensers (see Appendix). Various transportation networks perform critically important roles in medical markets, and they comprise a big business segment.

In fact, preliminary data from Pharmaceutical Commerce's annual Biopharma Cold Chain Sourcebook shows that managing the transportation of temperature-controlled products (refrigerated and frozen) was expected to total $12.6 billion in 2016 (Figure 1), continuing an 8–9% per year growth rate, which is roughly double the rate of pharmaceutical products overall. By 2020, cold-chain logistics activity is predicted to be worth $16.7 billion, while the non-cold-chain logistics activity is forecast to be $77.1 billion.

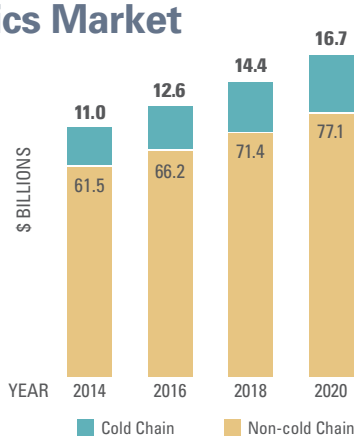
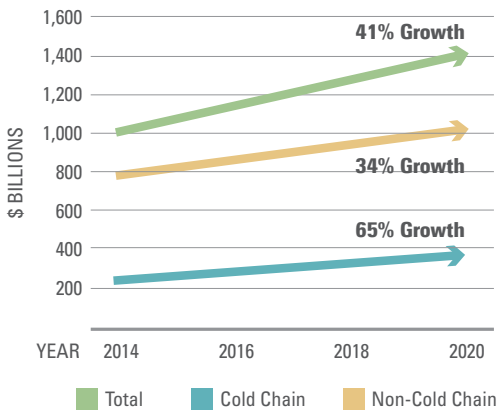


Figure 1: Global Biopharma Logistics Spending ($ Billions)

Source: Pharmaceutical Commerce's Biopharma Cold Chain Sourcebook (7th edition)



Based on 2015 Forecasts by IMS Health and Evaluate Pharma

Figure 2: Global Biopharma Sales ($ Billions) Trend 2014–2020

The global pharmaceutical industry today totals roughly $1.1 trillion, and between 2014 and 2020, it is projected to rise by 41%. Within that, products that require refrigerated storage and transport are worth around $260 billion, an amount predicted to rise 65% between 2014 and 2020. By contrast, non-refrigerated products are projected to rise by much less at 34% (Figure 2).

The main driver of the increased refrigeration is the continuing transition to biologic-based products in new product introductions. Other factors influencing the rise include the tightening requirements for life sciences shipments and the growing internationalization of the pharmaceutical trade.

The high rate of cold-chain logistics growth is attributable primarily to the shift to biologics and other specialty pharmaceuticals, many of which require refrigeration. Two other factors facilitating this trend are the continued strong growth in insulin products and vaccines, and the broader adoption of such products in underdeveloped economies, especially those in Asia and Africa.

According to Nicholas Basta, editor-in-chief of Pharmaceutical Commerce's Biopharma Cold Chain Sourcebook[1], "If anything, our estimate of current and future spending is slightly under-calculated. We see a small, but growing, trend for shipping ambient-temperature products in a monitored, controlled manner, which is a departure from past practices."

Non-Cold Chain Market Will Also Need Closer Monitoring

As government regulations become more stringent, the non-cold-chain portion of the market will tend to merge with the cold-chain portion with regard to monitoring and controlling environmental conditions. This presents a huge opportunity for companies providing logistics solutions for pharmaceutical goods.

> **"The recent Good Distribution Practice (GDP) Guidelines, that the industry is gradually adopting, require control of even room-temperature drugs, those that need not be refrigerated or frozen. With each passing year, the oversight of pharmaceutical and biologics shipping is getting tighter."**
>
> – Nicholas Basta
> *Editor-in-Chief of Pharmaceutical Commerce's Biopharma Cold Chain Sourcebook*

The Sourcebook also covers the clinical logistics field. It doesn't differentiate between cold-chain and ambient applications in this area, though, because most drug trials use temperature controls in parts of the evaluation process. Trial initiations and the scale of trials will generate a logistics volume of around $3.2 billion in 2016. Based on estimates of future trial volume, location (many trials are conducted globally) and industry R&D spending, the Sourcebook forecasts logistics spending to grow at about 2% per year, reaching about $3.4 billion in 2020.

