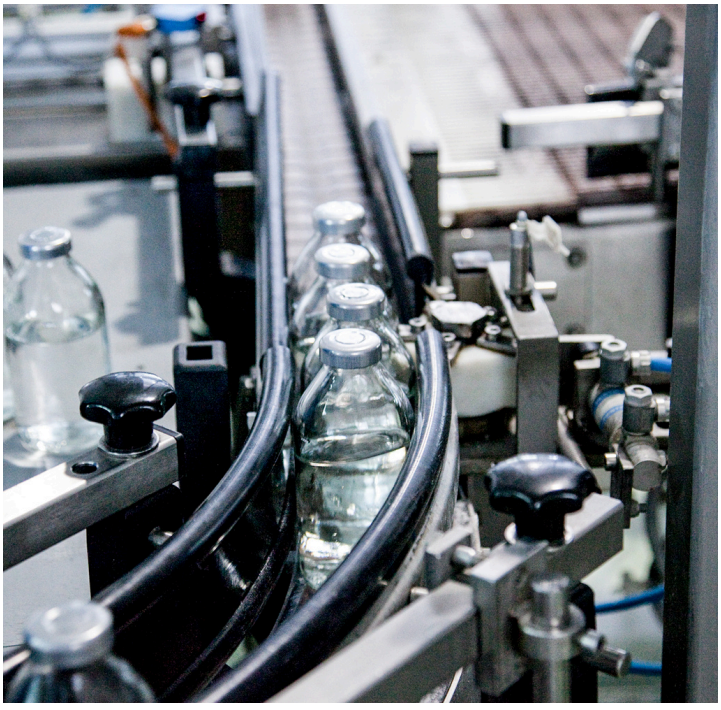
Does Your WMS Have the Necessary Functionality to Ensure Regulatory Compliance?

From pharmaceuticals and medical devices to food and beverage, 3PLs and warehouse operators today rely on technology more than ever before to help ensure compliance with FDA regulations. Regulatory compliance not only leads to good relations with regulatory agencies and a positive company reputation but also to data integrity, quality products, efficient warehouse operations, and customer/patient safety.

Over the years, companies that handle and store regulated goods have transitioned from manual compliance methods to technology. Today, regulatory agencies must keep pace in their training and acclimation efforts not only to warehouse management systems but also to newer technologies including web-based computer applications, blockchain and distributed ledger technology (DTL), biometrics, encryption, and much more. WMS remains one of the most used tools in warehouse operations in helping to ensure regulatory compliance.



Checklist of WMS Capabilities That Can Help Keep Your Warehouse Operation in Regulatory Compliance

Here is a checklist of WMS capabilities that can help keep you and your clients in compliance with various regulations such as FDA 21 CFR Part 11, the Food Safety Modernization Act (FSMA), and the Drug Supply Chain Security Act (DSCSA). Some items such as environmental monitoring may be accomplished via integrations to other systems or tools.

Real Time Visibility

- Provides tracking of storage conditions (i.e. temperature and humidity) for sensitive goods and other environmental monitoring as required.

Traceability/Lot Tracking and Chain of Custody

- Ensures tracking of inventory movements by lot or serial numbers for food and pharmaceuticals
- Assigns lot numbers to incoming goods
- Traces the movement of product both upstream from suppliers and downstream to customers
- Provides complete visibility of the journey of products from receipt to shipment
- Captures and stores data on the origin, handling and destination of products
- Provides on demand production of traceability reports
- Provides end-to-end visibility through integration with supply chain systems

Managing Batches, Expiration and Shelf-Life

- Automatically tracks and manages expiration dates to prevent that expired goods are not distributed
  - Provides multiple allocation strategies to help ensure
    - First-in-first-out (FIFO)
    - First-expired-first-out (FEFO)

Product Recall Management

- Enables rapid identification of affected products in case a product recall must be executed. Involves ability to track products at the lot, batch, or serial number. Provides traceability of goods to manufacturing dates, expiration dates, or supplier information. System identifies where impacted products are located within the warehouse or across multiple warehouses. Provides information on inventory status, for example, shipped, etc. System notifies stakeholders whenever recall is initiated. The WMS tags or assigns a quarantine status to products that are impacted so that they are not shipped out. For impacted products to be returned, the WMS provides automated notifications based on regulatory requirements or internal quality checks and designates specific locations within the warehouse for isolating products.
- Using the WMS capabilities, the warehouse operator should be able to facilitate the return of recalled products including coordinating this with logistics providers and carriers to enable efficient product returns.

