SAFETY & QUALITY CONTROL

PHARMACEUTICAL MANUFACTURING:
Improving Safety, Compliance and Quality Control With Mobile Technologies

Executive Summary

The Drug Supply Chain Security Act (DSCSA) signed into law in 2013 outlines critical steps to build an electronic, interoperable system to identify and trace certain prescription drugs as they are distributed in the United States.[1] Pharmaceutical manufacturers, repackagers, wholesale distributors, dispensers and other trading partners are all impacted by this legislation requiring greater safety and quality control measures. The Food and Drug Administration (FDA) will administer the DSCSA, and new regulations will require the tracking of pharmaceuticals along every production step, from sub-compounds to production to final delivery on pharmacy shelves. For example, by 2023, manufacturers and repackagers must put a unique product identifier on certain prescription drug packages. They, along with wholesale drug distributors and many dispensers (such as pharmacies), must provide product tracing information regarding who handled a drug each time it is sold in the U.S. market.[2]

These requirements are just a few of the new mandates placed on the pharmaceutical industry along the supply chain. Since legacy systems must be modernized to comply with these new requirements, now is an excellent opportunity for pharmaceutical manufacturers to consider data automation technology solutions to ease compliance.

Manufacturers will undoubtedly experience challenges in implementing these new mobile technologies. However, considering the significant business and regulatory benefits which data automation will offer across the entire supply chain, the pharmaceutical industry cannot afford to simply remain idle.

A Framework for
Track & Trace Compliance

The year 2015 marked the first compliance date for lot-level tracing, though the FDA has extended the compliance policy to 2016. According to the FDA's latest milestones,[3] manufacturers should by now have:

- Become familiar with the law themselves.

- Worked with trading partners to ensure they, too, are familiar with DSCSA requirements.

- Confirmed the status of authorized trading partners through respective state authorities or the FDA's drug establishment registration database.

- Provided product tracing information.

- Learned how to handle suspect or illegitimate product.

Tracking requirements will continue to increase until 2023 when the full requirements will be rolled out. These full requirements include a national pharmaceutical track-and-trace system, six-year record maintenance and trading partner transaction information for consumers. In full, the tracking requirements will impact the entire pharmaceutical supply chain.

These new regulations should enable greater safety and quality control, improved brand perception and a better a consumer experience, but they require pharmaceutical companies to address and alter their standard operating procedures and workflow management practices.

Rather than wait until 2023, pharmaceutical manufacturers need to start planning and considering their technology solutions today.

While newly acquired records can be kept physically or electronically, transitioning to electronic data collection while accommodating the new DSCSA requirements provides obvious synergies. This digital transformation and integration—especially through mobile technologies—represents a generational shift, a new phase in pharmaceutical manufacturing progress. Many industry experts are referring to these collective advancements as the Fourth Industrial Revolution or Industry 4.0.[5]

As anticipated with such a fundamental shift in manufacturing technology, some companies are failing to keep pace with the changes. Hundreds of thousands of U.S. warehouses still have no automated data technology of any kind. Even top 100 retailers are struggling to implement the technology necessary to meet the new FDA regulations. Those companies in the pharmaceutical supply chain that do integrate mobile and automated data capture technologies, on the other hand, will experience enhanced operational efficiencies and ensure compliance with the new regulations through digital automation.
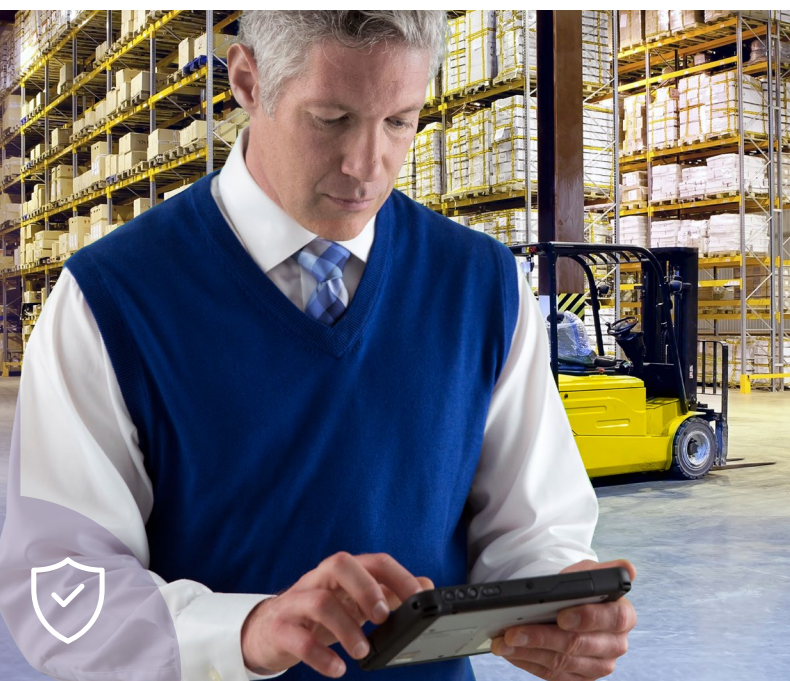
The shift to mobility represents a new industrial manufacturing revolution—one manufacturers must begin planning for today.