Note 1: 7th edition of Pharmaceutical Commerce's Biopharma Cold Chain Sourcebook, published in 2016

II. Increased Regulation Brings Opportunity

Government regulators and several other organizations work together to help ensure the safety of medicines being transported and stored by the pharmaceutical industry. Major legal influences and influence groups are covered in this section.

Drug Supply Chain Security Act (DSCSA)

The Drug Quality and Security Act (DQSA) became federal law on Nov. 27, 2013. Title II of DQSA, the Drug Supply Chain Security Act, outlines critical steps to build an electronic, interoperable system to identify and trace certain prescription drugs as they are distributed in the United States.

Ten years after enactment, the pharmaceutical monitoring system will facilitate the exchange of information — at the individual package level — detailing the passage of a drug through the supply chain. The new system will:

- Enable verification of the legitimacy of the drug product identifier down to the package level (SNI – Serial Number Identifier)
- Enhance detection and notification of illegitimate products in the drug supply chain
- Facilitate more efficient recalls of drug products

Over the next 10 years, drug manufacturers, wholesale drug distributors, repackagers, and many dispensers (primarily pharmacies) will be called on to work in cooperation with the Food and Drug Administration to develop the new tracking system.

Key provisions to be implemented include the following requirements:

Product identification	Manufacturers and repackagers will have to put a unique product identifier on certain prescription drug packages; for example, by using a barcode that can be easily read electronically.
Product tracing	Manufacturers, wholesale drug distributors, repackagers, and many dispensers in the drug supply chain will have to provide information about a drug and record who handled it each time that product is sold in the U.S. market.
Product verification	Manufacturers, wholesale drug distributors, repackagers, and many dispensers must establish systems and processes to be able to verify the product identifier on certain prescription drug packages.
Detection and response	Manufacturers, wholesale drug distributors, repackagers, and many dispensers must be able to quarantine and promptly investigate a drug that has been identified as suspect; i.e., a medicine that may be counterfeit, unapproved, or potentially dangerous.
Notification	Drug makers, wholesale distributors, repackagers, and many medicine dispensers will have to establish systems and processes to notify the FDA and other stakeholders if an illegitimate drug is found.
Wholesaler licensing	Wholesale drug distributors must report their licensing status and contact information to the FDA. This information will be made available in a public database.
Third-party logistics	Third-party logistic providers that provide storage and logistical operations related to drug distribution will be required to obtain a state or federal license.

The DSCSA legislation requires the FDA to develop standards, guidance documents, and pilot programs; conduct public meetings; and take other steps needed to support efficient and effective implementation. The FDA is developing a schedule for implementing the law's requirements.

When the new electronic monitoring system is implemented, it will enhance the FDA's ability to protect consumers from obtaining drugs that might be counterfeit, stolen, contaminated, or otherwise harmful. It will especially facilitate the detection and removal of potentially dangerous drugs from the drug supply chain. The FDA will issue penalties to companies that fail to comply with the requirements of the law.

The development of tighter pharmaceutical monitoring systems will be phased in with new requirements over a 10-year period. These requirements will include providing product and transaction information at each sale with lot-level information, in paper or electronic format. Additionally, individual drug packages will be required to have unique product identifiers. More information on these mandates is available on the FDA's site.

Strengthening and Focusing Enforcement to Deter Organized Stealing and Enhance the Safety Act of 2010 (SAFE DOSES Act)

Criminals who steal drugs to try to resell them to the legitimate supply chain now face longer sentences under new U.S. legislation known as the SAFE DOSES Act. This law does the following, among other things:

- Increases sentences for people who steal medical products
- Enhances penalties for persons ("fences") who knowingly obtain stolen medical products for the purpose of reselling them in pharmaceutical supply chains
- Increases sentences when harm occurs – where injury or death results from using a stolen substance or where the defendant is employed by an organization in the supply chain
- Makes the theft of medical products a predicate for the Racketeer Influenced and Corrupt Organizations (RICO) law, a provision that gives law enforcement officers needed tools
- Increases possible sentences for stealing controlled substances from pharmacies
- Provides restitution to victims affected by stolen medical products

Pharmaceutical Distribution Security Alliance (PDSA)

The Pharmaceutical Distribution Security Alliance (PDSA) is a multi-stakeholder and inter-disciplinary initiative committed to safeguarding patients. The organization's goal is to ensure that the medication distribution chain remains as robust and secure as possible.

