

Success Story



Pharmaceutical Inventory Tracking and 21 CFR Part 11 Compliance



Client Profile

Ironwood Pharmaceuticals (NASDAQ: IRWD) is an entrepreneurial pharmaceutical company dedicated to the art and science of great drugmaking.

Linaclotide, Ironwood's first in class compound, is being evaluated in a confirmatory Phase 3 program for the treatment of irritable bowel syndrome with constipation (IBS-C) and chronic constipation. Ironwood also has a growing pipeline of additional drug candidates in earlier stages of development.

Ironwood is located in Cambridge, Mass.

The Challenge

Challenge #1: Tracking inventory across multiple locations.

Ironwood tracks a number of compounds at its own facilities and at several contract manufacturing locations around the world. Inventory balances across each facility and through many different study sites were being main-

“Moving away from spreadsheets and paper documents was the best decision we ever made. With Slingshot, everything is much more efficient.”

– Kevin Durfee, Senior Director of Information Technology, Ironwood Pharmaceuticals

tained manually using spreadsheets and paper documents. “Lot traceability is critical in our industry,” says Kevin Durfee, Senior Director of Information Technology at Ironwood. “We need to be able to track lots, lot attributes and movement history through the lot lifecycle.”

In addition to their challenges with inventory balances, Ironwood also sought to maintain and advance its Good Manufacturing Practices and the certificates of analysis that support this and other predicate rules, by gaining full control of the quality, purity, location, custody and genealogy of each lot they manufactured.

The team at Ironwood recognized the inefficiency of existing processes and their inherent vulnerability to human error.

Challenge #2: Tracking small quantities of valuable inventory.

It is not uncommon for unit costs of the compounds that Ironwood works with to exceed six figures. Misplacing even a tiny amount of such compounds would be a costly mistake. Ironwood's inventory control and material handling processes were paper and spreadsheet-based, and therefore, more prone to error and inefficiencies.

"When a small amount of your inventory has such a large value, it's important to know exactly where it is at all times," says Durfee.

Challenge #3: Electronic versus hard copy signatures.

Ironwood also sought compliance with the U.S. Food and Drug Administration (FDA) regulation Title 21 Code of Federal Regulations Part 11. 21 CFR Part 11 calls for tight controls on electronic records and electronic signature approvals for all FDA program areas.

The Solution

A New Procedural Model

A new procedural model was required to effectively track inventory balances of compounds at Ironwood labs, contract manufacturing locations and study sites.

Internally, Ironwood program managers and study personnel request material

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– Kevin Durfee, Ironwood

and confirm its shipment and delivery. The chemistry manufacturing and control group is responsible for inventory management and recording inventory movements between contract manufacturing organization locations, Ironwood's own labs, and various third party study sites.

Ironwood's Quality Assurance department is responsible for the accuracy of lot attributes as well as the release or rejection of lots, with supporting Certificates of Analysis documents from Ironwood labs and contract manufacturing organizations.

Slingshot Software Systems

Slingshot systems automated Ironwood's existing processes to more efficiently use the data captured for reporting purposes and to provide real-time integration capabilities far beyond what could be generated using the old paper-based approach.

- Slingshot's Inventory Management application tracks inventory balances and lot information at Ironwood, its

external contract manufacturing organization locations and third party study sites.

- Slingshot's Procurement application is part of the process used to record and execute requests to issue, return or transfer compounds during the manufacturing process.

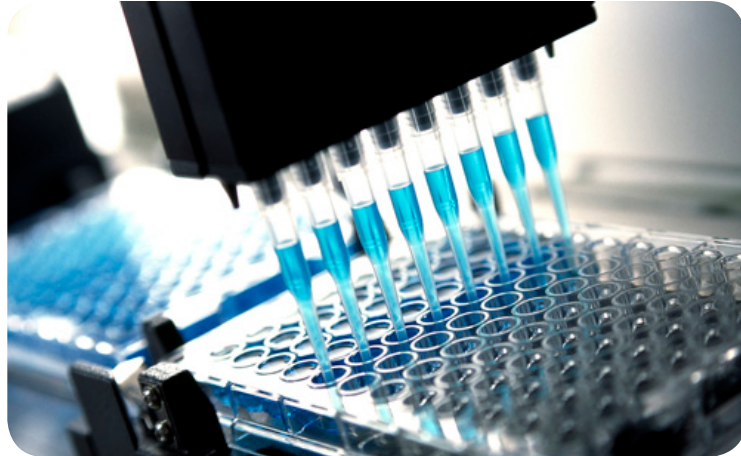
Compliance With Title 21 CFR Part 11

Slingshot Software supports regulatory compliance by implementing the necessary controls to allow its system to be validated consistent with 21 CFR Part 11 requirements. While 21 CFR Part 11 does not mandate that companies use electronic signatures, Ironwood has chosen this path because it will provide maximum efficiency and auditability in all of their manufacturing processes.