The Reach and Impact of Automation and Mobile Technologies on Pharmaceutical Manufacturing

A critical component to achieve DSCSA compliance is the integration of rugged and reliable enterprise-grade mobile devices with automatic identification and data capture (AIDC) systems, such as barcode or RFID technology. This hardware and software solution enables increased insight into the supply chain through all stages of drug production—from raw materials through to pharmacy shelves.

⌄ Raw Materials

To ensure accurate tracking of the origins of manufactured drugs, data automation and mobile technologies belong at the beginning of the pharmaceutical supply chain. These technologies aid the inventory management of raw materials from the source, helping to maintain accurate product supply information and prevent counterfeit drugs. In these environments, workers need bright devices that are visible in a variety of working conditions, such as daylight or inside brightly lit buildings. They also need network connectivity, locking controls, long battery life and the ability to physically wash off dirt, dust and grime. Devices in these settings also need security measures to prevent accidental or intentional harm. By deploying fully rugged devices based on enterprise versions of the Android or Windows operating systems, workers handling raw materials can gather DSCSA compliant data with minimal training.

⌄ Production Line

Automation and mobile technologies can improve and expedite quality control and inspection on the production line. This environment, however, requires devices with high reliability to maintain production uptime. Additionally, devices need to be customized for line workers, operation managers and other shop floor employees. In this environment, fully rugged tablets and handhelds, especially those with high reliability and long battery life, can improve uptime. As RFID and barcodes move with products from the production line to the warehouse, automation and mobile technologies help monitor and track the stored finished product, as well as provide quality controls.

⌄ Shipping and Receiving

In shipping and receiving or distribution centers, workers need to effectively access critical inventory and location information in real time. From receiving and moving, to ordering and picking, fully rugged handheld devices able to withstand drops and with built-in angled rear barcode readers ensure the smooth running of warehouse operations. On and off forklifts, these mobile technologies also provide built-in checks to ensure the correct lots have been received at the right locations, preventing drugs from reaching unintended destinations.

Using mobile technologies for track & trace boosts efficiency for the entire pharmaceutical operation.

⌄ At the Pharmacy

It is essential for pharmacies to respond quickly to recall notices. This process includes identifying and removing affected stock from shelves, comparing remaining stock with what has been sold and notifying potentially affected consumers. With handheld devices, pharmacists can rapidly scan existing stock and learn how many affected drugs are in the hands of consumers. This real-time data reduces recall response time significantly, even if affected drugs are mixed with non-affected items.

While the improved operational efficiency at any junction of the supply chain would provide worthwhile benefits, by adding these benefits at *every* junction of the supply chain, automation and mobile technologies provide significantly increased efficiencies.

Many manufacturing businesses are taking note of these advantages. An International Data Corporation (IDC) study forecasts that spending on mobile technologies will reach $1.2 trillion by 2019, with discrete and process manufacturing among the industries expected to spend the most.

Further, as more pharmaceutical companies explore adopting Internet of Things (IoT) technologies, mobility and automation will be key in harnessing big data collected by connected devices. Customized applications on handheld mobile devices can display IoT data collected along the supply chain in the form of useful, real-time reports all employees can use. Operations managers can understand, at a glance, whether any issues require attention. This insight dramatically improves efficiency for pharmaceutical manufacturing operations while reducing downtime.

