Inspec QA-QC Adherence to FDA Regulations

10/20/2021

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Purpose

The purpose of this document is to provide information on how Coolearth addresses FDA regulations within our Inspec QA-QC solution. Specifically FDA eCFR - Section 11.1

Coolearth invests heavily in developing timely new releases of all our solutions in response to customer needs, market direction and regulator suggestions/mandates. Inspec Quality Intelligence software is not an exception. In compliance with FDA regulations it should be noted that Coolearth has experience and standing in the development of said electronic systems discussed in section 11.1

Regulations are always changing/improving and Coolearth is up for the challenge. We take this very seriously.

Below is a list of how we accomplished this.

How Coolearth Addressed FDA regulations

Open and Closed System Functionalities.

Coolearth has taken an all inclusive approach by addressing necessary functionalities in an open system which would automatically include closed system needs. Functionalities like:

1. All system considerations stem from the idea of implemented controls. Inspec is a controls designed system which:
   - Limits access to authorized Individuals.
   - Its system performs operational system checks, authorization checks and device-side validation.
   - Offers system documentation and distribution/publishing.
   - Performs record generation, authentication and potential encryption.
   - Audit record generation for create, alter, delete operations; logging user, location, device and date-time stamps.
   - Record retention, source control and revision history.

2. User access that assures records are valid and genuine using meta-data fingerprinting.

3. Readable and searchable, time-stamped audit records for system access, configuration changes, data collection and record approval.

4. Authorization roles establish who can access/sign/approve/alter records or perform operations.

5. Client devices validate source connections and authenticity.

6. System documentation has source control operations and revisioning for publication and audit purposes.

7. Employ use of digital signatures, encryption and data (fingerprint) integrity.

8. Audit records for system config changes (who/when/where/device).

9. Access authorization is supported by 2-Part ID or more.

10. Series or group data is all signed individually.

11. Access/Security review functionality includes checks for uniqueness, age, unauthorized attempts and role drift.

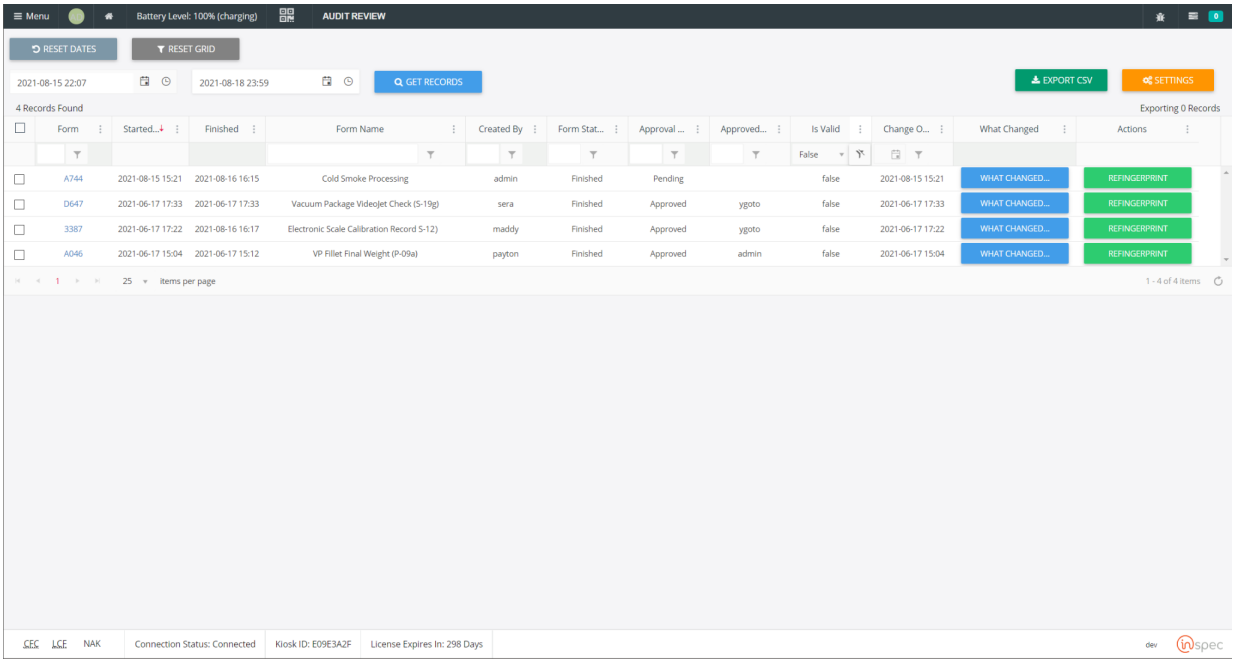
Example Screenshots

Below you will find screenshots with brief explanations of how we solved:

- Audit Review Enhancements, Validity Tests.
- Monitoring User Roles and Enhanced User Management.
- Quick Search/Find for User Activity and Settings Logs.

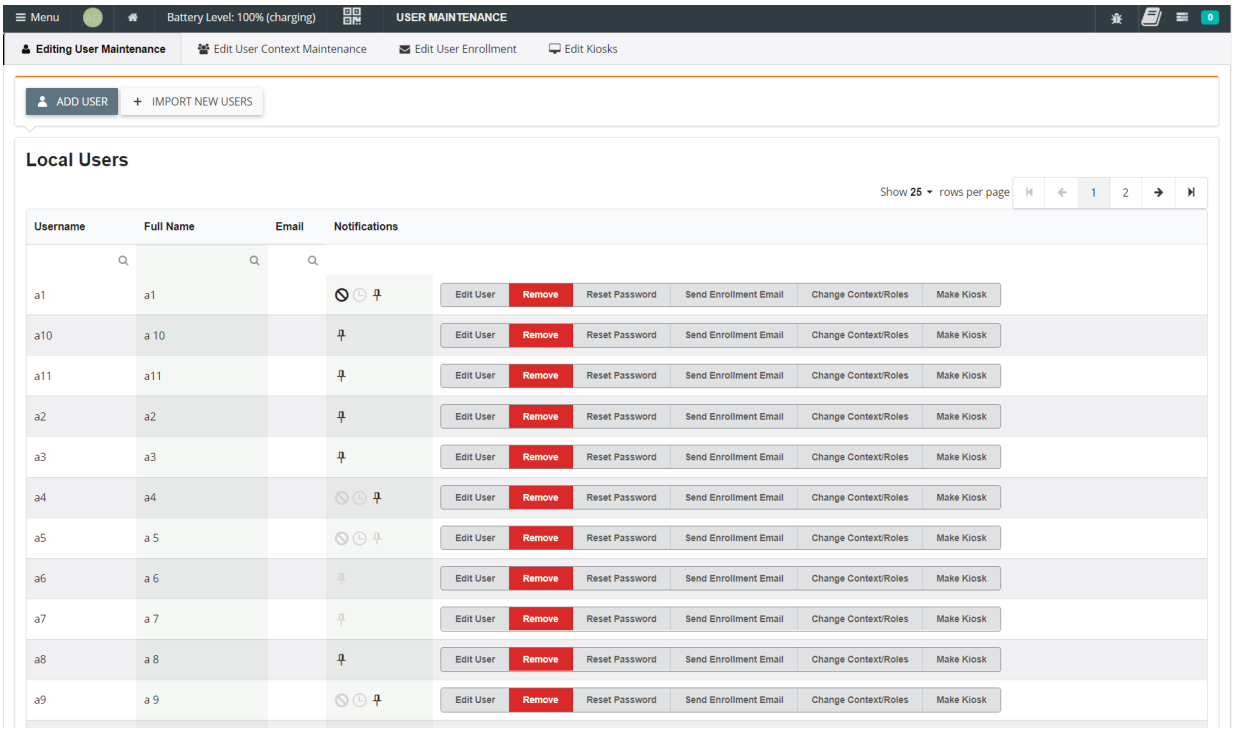
✓ Audit Review Enhancements, Validity Tests.

Audit Review screen displays all records that failed a validity test. A user can ‘refingerprint’ the record or a user can view what fields/values changed on the record.