Project Objectives

The objectives of the project were to ensure that inventory balances could be maintained accurately and that a comprehensive record of lot genealogy, confirmed by each signed Certificate of Analysis, lot attributes, and material movement was permanently recorded. Specific objectives of the material inventory tracking implementation included:

- Reduced operating costs
- Complete traceability of lot attributes and movement history (chain of custody)
- Provision of information to support



regulatory filings

- Increased information sharing between departments and offices within Ironwood
- Activation of required actions at appropriate times (i.e.: quality control and re-testing)
- Improved efficiency in filling inventory requests (including the time to complete shipping and regulatory documentation for material transfers and the audit of inventory balances)
- Elimination of the potential for lost material

The Results

"Slingshot's Inventory Management module has taken Ironwood's materials management function to the next level. It has been a major step forward for us," says Durfee. The Slingshot implementation offers Ironwood the following advanced operational controls and the following benefits:

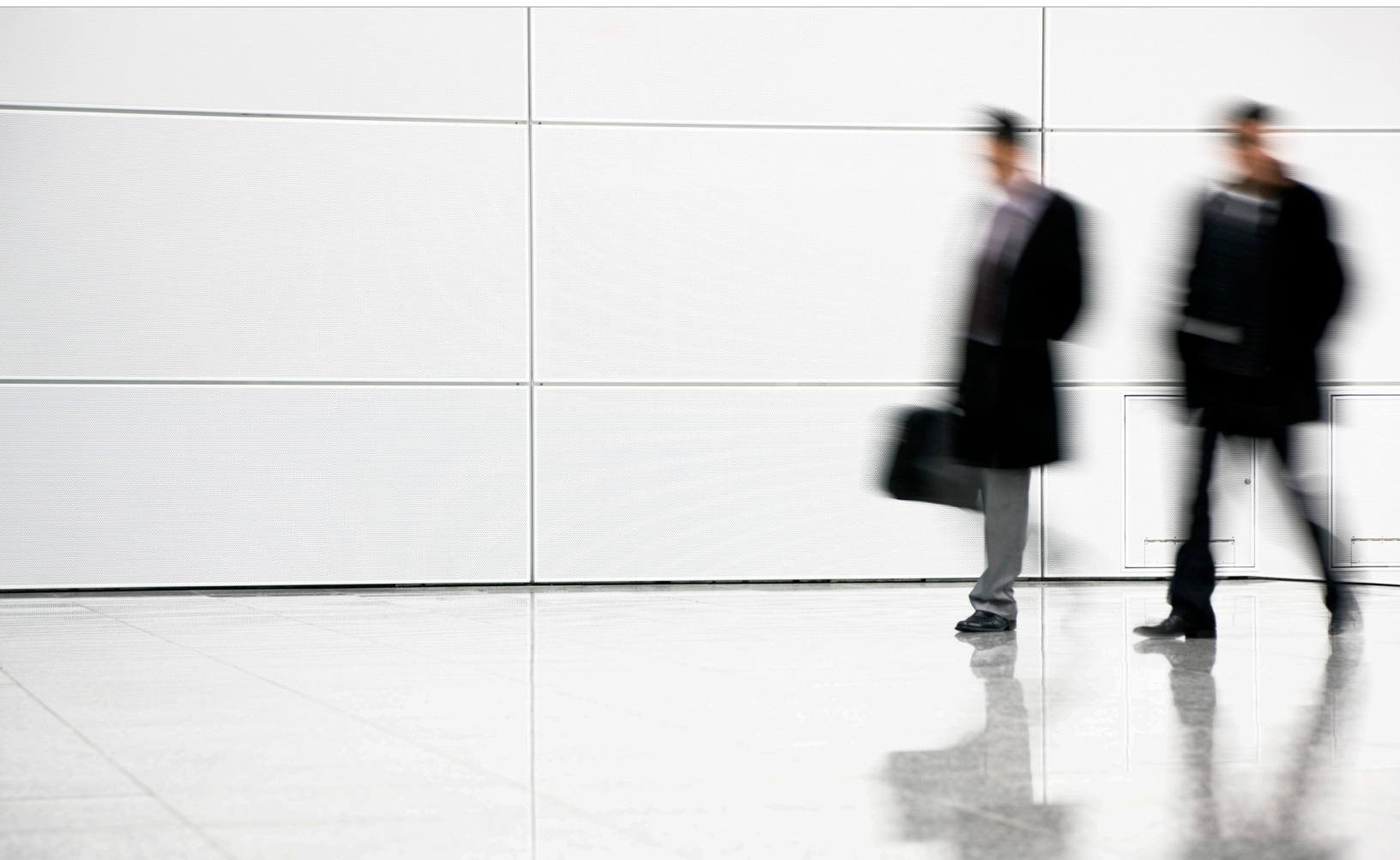
- **Lot Control:** Scrutiny of each Lot manufactured will be available to all participants in the process. Each Certificate of Analysis and key quality attributes are provided for in the new system.
- **Federal Agency Compliance:** Because they are a pharmaceutical manufacturer, the external controls and scrutiny placed on Ironwood's operations are stringent. Successful trials will bring increased focus from the FDA and other agencies to ensure all manufacturing and quality control processes are in order. With Slingshot systems in place, Ironwood can demonstrate more control over its materials management processes.
- **Electronic Approvals:** The application of electronic approvals to transactions and material movement replaces paper-based documentary approvals in the new system and will meet the same high level of audit scrutiny as the old paper-based system.



- **Operational Efficiency:** Slingshot's web-based solution enables communication across departments, offices and physical locations at a level previously unavailable to Ironwood. Efficiencies gained, as well as reduced costs by avoiding human error and material loss, will help Ironwood achieve their growth and profit objectives.
- **Operational Scalability:** After deploying Slingshot's applications, Ironwood will have the capacity to meet the increase in demand that will follow in the wake of successful trials.

“ In our business, mishandled materials could invalidate a study. Slingshot's system ensures this cannot happen. We're much more confident in our inventory controls now that we have Slingshot tracking inventory movement. ”

– Kevin Durfee, Senior Director of IT, Ironwood Pharmaceuticals



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