Challenges of Implementing Mobile Technologies and Automation Along the Pharmaceutical Supply Chain

While the regulatory and business benefits to implementing data automation for the pharmaceutical industry are abundant, mobile technology implementation can result in some challenges.

1. Cost: The costs associated with compliance of new regulations must be considered. Rather than rolling these out on a timeline that best suits the company, these companies must meet the FDA's enforced timeline. Costs involved with compliance include the initial investment in new technologies, followed by integrating those technologies with existing legacy equipment. Re-evaluating and redesigning workflows and employee training can also be resource-intensive. The full costs of implementation can be quite sizeable. However, companies should asses the overall ROI associated with the improved operational efficiencies and business functionality. Unfortunately, with the pending FDA compliance requirements and milestones, these expenses are not optional costs.

2. Time and complexity of the transition: Depending on how significant a specific company's technology upgrades are, transitions to new technology can expend significant IT resources and may even require additional temporary IT investments. Transition times will also vary depending on how well existing processes are documented (and how easily teams can migrate to new processes). Companies should take stock of any existing infrastructure new technologies will have to integrate or connect with, and implement a phased approach to their mobile technology deployment plans.

3. Employee training: Many workers are accustomed to paper-based systems or, at best, keyboard-based devices and PCs connecting to old mainframe technologies. Traceability requirements may oblige a new way of thinking for many experienced employees. These challenges are multiplied due to the struggle many manufacturing companies have recruiting millennial workers. A Manufacturing Institute and Deloitte study anticipates that there will be 2 million unfulfilled manufacturing jobs by 2020. This, combined with Nielson's reported 77 million millennials entering the workforce, means companies need to attract younger workers and enable more efficient processes to make up for the gap. Regardless if the worker is a baby boomer or millennial, initial user training is critical as users of all ages adjust to new ways of doing their jobs. Prioritizing this training keeps the natural slowing of productivity to a minimum during times of technology transition. What many organizations forget, however, is that ongoing training is also necessary as technology is customized and updated throughout its lifecycle.

Benefits of Adopting Mobile and Data Automation Technologies for the Pharmaceutical Industry

While the cost to integrate new technologies in pharmaceutical companies can be daunting, the benefits are undeniably significant. The industry is currently at a tipping point in recognizing those benefits. A recent survey conducted by Manpower Group Manufacturing Workforce among manufacturing managers in North America finds that 49% believe "manufacturing will soon be an industry where 'big data' is used to create competitive advantage." Much of that big data will be gathered from RFID and barcode solutions. But pharmaceutical manufacturers are poised to benefit from automation and mobilization in other ways, as well.

Real-time data via mobile technologies will significantly reduce preparation time for FDA audits and inspections.

⌄ Assisting with Compliance

Perhaps the most pressing benefit for most pharmaceutical companies is compliance with new DSCSA regulations. These technologies will prepare companies for FDA inspections and audits. Automated data collected in real time through mobile technologies will significantly reduce preparation times and give companies the tools to ensure ongoing compliance.

When using physical documentation, even the best available data is almost instantly outdated. Automation and mobile technologies facilitate real-time data, which provides not only better decision making, but more frequent interventions to ensure quality and efficiency.

⌄ Improving Productivity & Security

Through automated data collection on mobile devices, operational efficiency will increase. Automated data collection reduces human error, eliminates transcription mistakes, provides time stamps and increases the granularity of the data to identify better indicators and more detailed information.

Improving technology also means access to more robustly layered security options. Automated data collection easily facilitates stricter control of data to help prevent fraud and unauthorized access to the network. In a layered security environment, devices can be locked down, allowing companies to protect themselves from internal users and external threats who wish to access and use their data maliciously.

These approaches to automation technology provide a level of control and pharmaceutical supply chain visibility that was previously considered impossible. All supply chain data can be monitored, from remote production locations all the way to delivery in a pharmacy. Providing big data through mobile and automation technologies allows for more agility, responsiveness and efficiency. It also enables more security; for example, remote access to data supplied by IoT devices can be restricted for devices outside a facility, protecting data on lost or stolen devices.

⌄ Shifting Demographics

As younger employees enter the workforce, they bring with them a preference for more modern technologies. This penchant means that younger employees' familiarity with these devices will improve training time for software applications on handhelds, tablets and other mobile technologies over software presented on legacy hardware.

