The Internet of Things: The New Rx for Pharmaceuticals Manufacturing & Supply Chains

Using IoT platforms and solutions, pharmaceuticals companies can digitize and connect vital functions, elevate efficiencies, and assure product quality and compliance.

Executive Summary

Product quality, regulatory compliance and operational efficiencies top the long list of business priorities for pharmaceuticals executives, who lead the charge in improving manufacturing and supply chain performance. Investments in areas such as shop-floor automation, electronic batch records, ERP, and warehouse management systems (WMS) have been made in part to address these concerns, with varying degrees of success. But due to the challenges of batch manufacturing, especially when it comes to monitoring the logistical journey of pharmaceuticals, industry players continually face issues related to product degradation and recalls, compliance with best practices for manufacturing (GMP) and distribution (GDP) - not to mention exorbitant operational costs.

The Internet of Things (IoT), the global network of small, powerful sensors and interconnected “things”, allows physical objects - from heavy equipment, to mobile and wearable devices, to vehicles, physical structures, and appliances - to connect, interact and share data with one another or with a central system through the Internet. This affords higher levels of efficiency, accuracy, and security by digitizing and optimizing critical functions, including manufacturing and supply chain management. According to IDC, there were 9.1 billion IoT units installed in 2013 – a number that IDC predicts will increase to 28.1 billion by 2020.1

There are multiple scenarios in pharma manufacturing and supply chain management where the Internet of Things can help clear bottlenecks, ensure greater GMP/GDP compliance, and reduce operational expenses.

This white paper explores how pharmaceuticals companies can employ the Internet of Things to automate and revitalize manufacturing and supply chain management. We also present an IoT framework and best practices for accelerating the transition to digital.

Connecting Opportunities Across the Pharma Spectrum

In an IoT environment, every “thing” is equipped with a sensor that allows it to intelligently communicate and interact with other objects and systems within the IoT ecosystem. Each object represents a
node in the virtual network - continually transmitting vital data pertaining to such things as environmental and equipment conditions.

These capabilities are transforming peoples' lives, and empowering the competitive forces that drive business. Consider the automotive industry's focus on connected cars, and health care providers' enthusiastic adoption of wearable devices. As organizations across sectors examine and evaluate how the IoT can improve how they manufacture products, provide services, and manage their supply chains, the pharma industry has a compelling opportunity to adopt and profit from these game-changing technologies.

**IoT in Pharma Manufacturing/Supply Chain Management**

IoT solutions such as wearables and mobile products have enabled healthcare professionals to make significant inroads in subject/patient health monitoring. The use of intelligent pills in clinical trials is among the applications gaining traction.

IoT applications for manufacturing and supply chain management have become popular investment areas for many industries.

Connected equipment, men and material tracking, sample lifecycle management, smart packaging, and cold chain monitoring are among the IoT applications that are particularly well suited to the pharmaceuticals industry, as shown in Figure 1.

**Connected Equipment**

Pharmaceuticals manufacturing is generally performed in batches, and equipment is usually self-contained. Although industrial automation and control technologies are well established in life-sciences manufacturing facilities, integrated information on the real-time status or condition of equipment is still not readily accessible to help executives make informed decisions and improve overall equipment effectiveness (OEE) in areas such as scheduling batches, cleaning, maintenance, etc. These issues point to the shortcomings of current industry solutions.

Because pharma companies rely heavily on batch manufacturing they must constantly move men and material on the shop floor. At the same time, CGMP dictates that equipment be continually maintained and calibrated to assure the safety and efficacy of drug products. Some raw materials, as well as finished products, require very specific storage conditions. IoT technologies allow companies to connect and extend visibility into shop-floor activities, which can significantly increase productivity and assure GMP compliance (see Figure 2, next page).

The backbone of such a solution is made up of sensors attached to manufacturing equipment. The sensors collect and send data to a central system that connects the sensors, then analyzes and converts the raw data into meaningful information on such things as performance and conditions.