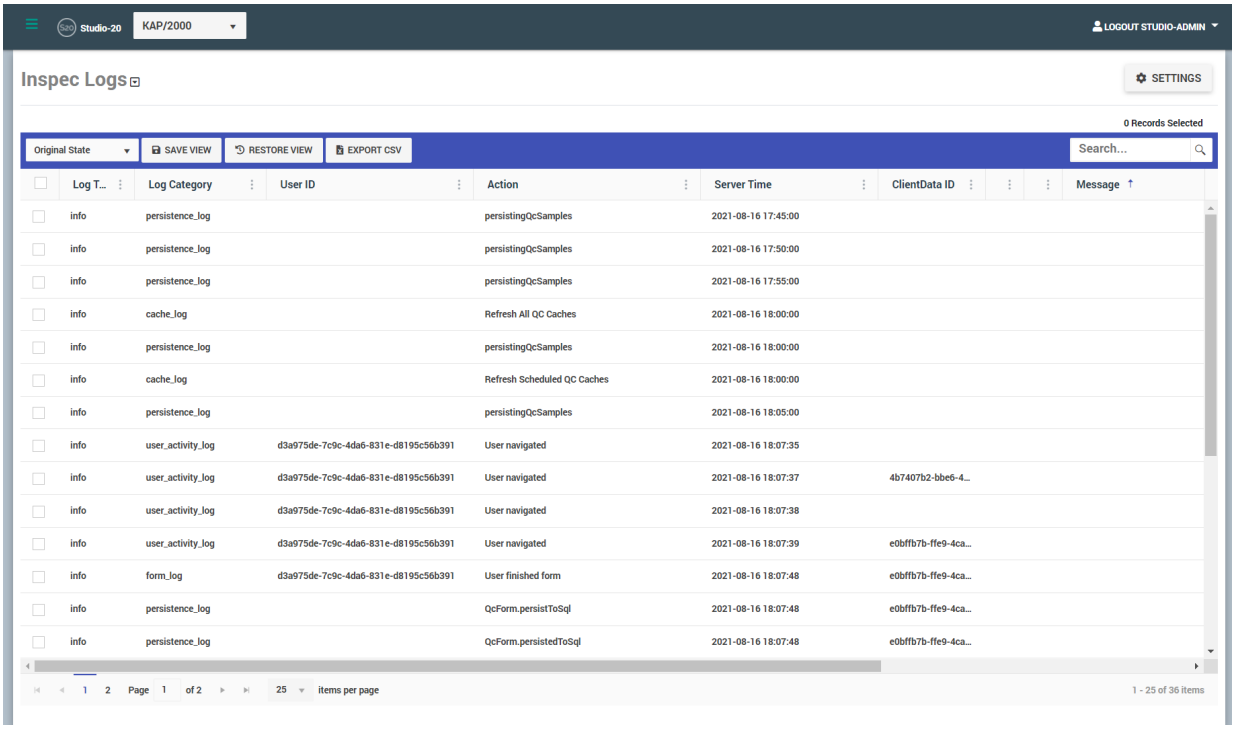
✓ Monitoring User Roles and Enhanced User Management.

Ability to track users that may be experiencing ‘role drift’. In addition to monitoring user roles, administrators can now set temporary roles and set expiration dates on users.



✓ Quick Search/Find for User Activity and Settings Logs.

Quickly search/ find system, user activity, and settings logs.



Highlights of Inspec QA-QC Solution

Coolearth's Quality Intelligence - Inspec QA-QC.

- Knock out your keypunching! Smart, intuitive, interactive software replaces repetitive chores. With Inspec QA-QC, your quality data collection is automated!

- Enjoy safe, versatile data storage on an industry-standard SQL database for all your quality data: process controls, intake and outgo status measurements, machine conditions, maintenance procedures, food quality tests, environmental conditions, bacterial sweeps… everything.

- Fix your filing problems forever. Now you can have the best HACCP plan in the business, without a single file cabinet!

- Turn quality control into process automation! Now, in real time, you can know the instant a trend is tipping south … before the specter of product failure can endanger the health of consumers, your relationship with customers, or your bottom line.

- Feedback alerts your operators to situations that require action.

Contact

Contact Coolearth Software for more information and discussion:

Coolearth Software

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