The PDSA has played a critical role in helping develop and enact federal legislation that protects patient safety. By maintaining a single national uniform product serializing and traceability system, it aims to keep the drug supply chain secure. The Alliance collaborates with congressional policy makers and FDA regulators to clarify and implement this new system, as enacted by the federal Drug Supply Chain Security Act (DSCSA). This organization also addresses other issues important to the pharmaceutical distribution supply chain.

Specifically, the PDSA performs three main functions:

- Identifies ambiguities and challenges in the DSCSA law that require clarifications or the development of operational solutions
- Engages the FDA to ensure that regulation is consistent with PDSA objectives and the best reading of the Drug Supply Chain Security Act
- Works with members to identify, develop and promote industry conventions for improving implementation and interoperability issues among stakeholders

Pharmaceutical Security Institute (PSI)

The Pharmaceutical Security Institute is a not-for-profit, membership organization dedicated to:

- Protecting the public health
- Sharing Information on the counterfeiting of pharmaceuticals
- Initiating enforcement actions through the appropriate authorities

International Air Transport Association (IATA) – Sensitive Healthcare Products Procedure

For the international air transportation of pharmaceutical products, the transit rules are different from those that apply to surface modes. The IATA helps manage this part of the in-transit medical product distribution system, in part by creating "TTTF" package labels that clearly identify packages containing time- and temperature-sensitive goods (Figure 4).

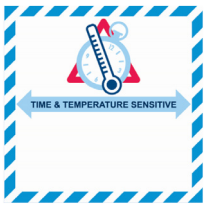


Figure 4: An IATA TTTF Sticker

The IATA's Time and Temperature Task Force (TTTF), operating under guidance from the Live Animals and Perishables Board (LAPB), performs the following activities, as well as other tasks delegated to it by the LAPB:

- Establishes and maintains a time and temperature quality management system by means of a documented process
- Liaises with all stakeholders from the health care industry or their intermediaries to establish common standards
- Produces, develops and implements guidance material for maintaining drug quality and efficacy when shipping time- and temperature-sensitive pharmaceuticals
- Acts as the coordinating body between the IATA and the pharmaceutical industry for the health care logistics forum during the World Cargo Symposium
- Promotes its activities with industry associations and shippers
- Actively encourages government agencies, intergovernmental organizations, stakeholders, carriers, shippers and their intermediaries to recognize and adopt applicable standards

III. Pharmaceutical Supply Chain Security

As previously mentioned and described in the Appendix, the pharmaceutical distribution supply chain moves medications from the manufacturing facility to the pharmacy shelf. This path typically involves many steps before a consumer receives the medicine.

Security is a priority throughout the distribution process, and U.S. consumers are fortunate to have a pharmaceutical supply chain that is among the safest in the world. Yet greater efforts to enhance security are now needed because a growing number of increasingly sophisticated criminals are attempting to infiltrate and defeat the system in multiple ways (see Figure 5). Implementation of the DSCSA will strengthen the supply chain to foil their attacks and reduce the causes of accidents.

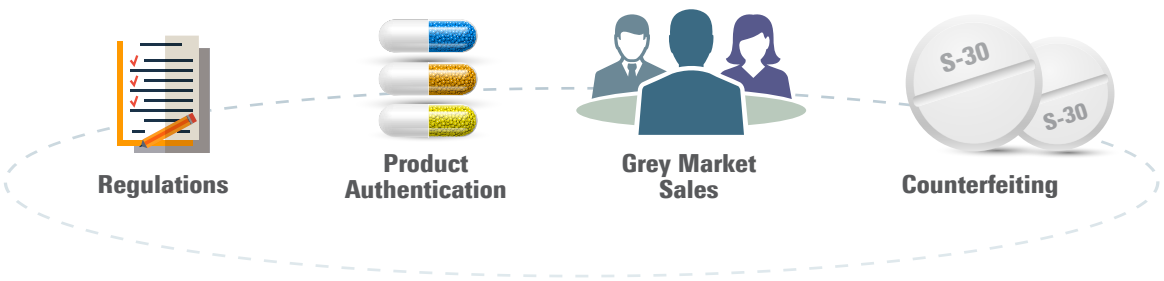


Figure 5: Major Supply Chain Security Challenges

Problems targeted by DSCSA provisions include environmental exposure, counterfeiting, illegal diversion, and theft. They are summarized below.