**The IoT in Pharma Manufacturing & Supply Chain Management**

![Figure 1](image-url)
### Increasing Shop Floor Visibility

<table>
<thead>
<tr>
<th>Business Need</th>
<th>Methods</th>
<th>IoT Solutions</th>
<th>Business Benefits</th>
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</table>
| **Increase Manufacturing Efficiency** | • Allow visibility across equipment for scheduling.  
• Reduce equipment downtime.  
• Automate incident-related requests.  
• Improve incident response times.  
• Reduce variability and improve yield. | • Smart equipment that collects operational data and status (run time, temperature, load, ready to use/in operation/under cleaning/under maintenance).  
• Add sensor packs to collect device data; build a back-end platform using industrial IoT platforms such as Microsoft Azure, Amazon Web Services or PTC’s ThingWorx.  
• Run analytics on the data to predict when a piece of equipment might shut down.  
• Automate incident requests triggered by integration with ticket management systems.  
• Sensors that collect metadata for analysis to identify and reduce causes of process variability and improve production yield.  
• Visibility into human and material movement across the shop floor through tracking and monitoring technologies. | • Real-time dynamic scheduling of shop-floor activities.  
• Better equipment utilization and less downtime.  
• Ability to track overall equipment effectiveness (OEE).  
• Improved productivity, efficiencies, and cycle time.  
• Increased production yield. |

Using sensor information to remotely monitor equipment allows technicians to develop self-learning predictive models and perform diagnostic services across the company’s equipment portfolio - increasing availability and reliability and ensuring minimal disruptions in the supply chain. (See Figure 3 below).

The ability to gather real-time information about equipment availability, calibration and utilization can help manufacturing teams make better decisions, optimize equipment performance, reduce machine downtime and improve resource allocation, which can lower manufacturing costs and shorten cycle times.

The true value of connected manufacturing varies among companies, since many are at different stages of automating manufacturing. (For more on this topic, read “How Digital Makes Connected Manufacturing Possible.”) The IoT provides a non-linear opportunity to scale by focusing on specific business outcomes.

The biggest challenge is connecting industrial equipment to sensors or devices to access back-end

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**Figure 2**

**Figure 3**
databases or cloud services. Many companies still operate legacy equipment that does not support standard communications protocols. Pharma companies will thus need to invest in outfitting existing equipment, or acquire new manufacturing systems to support IoT instrumentation and the digitization of manufacturing and the supply chain. This requires open automation software that is compatible with a wide range of communication protocols and ensures a seamless transition to the industrial IoT.

Real-Time Visibility Into Warehouse Operations

Warehousing is a crucial area for the pharmaceuticals industry. Most companies manage a large number of storage facilities across countries to ensure a continuous and timely supply of essential medicines in a cost-efficient manner. Keeping warehouse operations in-house is a strategic decision for most pharma companies, many of which choose to manage their warehouse processes and storage environments internally, given the nature of their products.

Nonetheless, warehousing operations is a costly business; according to a McKinsey study, it accounts for 95% of pharma logistics costs. Without real-time visibility into operations, it can be difficult to track products in the warehouse and fully utilize operators and transport equipment.

Smart warehouses can increase visibility and efficiency by relaying metrics and real-time data to warehouse managers and technicians. Sensors are placed in the storage area and on inventory items to interpret and transmit vital information (product location, inventory details) and report inconsistencies, such as misplaced products, directly to warehouse managers’ handheld devices/dashboards. Corrective measures take place in real time – significantly improving the speed, accuracy, and efficiency of the picking process.

Having real-time visibility and a 3-D view of warehouse operations with detailed, contextually relevant data at their fingertips allows warehouse managers to:

- Monitor and track the storage of sensitive medicines in controlled zones.
- Optimize warehouse floor space.
- Track inventory of finished goods.
- Identify problem areas and assign resources to deal with issues requiring human intervention.

Another area where IoT technologies can add value is the storage of temperature-sensitive products. Active and passive temperature loggers attached to refrigerators in warehouses and at other sites continuously record temperature. An IoT solution could connect these devices, compare their measurements against thermos stability tables, and prompt them to generate alerts in case of temperature variances.

Sensors can also be used to analyze inventory movement. Data pertaining to the volume and dimensions of packages transmitted from smart pallets can be captured by wireless readers, aggregated, then sent to the central Warehouse Management System (WMS) for analysis.

Figure 4 illustrates how sensor data from warehouse storage areas can be used to dispatch inventory to vacant spaces or reposition misplaced items.

Real-Time, 3-D Inventory Management

Figure 4
Track Shipments Across the Pharma Supply Chain

Pharmaceuticals packaging is critical to ensuring products quality. Companies must follow strict guidelines for determining the way a drug is transported, administered, and consumed. Smart pharma packaging can help ensure that shipments and medications are accurately tracked, and that the supply chain remains fluid, efficient and cost-effective.