Labeling

- Adheres to industry-specific labeling requirements so as to help ensure compliance with labeling standards
  - GS1 barcodes for global trade

Documentation Management

- Stores and properly manages documents including:
  - Bills of lading
  - Certificates of Analysis (COA)
- In addition, the WMS should be able to manage and store images and video as well as other documentation for safekeeping and easy retrieval.

Documentation and Audit Trails

- **Comprehensive Immutable Audit Trail:** provides a comprehensive record of all activity in the warehouse by individual user. Ability to track lots through all warehouse processes including receiving, storage, picking, shipping).
- Provides that all records are properly timestamped to support regulatory investigations.

Quality Control

- **Inspection Workflows:** automated quality inspections to ensure compliance with regulatory quality standards during:
  - Receiving
  - Shipping
  - Storage
- Identifies and quarantines products as non-compliant inventory or defective as part of proper non-conformance management efforts.

Retainage and Archiving of Records

- **Long-Term Data Storage:** helps meet regulatory requirements for maintenance of records including:
  - FDA 21 CFR Part 11 for electronic records and signatures.
- **Searchable Archives**: needed to provide easy retrieval of historical data for inspections and audits.

Compliance Reporting

- **Regulatory Reporting:** generates the required compliance reports for government agencies including the FDA, USDA and customs.
- **Configurable Reporting:** enables warehouse operators to facilitate the creation of reports that can be tailored to each specific industry or regional requirement.

E-signatures and Approvals

- Ensures that processes requiring authorization or approval are recorded using electronic signatures to meet regulatory standards.

Compliance Reporting

- **Role-Based Access Control:** ensures that access to sensitive data is restricted to authorized personnel. This is to help ensure compliance with FDA and data protection laws including CCPA and GDPR.
- **Data Validation:** used to help ensure the accuracy of data entry as well as to prevent errors which could lead to breaches in compliance.
- Ensures that records cannot be tampered with or altered as required to meet regulatory standards such as FDA 21 CFR Part 11.

Important Tools for Ensuring Regulatory Compliance

User-Defined Fields (UDFs)

Using a WMS that includes the ability to use UDFs helps ensure that warehouses can capture and track data that is unique to their regulatory requirements. As an example, UDFs can be used to track batch certifications, inspection results or specific regulatory codes. As regulations evolve, UDFs provide the needed flexibility to immediately adapt or add fields without time-consuming, costly software changes.

Here are some of the most frequent use cases for WMS user defined fields in the instance of regulatory compliance:

- **Audit tracking:** Storing government identification numbers for tax or customs purposes as this data is often required in audits.
- **Product-Level Compliance Data:** UDFs may be used for fields including allergen presence, organic certifications, or hazardous material classifications.
- **Inspection Logs:** Detailed results from quality inspections can be captured and tied directly to inventory records using UDFs.

Automated Workflows

Using workflows helps warehouse operators to automate compliance processes, ensuring that processes are properly followed. Critical processes are then standardized to ensure that human errors are reduced, and consistency is ensured. This also serves to enforce operational discipline, ensuring that all steps are completed before moving to the next stage of each process.

Alerts and Notifications can be automated to help ensure that any compliance-related issues are addressed promptly.

Get the Best Results by Using UDFs and Workflow Together

	UDFs	Workflow
Tailored Compliance Monitoring	Store the data	Act on data, triggering compliance-related tasks for systematic completion
Audit-Ready Systems	Ensure data granularity and accuracy	Ensure all necessary actions are traceable and documented in the system
Regulatory Flexibility, Scalability for Growing Businesses, New/Evolving Products	Facilitates ability to capture unique aspects of regulatory compliance or data	Make regulatory processes repeatable and minimize risk of deviation from required procedures, improving operational governance

Conclusion

Over the years as regulations have become increasingly complicated, warehouse operators have begun to embrace the use of technology to help ensure regulatory compliance of the goods they handle and store. Using warehouse management systems is now a common practice, but not all WMS have the same capabilities. When purchasing new warehouse management software, it is imperative to ensure that the system purchased can provide the needed functionality to make regulatory compliance efforts in the warehouse less cumbersome and as accurate and automated as possible.

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Engineered for Easy™

Get in touch.

marketing@datexcorp.com

https://www.datexcorp.com