Environmental Exposure — Different types of medicine are more or less sensitive to environmental changes (temperature, air, humidity, pressure, etc.). A drug exposed to extreme conditions or prohibited temperature deviations can become ineffective in treating a patient's condition; even worse, its use might result in a casualty. So it's critical to ensure that the medicine has remained within the boundaries it can tolerate during transportation.

Counterfeiting — The World Health Organization (WHO) defines counterfeit medicine as products deliberately and fraudulently produced and/or mislabeled with respect to identity and/or source to make them appear to be genuine. This definition applies to both branded and generic drugs.

Counterfeit products can have a wide range of deficiencies. For example, counterfeit medicines have been found to contain less than or more than the required amount of the active pharmaceutical ingredients (API) used in the authentic version. Even if they contain the correct amount of API, they may have been manufactured in unsanitary, unsafe conditions. Counterfeit medicines containing harmful ingredients are quite common and present substantial risks to consumers.

Genuine medicines can also be counterfeited. For example, instances have been discovered in which genuine medicines have been placed in counterfeited packaging to extend the expiration date or to commit fraud against government programs.

Illegal Diversion — A genuine pharmaceutical product, approved and intended for sale in one country, might be illegally intercepted and sold in another country. Diversion schemes are often accomplished through the use of false statements or declarations. Often diverted drugs aren't approved for sale at their final destination.

Illegal drug diversions can also occur within the same geographic area, country or city. Instead of going to the intended consumers, the medicines are sold elsewhere. For example, in Latin America, illegal diversion occurs when a government purchases drugs for state hospitals at discounted prices, but then covertly profits by diverting them to black markets that sell to the public.

Pharmaceutical Theft — The illegal taking of medicines via burglary, robbery or embezzlement constitutes a very real and substantial threat to the pharmaceutical supply chain. The criminals may be insiders such as employees or outsiders such as professional thieves. Moreover, thefts occur anywhere in the distribution chain—at manufacturing plants, freight forwarders, distribution centers, warehouses, pharmacies, hospitals, clinics, etc.

IV. Statistics on Crime in the Pharmaceutical Supply Chain

The Pharmaceutical Security Institute (PSI) documented 3,002 incidents of pharmaceutical crime during CY 2015 (Figure 6). This was a significant increase from CY 2014; in fact, it was an all-time annual high. From CY 2011 to CY 2015, total incidents of criminal activity increased by 51%.

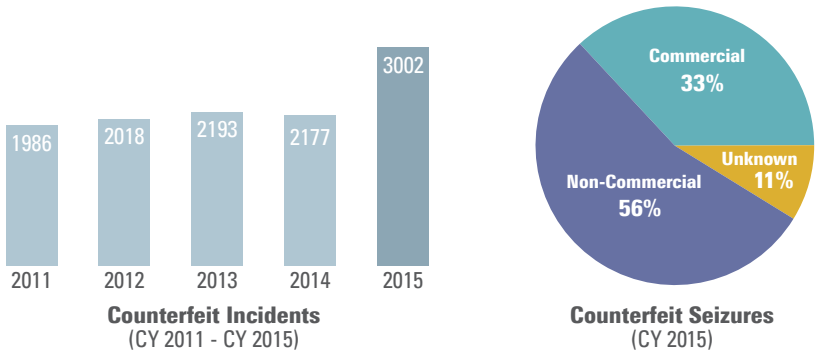


Figure 6: Drug Counterfeit Market Data

Source: http://www.psi-inc.org/incidentTrends.cfm

To better understand the magnitude of the counterfeiting incidents in CY 2015, PSI continued to track the quantity of drugs seized in each law enforcement action. Any incident involving the seizure of more than 1,000 dosage units was classified as a commercial incident, while those involving less than 1,000 dosage units were classified as non-commercial.