When applied to packaging, the Internet of Things affords several advantages, including bi-directional communication, tracking, and status-display mechanisms. This is especially relevant in markets where counterfeit drugs regularly enter the value chain. Tracking the movement of drug inventory at every point can potentially save supply chain participants billions of dollars.

2-D bar codes, RFID tags and smart packaging labels make it possible to track each handshake in the supply chain, from manufacturing to dispensing. The result is a complete digital footprint. Electronic circuits/chips in packaging material and the use of Auto-ID with Automatic Information Data Collection (AIDC) for smart serialization can help control how substances enter healthcare environments and ensure that suitable conditions are maintained in cold chains during the transport of temperature-sensitive drugs. (See Figure 6, see next page).

### Control Cold Chain Conditions

Pharmaceuticals manufacturers increasingly deal with products such as biologics, which are highly sensitive to storage conditions. These are high-ticket drugs. Last year alone, eight of the top ten drugs (measured by highest sales) were biologics.

Moreover, the projected growth of...

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### Tracking Products in the Warehouse

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<th>Benefits</th>
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| Increase Operational Efficiency in the Warehouse | - Optimize the movement of warehouse assets. | • Sensors on product/holding items transmit information on product location, inventory and inconsistencies directly to the warehouse manager’s handheld device/dashboard.  
• The device uses sensor data to simulate a real-time, 3-D view of the warehouse. Asset movement and location are tracked using RFID tags on material-handling equipment in the warehouse.  
• Embedded sensor packs on forklifts track their location and utilization.  
• A wireless reader captures data (volume, dimensions) transmitted from pallets as they arrive. | • More efficient utilization of assets and operators.  
• Higher productivity. |
| Maintain Desired Storage Conditions | - Track storage conditions of sensitive drugs. | • Environmental sensors collect data in temperature-controlled areas of the warehouse to track drugs’ environmental conditions in real time.  
• Active and passive logger data is compared with thermo stability tables to generate alerts in the event of temperature excursions. | • Less drug expirations and degradations from temperature excursions. |
| Align Production & Demand | - Feed real-time data on inventory movement from the warehouse to production. | • Sensors collect and analyze data on shipment movements – from the warehouse, to distribution, to production planning. | • Optimized inventory and reduced stock outs.  
• Improved fulfillment. |

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Figure 5

Track Shipments Across the Pharma Supply Chain

Tracking the movement of drug inventory at every point can potentially save supply chain participants billions of dollars.
## Tracking Products at Every Point

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</tr>
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</table>
| **Ensure Product Integrity & Traceability Across the Supply Chain.** | • Bi-directional communication and product authentication at every point in the supply chain. | • 2-D bar codes, RFID tags and smart labels for packaging.  
• NFC sensors for drug and vaccines packaging.  
• Electronic circuit/chip for packaging material.  
• Packaging data transmitted throughout the transport of drugs and during drug dispensing.  
• Data collected in the central system transmitted over private or public cloud to assure traceability and inform decision making. | • Products’ digital footprints can detect counterfeiting as products move through the supply chain.  
• IoT-enabled packaging continuously tracks environmental conditions in cold chains during transport – assuring product quality and efficacy. |
| **Optimize Inventory Costs Among Supply Chain Partners.** | • Increase visibility into product movement and inventory in supply chain hubs. | • 2-D Bar codes, RFID tags and smart labels used in packaging.  
• Transmitters at warehouses capture consignment movement and report to central location.  
• Inventory and supply chain decisions leverage real-time information on product movement to ensure optimal stock levels. | • A highly efficient supply chain.  
• Assurance that product inventory aligns with demand.  
• Increased collaboration among supply chain partners; agile, cost-effective, optimized supply chains. |

Figure 6

cold-chain biopharma products will be twice that of the industry overall – expected to reach more than $361 billion worldwide in 2019.  

These products often have a larger proportion of high-value active ingredients with shorter shelf lives, and carry strict temperature requirements. Many must be maintained at temperatures lower than 77 degrees Fahrenheit; some require 35 to 46 degree Fahrenheit during cold chain transportation. Quite a few must be stored at controlled room temperature. These drugs are safe at ambient temperatures, but must be kept in temperature-controlled containers during

### Monitoring Cold Chain Conditions on Shipping Vehicles

- Embed or place temperature-sensing tags with shipments.  
- Tags continually record temperatures and environmental conditions.  
- Data is uploaded to the cloud.  
- Recordings are instantly available to the control room.

