Carry the approved process through to the product and its evidence.

An approved specification must reach the equipment, govern the work, and remain connected to the products made under it. IntelliTrack combines production checks with product history, approvals, and audit records so your staff can investigate a concern and explain how the process was controlled.

Gaps between approval, execution, and product history create avoidable uncertainty.

Planning and business systems describe the intended work. Quality still needs evidence of what happened at the station: which revision ran, which material was consumed, how results were evaluated, and who authorized an exception. IntelliTrack connects those production events with controlled approvals, electronic signatures, audit trails, and quarantine workflows. Staff can follow the record from an approved process to an individual product and any related items under investigation.

Quality leadership

Review the chain from requirements and approval to executed production, deviations, and product disposition.

Engineering

Keep recipe revisions, calculations, issued snapshots, and associated results connected as the process changes.

Production leadership

Understand which products can continue working or shipping while the affected population is investigated.

A recipe question reaches both the audit team and the shipping dock.

Quality identifies the recipe snapshot used for the affected runs, reviews its approvals, and finds the recorded product population. The team applies the appropriate restrictions and investigates related components and assemblies. Auditors can follow the permitted history and signed decisions. This illustrates coordinated control; physical containment and any customer action remain operational responsibilities.

Review the controls and records your process requires.

Bring your process, record requirements, and a representative audit question. We can identify the controls and evidence needed at each step.

Read the full FAQ: factorydatasystems.com/intellitrack-regulated-manufacturing

How it works and what to consider

1. Define and qualify the intended workflow

Use the validation library and URS-based draft package to organize coverage. Configure roles, multi-party approvals, signature policies, and recipe release, then review and execute the required validation procedures.

2. Apply the approved process at the station

IntelliTrack does not assume the PLC pass/fail result is correct. It evaluates the required production data against the control recipe, rejects missing required readings, and applies the configured limits before accepting the product. The data must support the decision. The issued recipe snapshot, measurements, approvals, and change history remain associated with the product.

3. Account for exceptions and explain decisions

Investigate a suspect population through genealogy, apply the appropriate work and shipping status and record disposition. Give auditors permitted access to the product, approval and change records behind the decision.

Recheck the product before shipping.

Shipping Check verifies the finished product and its consumed genealogy, including holds, failed components, expiry, and completion of the final operation. With Include PPD validation selected, it also checks that required production readings are present and that the latest evaluated readings passed. A late hold or component failure can therefore prevent release even after the final operation was completed.

Questions your team may ask

Do we need AI to run the controlled process?

No. Core production, traceability, approvals, and reporting do not use an AI provider. The Document Library is also available without AI; AI-assisted package generation uses a configured provider.

What makes multi-party approval useful?

It allows the configured number of approvers to be enforced before a lifecycle move or applicable change. Confirm responsibilities, independence, and signature policies against your procedures during configuration and testing.

Can we say every product is accounted for automatically?

The system connects the events and relationships it receives. Reliable capture, exception handling, physical inventory reconciliation, and shipping records are necessary to establish accountability for the complete population.

Does a generated package mean the process is validated?

No. Generated documents are drafts. Your team must assess coverage, approve, and execute the protocols, retain evidence, and resolve deviations for the intended process and environment.

Plan the setup

These functions support a regulated quality system; they do not establish compliance by themselves. Validate the configured application for intended use, execute approved procedures, and maintain training, access, retention, and review. Audit trails and quality rules remain active with GxP Mode off; signature gates differ. Product accountability depends on complete capture and reconciliation.