In CY 2015, there were 971 counterfeiting incidents that involved either customs seizures or police/health inspector raids. This represents a 34% increase over the prior year. As Figure 6 shows, 33% of counterfeit medicine seizures made by law enforcement were of "commercial" size. The number of the smaller, non-commercial seizures also increased significantly in CY 2015. In fact, seizures of one thousand or fewer dosage units were 56% of the total.

In CY 2015, the PSI analyzed the pharmaceutical incident data with respect to seven regions of the world, a total of 3,002 crimes (Figure 7). Every region experienced a pharmaceutical crime incident. As a matter of fact, criminal activity was recorded in the medicine supply chains of 128 countries. PSI documented a 38% increase in the 2015 worldwide incident total compared to 2014. Incidents impacting the Asia Pacific region surpassed one thousand incidents annually for the first time in CY 2015. Importantly, incidents in North America doubled during that year.

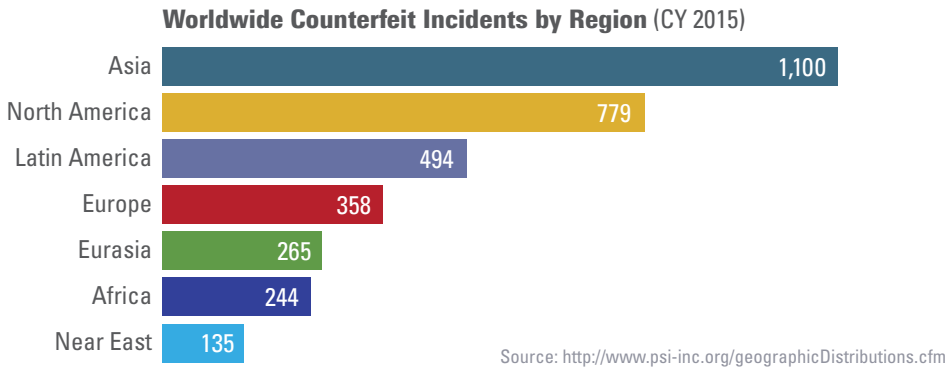


Figure 7: Illegal Pharmaceutical Incidents, Based on Region

Note: Totals exceed 3,002 incidents because a region is included if it is the "origin, point of seizure or transit, or destination" of illegal pharmaceuticals.

The 3,002 crime incidents that occurred in CY 2015 involved 1,095 different pharmaceutical products. The number of products found in a single incident ranged from one drug to 37 different medications. Pharmaceuticals in every therapeutic category were copied by criminal organizations. CIS data revealed that medicines in the genito-urinary, anti-infectives, and central nervous system (CNS) therapeutic categories accounted for the largest number of pharmaceutical counterfeiting incidents. Extra scrutiny of the drugs in those three categories is recommended.

The PSI's rankings of criminal activity in the top therapeutic categories remained relatively unchanged in 2015. However, as Figure 8 shows, the Institute noted that seven therapeutic categories experienced a percentage increase on a year-to-year basis. Specifically, the genito-urinary therapeutic category had the highest increase of 65%. Other categories with percentage increases included dermatologicals (+57%), cytostatics (+29%), cardiovascular (+29%), respiratory (+28%), CNS (+11%), and alimentary (+4%).

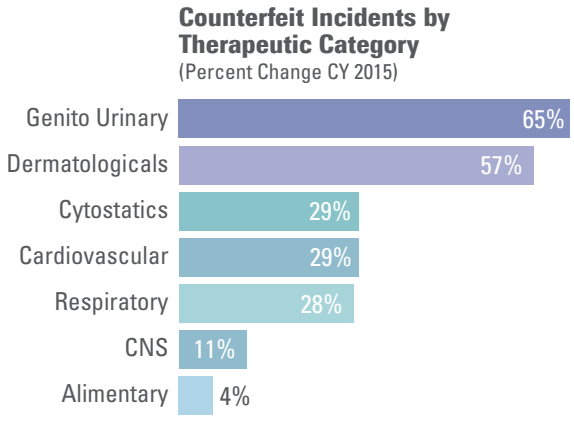


Figure 8: Counterfeiting Incidents by Therapeutic Category (Year-to-Year Change, 2015)

V. Key Issues Impacting Medication Management

Problems faced today by logistics providers in pharmaceutical supply chains are creating strong pressures for innovative solutions for improving track and trace and cold-chain management. Here are some of the issues encouraging the industry to invent and deploy enhanced end-to-end ITMM systems:

- Shortages of both common and disease-specific drugs frequently create supply chain interruptions. Manufacturing problems or production cutbacks driven by economic factors often cause shortages. Insufficient volume to meet demand leads to hoarding and gray market distribution, while encouraging off-spec manufacturing by secondary suppliers. Drug shortages have increased over 300% since 2005, enabling price increases up to 650%.
- Prescriptions for uncommon, limited-use medications for treating relatively rare diseases are proving to be economically difficult for large pharmaceutical companies to support.
- Outsourced manufacturing for lower-profit drugs broadens the need for verifying not only the drug's pedigree, but also the integrity and validity of the cold-chain supply network's infrastructure.
- Differences between medical markets in western and emerging countries create distribution complexities as drugs travel bi-directionally between them.
- The limited visibilities in global medical inventories make it difficult to spot the early stages of drug shortages, hampering the efforts of governments and purchasing groups to react quickly to serious health emergencies.
- Primary medical product distributors in the U.S. deliver drugs to over 240,000 healthcare providers and end users every day. To maintain and expand that flow, while providing secure and efficient service and complying with new laws, these distributors need improvements to the distribution network infrastructure. They want a more sophisticated, reliable and universal supply chain monitoring system to better track and validate end-to-end quality of products being shipped and stored.
- About two-thirds of U.S. drug patents are due to expire in the next four years. This will increase the proliferation of available generics and boost the number of outsourced and alternative manufacturers globally.
- The number of drugs currently in use that have to be tracked is rapidly increasing. Today there are over 150,000 different medications. Fully 75% of them did not exist 10 years ago.
- The pharmaceutical industry has been globalized on a big scale. About 40% of the drugs consumed in the United States are manufactured outside the country, and 80% of those drugs contain ingredients from foreign counties. For instance, 70% of U.S. drug companies have suppliers in China, while 60% of them have suppliers in India.
- Drug counterfeiting is a growing problem. Of all the prescriptions filled in the U.S., over 40 million of them are bogus—approximately 1% of the total. Higher drug prices are encouraging greater levels of unlawful activity.

VI. Internet of Things (IoT) Technology Provides ITMM Solutions

Electronic technology advances are the keys to improving in-transit medication management (ITMM). Pharmaceutical supply chains traditionally have had various links, each of which serves a specific function. Today, however, using wireless communication technologies, among others, the Internet of Things makes invisible links visible. In turn, this makes possible the concept and future reality of integrated, virtually real-time supply loops.

Figure 9 illustrates end-to-end ITMM solutions made possible by the ongoing expansion and enhancement of the IoT.

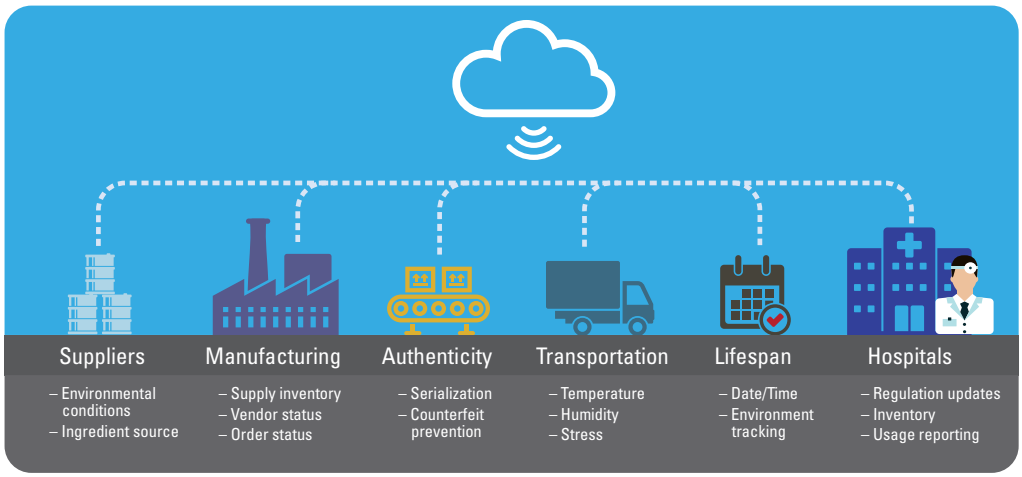


Figure 9: Pharmaceutical Supply Chain and the IoT

All parties in IoT-enabled, cloud-based ITMM systems can interact with each other and perform the actions needed to implement and improve dynamic medical product transportation and storage systems. Many electronic technologies available today provide the advantages and capabilities needed to design and deploy robust and efficient ITMM systems:

- Small sensors can report on temperature and humidity conditions, detect physical stresses, pinpoint package locations, send tampering alerts, and verify the identity of drugs at any point in the supply chain.
- ITMM items can use wireless transmitters to send data to the Internet "cloud" without clumsy or constricting wires.
- Mobile devices can give operations personnel in pharmaceutical supply chains easy ways to access ITMM data in the cloud. When problems arise, they can also raise personal alerts.
- Intuitive mobile apps enable logistic providers to manage their supply chains efficiently.
- Cloud-based platforms let logistic providers log and manage events within the supply chain. Additionally, they can be used to automate the reports required by regulatory bodies.

These and other technology advances from the IoT make possible a new class of ITMM solutions that solve key problems associated with transporting drugs, and they do so in ways that facilitate the adoption of supply system upgrades. This is truly a case in which technology is helping to solve important problems. The safety and economic benefits IoT solutions can deliver will become clear as new equipment, procedures and applications are put into widespread operation.

VII. Advanced Technology for ITMM Applications

One company that is presently delivering advanced technology for ITMM applications is Renesas Electronics, a leading global provider of semiconductor solutions, especially for embedded system applications such as IoT applications. Renesas supports customers building products for the In-Transit Medication Management Industry with chips, software, development systems and support services. The broad portfolio of technologies and products that are offered provide substantial value propositions and important system design advantages. They are summarized below in Table 1.

Table 1: Key Elements in the Renesas Technology Portfolio and Examples of Their Capabilities

Technology	Function
MCU/MPU	Chips that serve as the heart of an electronic device, controlling its operation and processing data collected from different sources
Bluetooth® low energy technology	A low-power PAN wireless protocol that can be used to connect a product in a pharmaceutical supply chain to a gateway or provisioning field device
Image Sensor	Devices for scanning barcodes, QR codes, etc., for tracking and identification
Analog Interfaces	Data converters that enable an MCU or MPU to collect data from analog temperature, humidity, pressure/shock, and tamper-detection sensors
Fuel Gauge	A battery-status function useful for extending battery life in portable devices
Power Management	Chips that enable more efficient power conversion, regulation, and charging
USB Interface	An I/O function that handles data transfers, programming, and charging

To aid the development of ITMM applications, Renesas offers evaluation/starter kits, reference designs, and more. Our development tools speed customers' R&D projects in areas such as Human Machine Interface (HMIs), cloud connectivity, security, safety standards, motor control, and imaging and sensing.

VIII. Renesas ITMM Reference Solution

High-End Data Logger for DSCSA Compatibility

As the implementation of DSCSA gains momentum, it will dictate the need for new hardware to track medicine within the supply chain. Renesas has a reference solution which can be thought of as a data logger for DSCSA compatibility. The ITMM solution has GPS, temperature, humidity, pressure, shock, and tamper-detection sensors on board for meeting various requirements of DSCSA. It connects to the mobile app via Bluetooth® low energy technology. The mobile app will display the sensor data and can also read the NFC tag, linear barcode, and 2D barcode printed on the medicine package. Capacitive touch buttons can toggle between modes of operation and

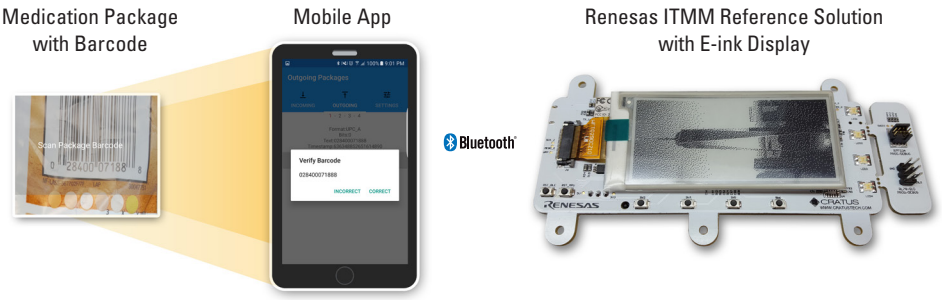


Figure 10. Data logger with mobile app enables tracking of sensitive medications

change the sensor data being displayed on the screen. The screen is capable of displaying data in linear barcode format, which can be read by traditional handheld scanners, making the ITMM solution compatible with existing infrastructure. Battery operation ensures portability along with a fuel gauge for USB-based charging.