Figure 7
Digital technologies such as GPS location and condition monitoring afford real-time visibility and security during transport.

Generics make up 80 percent of today’s pharma market and competition is fierce. This underscores the importance of developing transport and logistics capabilities that heighten efficiencies and drive down costs.

Digital technologies such as GPS location and condition monitoring afford real-time visibility and security during transport. Figure 9 on page 8 illustrates how pharma manufacturers can unify the view of vehicles, drivers, and performance across locations by collecting data from vehicle telematics. This information can be captured via Global Positioning Systems (GPS), then relayed to control rooms through GPRS (General Packet Radio Service) - allowing complete visibility into product and transport conditions, and enabling control-room personnel to analyze and compare data on fleet performance from virtually anywhere. This can reduce time to market, prevent product damage and waste, and lower carrying costs.
IoT Adoption: The Challenges

To fully capitalize on the potential of the Internet of Things and enjoy the benefits throughout their value chain, pharma companies must first invest in a supportive IoT infrastructure with the capacity needed to handle heavy-duty requirements. Since security is paramount, companies must also be prepared to invest in IoT-based security solutions.

In cases that require integration with underlying applications, working with various vendors and ensuring common vocabularies and standards can be challenging. Moreover, the manufacturing floor typically houses a broad spectrum of equipment and associated software, some of which, while fine for production purposes, are no longer under warranty by vendors. Workarounds for IoT solutions can be costly.

Another hurdle pertains to the availability and suitability of manufacturing equipment to modify and validate IoT solutions. Balancing project requirements with commercial supply needs and key performance indicators (KPIs) for gauging operational efficiency can be overwhelming. The IoT solution may require validation if its purpose is to support GMP best practices. This could extend project timelines and efforts.

IoT solutions such as shop-floor visibility augment and enrich organizational capabilities. At the same time, they can present challenges when it comes to change management - a sensitive issue that must take into account people, processes, and responsibilities. Organizations need to establish and clarify business drivers and develop communication strategies for assuaging the concerns of employees and other key stakeholders to ensure a successful transition.

Pharma companies must view their IoT investments from the standpoint of fostering innovation, heightening efficiencies, improving processes and operational performance, and adding more value for the business, its suppliers, and its customers. By adhering to IoT best practices and learning from others that have successfully implemented IoT platforms and solutions, pharmaceuticals companies can be better prepared to face the growing demands of today’s hyper-competitive, hyper-connected global economy. (See Figure 10, next page).

Recommendations

Investing in transformational technologies has its own set of challenges. Following are our recommendations and best practices for implementing and benefiting from the Internet of Things.

- Think big, start small, fail fast, scale quickly. This is critical; IoT investments in sensors and network capacity for data management can be huge, and it can take time to realize the returns.
- Choose the most compelling application/solution with the highest potential business value for the first implementation.
- Bring key decision makers on board; define success criteria early in the project lifecycle.
Perform pilots; establish business benefits through a proof-of-concept (PoC).

Employ agile methodologies for proof-of-concept implementations to realize tangible benefits from greater user interactions, with the flexibility to customize solutions in a structured way.

Augment your team with a suitable partner that offers a dedicated infrastructure and facilities, plus expert industry and technology teams focused on integrating various skill sets to effect digital transformation across the implementation lifecycle.

Looking Ahead

In virtually every industry, advances in digital technologies are redefining how enterprises conduct business – internally, with external stakeholders, and in the marketplace. The ubiquity of mobile computing, the dominance of social media, and a growing portfolio of smart products and capabilities provide real-time, actionable intelligence at a pace that continues to increase.

Enterprises must constantly innovate and utilize emerging technologies to remain relevant, competitive, and profitable.

For pharmaceuticals companies, the Internet of Things extends visibility in virtually every area of the business – from development, to manufacturing, transport, distribution, dispensing and consumption. Real-time information, when coupled with advanced analytics engines, can become the basis for making faster, more accurate decisions; heightening efficiencies, verifying product quality, and assuring regulatory compliance.

As the IoT becomes mainstream, it presents an opportunity to digitize business processes and enable collaboration and monitoring beyond what was possible before now. The risk of doing nothing must be evaluated against changing customer and regulatory expectations and market dynamics. The time is right for pharmaceuticals companies to accelerate their implementation and utilization of IoT platforms and solutions.
Footnotes

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