



TECHNICAL BRIEF



Warehouse Management Technology And 21 CFR Part 11



" . . . achieving compliance involves implementing a collection of administrative, procedural and technical controls."

The FDA does not formally review, approve, or disapprove products or services that enable people to comply with FDA regulations. FDA 21 CFR Part 11 is a regulation with evolving compliance guidelines that can differ for various manufacturers and distributors of pharmaceuticals, cosmetics, and medical devices. As such, Irista is reluctant to represent our software as "Part 11 Compliant". The term is a misnomer because those who are subject to Part 11 are responsible for compliance with the rule and because achieving compliance involves implementing a collection of administrative, procedural, and technical controls. Irista feels that where the technical features of our software are required for 21 CFR Part 11, we would map those features to particular 21 CFR Part 11 controls and let prospective customers determine for themselves the potential suitability of the software in their own circumstances.

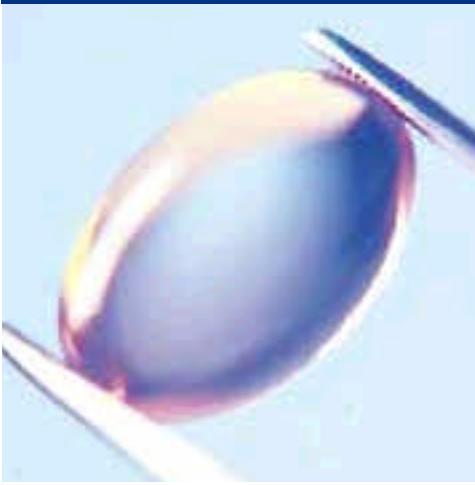
The design and deployment methodology used by Irista provides clients with the ability to easily qualify and obtain compliance with FDA's 21 CFR Part 11; Electronic Records; Electronic Signatures Validation. Irista's base functionality addresses key concerns in implementing a computerized system utilizing electronic records and electronic signatures. Controls in IristaWarehouse include user authentication; system access, controls, and security; audit trails; record retention, systems validation.

User Authentication

The application level security system provides both program level and data level security. The system controls access to the application by ensuring valid user ID's and passwords, the authority to execute IristaWare functions, and the authority to access the database. Data security is maintained by controlling access to the application's data and objects. The system ensures that users are allowed to execute only the actions that have not been restricted for them. As a closed system, IristaWarehouse limits information and system access to authorized individuals thereby ensuring authenticity, integrity, and confidentiality of electronic records. The system provides the security that prevents users from repudiating a transactional process as not genuine.

System Access and Controls, and Security

User attributes control access to the system as well as access to specific dialogs/objects with the client applications. They identify the types of computer hardware the user may have access to and point to work details which control the types of tasks a user will be able to perform, and in which order. A user's area of responsibility is also assigned to specific zones, plants, and/or inventory ownership groupings through these attributes.



" Interpretation of 21 CFR 11 is continuing to change. As such companies need to select systems with compliant enabling features from a supplier who will support the requirements as they evolve."

Dan Mahoney, Director
Irista Business Development
WMS Solutions

Audit Trails

The system maintains an audit trail of activities performed and crosschecked against user id. The applications maintain an archive database with the same schema as the production database. An archiving utility within the application moves old operational data from the production to archive database after a user configurable period of time. The archive process is performed on related groups of data like transactions, order documents, reference data, etc. to ensure production and archive data integrity. All transaction data are secure and cannot obscure preceding data with current changes. The system can provide the ability to generate accurate and complete copies of records in both human readable and electronic form, which would be suitable for review by the FDA.

Record Retention

Transaction records can reside in the production database or in a data warehouse. Access to these records is restricted to appropriate personnel with the proper security clearance. Modifications, additions, or deletions are tightly controlled and audited by user and group profiles and security permissions.

Systems Validation

Irista software development methodologies include validating the system to ensure the accuracy, reliability, and consistent intended performance of its applications. Regression analysis is used to test portions of the system that were unchanged from a previous release but are susceptible to performance/reliability losses that the changes can cause. Additional components of Irista's software development life cycle include system documentation, verification, testing, and field format data audit checks.

iristaWarehouse provides operational validation through lot tracking, expiration date tracking, and quality control capabilities. In addition, the system permits you to place multiple holds on product or lot simultaneously using one or many user defined hold classifications. The system supports the ability to pick specific lots; FIFO, LIFO, and FEFO configurability; and quality control testing.

Moving Forward

While most of the system and functional aspects of iristaWare products lend themselves to Part 11 compliance, there will certainly be a need for enhancements to meet specific project compliance requests. As interpretation is continuing to change, it is important to consider partnering with a supplier who has the capabilities to develop products and services that will enable you to achieve full compliance with governmental regulations both now and in the future. We are prepared to work closely with you in developing a plan that will achieve full compliance with 21 CFR Part 11.



" . . . the FDA does not validate software products, but software suppliers can assist you in compliance."

Bill Friend
Roud Engineering

About Irista

Irista, Inc. an HK Systems company, has a proud history of delivering unique logistics solutions that enable the efficient and accurate flow of raw materials and finished goods through the production, distribution and delivery process for manufacturers and their 3PL partners. Working in concert, Irista's warehouse and transportation management applications optimally direct logistics activities based upon the real-time conditions, constraints and priorities of an enterprise's logistics assets. By leveraging Irista's extensive industry experience, proven methodologies and advanced logistics technologies, organizations continually realize an increase in asset utilization, accuracy, quality and compliance, while lowering overall production and distribution costs.

For more information regarding Irista, call 1-866-4IRISTA or visit our website at www.irista.com