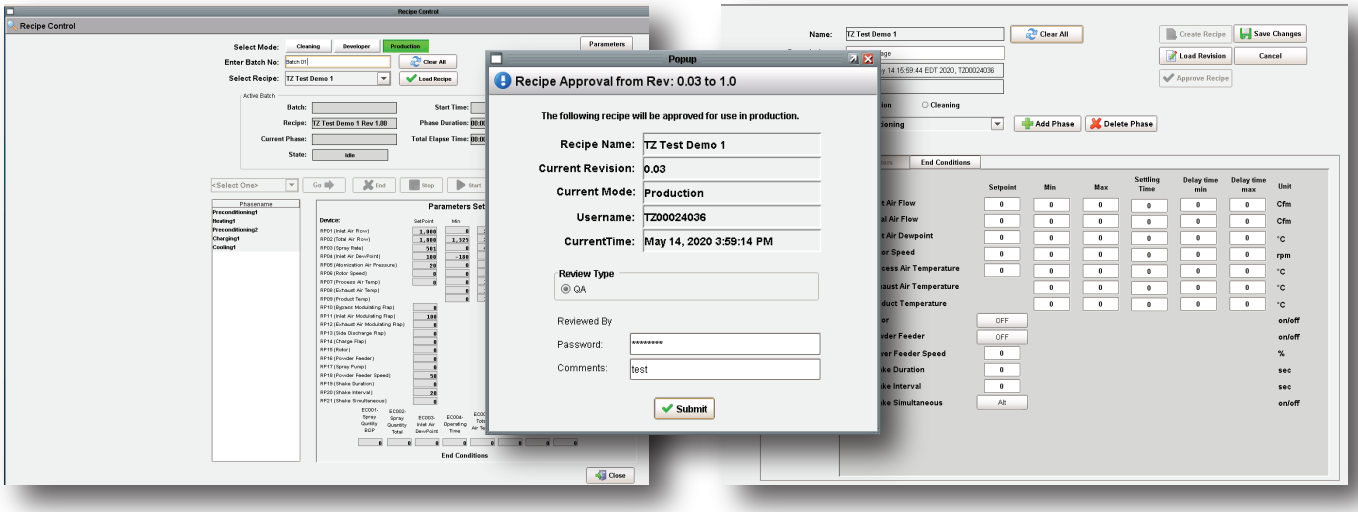
Ignition-Based Batching System

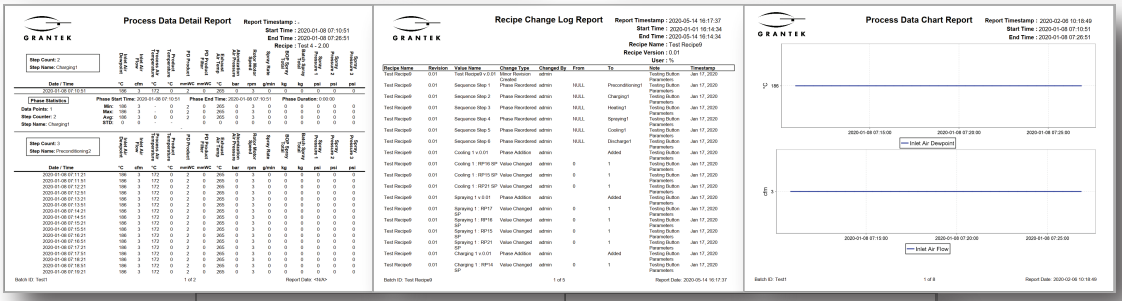
The goal of the project was to develop a single-threaded batching engine for a fluid bed dryer that would be flexible and robust while being a fraction of the cost of alternative solutions. By leveraging the Ignition platform and the Sepasoft Recipe module, the Grantek team developed a fully-validated solution that enables 21 CFR Part 11 compliance by supporting electronic signatures, enhancing Ignition's built-in audit trail functionality, and maintaining Electronic Batch Records (EBR) that adhere to Data Integrity principles.

For more information please contact Grantek at info@grantek.com

Ignition Screens



Reports



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CAPABILITIES

LIFE SCIENCES DATA INTEGRITY

Regulatory agencies worldwide charge manufacturers in the life science industry with assuring that their products are manufactured in a manner that protects patient safety, product quality and data integrity. These concepts form the bedrock of the Good Manufacturing Practices (GMP) that govern the industry. In 2016, following an increase in the number of GMP violations specifically involving data integrity, the US Food & Drug Administration (FDA) issued a draft guidance on the topic of maintaining data integrity for pharmaceutical production resulting in waves throughout the industry. Data integrity goes above and beyond 21 CFR Part 11 (electronic signatures) requirements. Manufacturers must ensure that recordkeeping requirements for completeness, consistency and accuracy of production data are maintained throughout a product's lifecycle.

Regulatory agencies are focusing on:

- Shared user logins
- Missing or disabled audit trails
- Failure to investigate data discrepancies
- Testing into compliance
- Lack of basic access control
- Lack of contemporaneous recording of activities
- Incomplete collection, retention and review of data
- Overwriting or deletion of original data
- Data falsification
- Unauthorized changes

Grantek offers data integrity auditing to help establish a baseline and identify gaps in data integrity that could result in failure to retain adequate records and/or potential regulatory agency observations. Grantek's data integrity audits cover more than 21 CFR Part 11 compliance: we assess the computerized systems using checklists and methodologies that follow ISPE GAMP guidelines to ensure we evaluate the customer's systems against all applicable regulatory controls. The audit includes a risk rating for each identified item, as well as a remediation list to help prioritize corrective actions. This serves as the basis for a remediation plan to provide a path forward to meeting the data integrity guidelines.

COMPLIANCE ASSESSMENT	Grantek bases our data integrity assessments on a checklist template that is tailored for each customer based on the architecture of the target systems. Data is evaluated for each stage of production, from the machine PLCs all the way up to the Enterprise Resource Planning (ERP) reports. The assessment includes a compliance risk rating for each item.
RISK REDUCTION PLAN	Grantek provides a risk reduction plan which is designed to help prioritize corrective actions and to determine a remediation plan per identified risk. This often includes administrative, configuration, date and time synchronization, e-record, record storage, security, and third-party vendor risks.
DESIGN SOLUTIONS	Grantek will help to design remediation solutions and estimated costs for risks identified. Risk remediation designs may include projects, procedures, standards documentation for future systems, or a combination of these solutions.
VALIDATION	Grantek may assist in validating a data integrity risk remediation solution through developing qualification documention, change management documentation, and performing system tests.
CONTINUOUS IMPROVEMENT	A continuous improvement and internal-auditing program should be developed and followed with any data integrity improvement plan. These plans typically include proactive compliance checks, reviews of remediation projects against the risk reduction plan, and approvals of new projects that may alter existing plans or provide new data for consideration.

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