Younger workers can also help lower the barrier to the adoption of new technologies company-wide. As manufacturing companies struggle to recruit younger employees, working with familiar technology offers an easy access point to bring millennials into the company culture. In fact, a Microsoft survey reports that 93% of millennials say working for a company with updated technology solutions is important. Additionally, 48% say the technology used by a company is very important in their decision on where to work.[4]

Evaluating Mobile Technology and Data Automation Solutions

Given the strong cost-to-benefit ratio of adopting automation and mobile technologies in the pharmaceutical sector, many companies will be looking at how to identify the best rugged computer, tablet or handheld solution for their environment. Companies should consider the following criteria when making their selection:

> **Rugged devices enable secure mobile data gathering across the entire supply chain.**

1. Flexible Form Factors: One important factor that pharmaceutical companies should consider is the flexibility of the mobile solution. It's critical that mobile devices work seamlessly across all areas and meet the varied needs of pharmaceutical manufacturing requirements—from shipping and receiving docks, to labs and everywhere in between. Devices will need screen technology that can support the more rugged warehouse operations to the stringent requirements of a clean room, as they will need to be washed down or sanitized each day. Operation managers will want a device that is just as easy to use in a back office as on a plant floor.

A forklift driver, on the other hand, will want a device that has the ability to be easily docked and undocked, as well as barcode and/or RFID scanning functionality. Finally, all workers need a device with reliable network connectivity so they can stay connected no matter where they are in their facility as they go about their day.

2. Security Measures: Another factor that pharmaceutical manufacturing companies should consider in choosing a mobile and automation technology solution is the degree of security controls. Ideal devices will include security features built directly into the device. These devices must have security that well exceeds that found on typical consumer devices, including support for company data encryption. Other important features should include network security, security at the software level and even security on the hardware itself. These devices should further restrict individual users access to those specific applications required for their position, to avoid distraction (or accidental damage to the device).

3. Software Considerations: Another factor in choosing a mobile technology solution is the ability to support multiple operating systems. An ideal solution would include the ability to bridge the gap between the software needed on the mobile front and the full PC operating experience. For example, the most recent version of Windows 10 Enterprise could be installed onto custom-built mobile devices. Enterprise versions of the Android operating system are also available. Both software options deliver the features described above.

4. Reliability: Finally, mobile devices should help minimize downtime. When a device fails on the production line or in the warehouse, productivity and profits can be compromised. Investigate mobile device failure rates as part of the selection process to ensure the highest levels of productivity when in use.

Panasonic Mobile and Data Automation Technology Solutions

Panasonic delivers enterprise-grade mobile solutions to meet these technology needs and unlock the many benefits of data automation in the pharmaceutical manufacturing industry.

By creating a customized roadmap to integrate new technology solutions into companies across the pharmaceutical supply chain, Panasonic can help develop a deployment plan for new technologies and offer services to its customers that will help them reduce the time, complexity and costs of transitioning to the new technologies. These services include consultation, staging, kitting, deployment, forklift installation and even training to help reduce the long-term burden on IT services.

Panasonic Toughbook computers, tablets and handheld barcode scanners are purpose-built to meet the strict guidelines and requirements of the pharmaceutical industry. These enterprise-grade devices are designed for use from the field to a clean room. For long shifts on the warehouse floor, devices can be equipped with extended-life batteries to deliver exceptionally long operating times.

A wide range of device options are available, including screen sizes from 4.7" to 20", varied durability and form factor options, all providing versatility to a specific company's needs. Devices can also be configured for extreme screen visibility and gloved operation functionality, so employees in cold chain environments can easily and seamlessly operate them.

As a core manufacturer, Panasonic sets the industry standard for computer reliability with a less than 2% failure rate. Toughbook devices remain functional and connected in the harshest environments, such as in extreme inclement weather, sterile conditions and around heavy machinery. Loaded with enterprise versions of Windows 10 or the Android operating system, security never compromises ease-of-use.

As pharmaceutical companies begin to look for ways to come into compliance with impending DSCSA regulations and seek out additional operational efficiencies, they will find the mobile solution they need in Panasonic.

Pharmaceutical manufacturers seeking to improve safety, compliance and quality control through mobile technologies should contact Panasonic today.

us.panasonic.com/Toughbook
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Sources

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