Table 2: Data Logger Features

Technology	Function
Fuel Gauge	Accurate measurement of the battery charge to avoid shutdown
USB	Standard micro-USB for data transfer and firmware upgrade
Alert	Out of range event in transit
Push Buttons	Toggle between human readable and barcode format on display, and scan through different parameters displayed on the screen
Bluetooth® low energy technology	Secure, reliable and low power method to communicate to the mobile device
GPS	Track location history of the medicine
Temp./Humidity/ Pressure/Shock Sensor	Ensures medicine has not been subjected to extreme conditions
Tamper Sensor	Ensures medicine has not been tampered with
E-ink Screen	Displays various sensor data in barcode format, which can be read by a traditional handheld scanner
NFC Tag or Barcode Reading	Mobile app enables the mobile device to read NFC tag or barcode so that information at medicine package level can be combined with data logger data
Mobile App	Forms database of medicine information from labels, GPS history, and sensors data, and has the capability to report suspicious drugs to FDA
LEDs	Power and battery level status, Bluetooth low energy technology connection and activity status, and general status

Optional Enhancements

Renesas developed these solutions to show proof of concept and give customers a head start for designing world-class products. This solution showcases the Renesas Synergy™ Platform, featuring the Synergy S3 MCU; the RL78/G1D MCU; and the USB Charger IC. Renesas Synergy is a complete and qualified platform that accelerates embedded development, inspiring innovation and enabling differentiation. The RL78/G1D is an industry-leading, true low power MCU featuring Bluetooth low energy technology (v4.1). Renesas has a portfolio of power management ICs.

Customers have the option to use Wi-Fi, LoRa or cellular technology for connectivity instead of the provided Bluetooth low energy technology. The mobile app can be further enhanced by providing back-end connectivity to a cloud platform and building a dashboard on the cloud. This dashboard can be a single point of interaction between the manufacturers, third-party logistics providers, distributors, and dispensers.

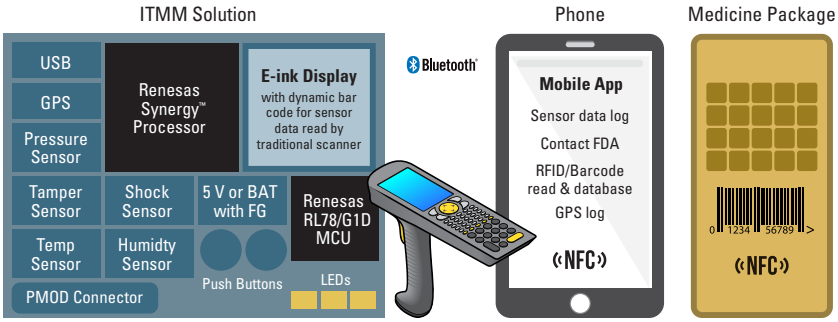


Figure 11. Renesas ITMM Proof of Concept Kit

Appendix – The Pharmaceutical Supply Chain

When a finished drug or biologic product completes the packaging process at a manufacturing facility, its journey to a patient is just beginning.

For most products, the next leg of the journey takes them to a facility controlled by a wholesale distributor. Manufacturers may also connect with Third-Party Logistics Providers (3PLs) to coordinate the logistics. Wholesale distributors, including primary and secondary distributors, are responsible for maintaining the integrity of medicines from the manufacturer to the dispenser, which distributes the medicine to patients. Distributors are the critical link between more than 1,000 manufacturers and over 200,000 dispensers throughout the country.

Dispensers include hospitals, long-term care facilities, healthcare clinics, physician offices, and, of course, pharmacies. Some of the latter are independent drug stores, while others are major departments in chains of drug stores. Figure A summarizes the main elements of the process.

Figure A: The Pharmaceutical Supply Chain

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