

Inspec QA-QC Adherence to FDA Regulations



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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](#).

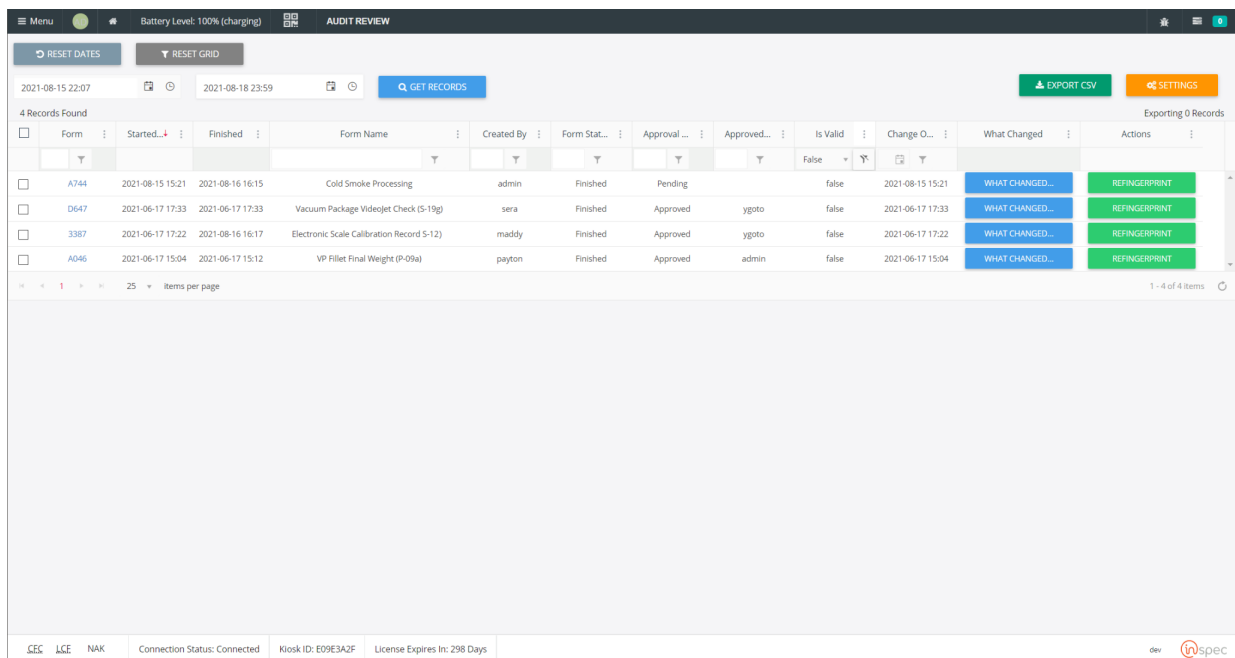
Example Screenshots

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.



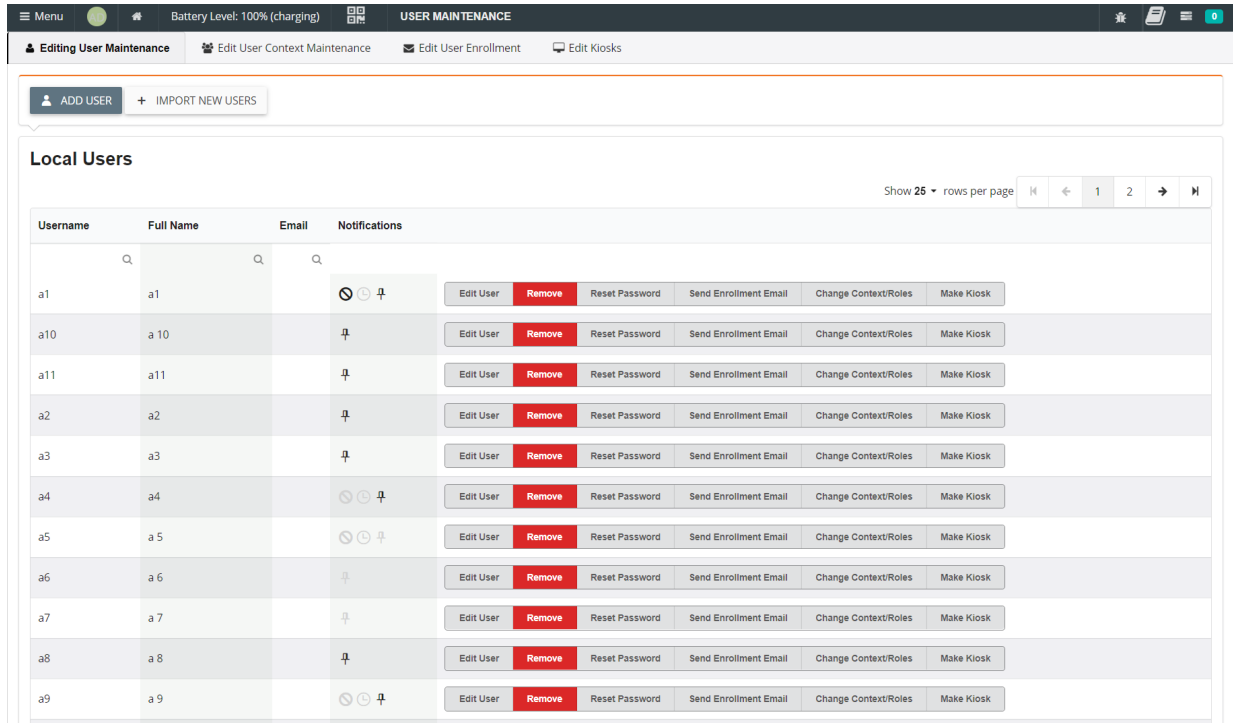
Form	Started	Finished	Form Name	Created By	Form Stat...	Approval ...	Approved...	Is Valid	Change O...	What Changed	Actions
A744	2021-08-15 15:21	2021-08-16 16:15	Cold Smoke Processing	admin	Finished	Pending		false	2021-08-15 15:21	WHAT CHANGED...	REFINGERPRINT
D647	2021-06-17 17:33	2021-06-17 17:33	Vacuum Package Videjet Check (5-19g)	sera	Finished	Approved	ygoto	false	2021-06-17 17:33	WHAT CHANGED...	REFINGERPRINT
3387	2021-06-17 17:22	2021-08-16 16:17	Electronic Scale Calibration Record S-12)	maddy	Finished	Approved	ygoto	false	2021-06-17 17:22	WHAT CHANGED...	REFINGERPRINT
A046	2021-06-17 15:04	2021-06-17 15:12	VP Fillet Final Weight (P-09a)	payton	Finished	Approved	admin	false	2021-06-17 15:04	WHAT CHANGED...	REFINGERPRINT

1 - 4 of 4 items

Connection Status: Connected | Kiosk ID: E09E3A2F | License Expires In: 298 Days

✓ 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.

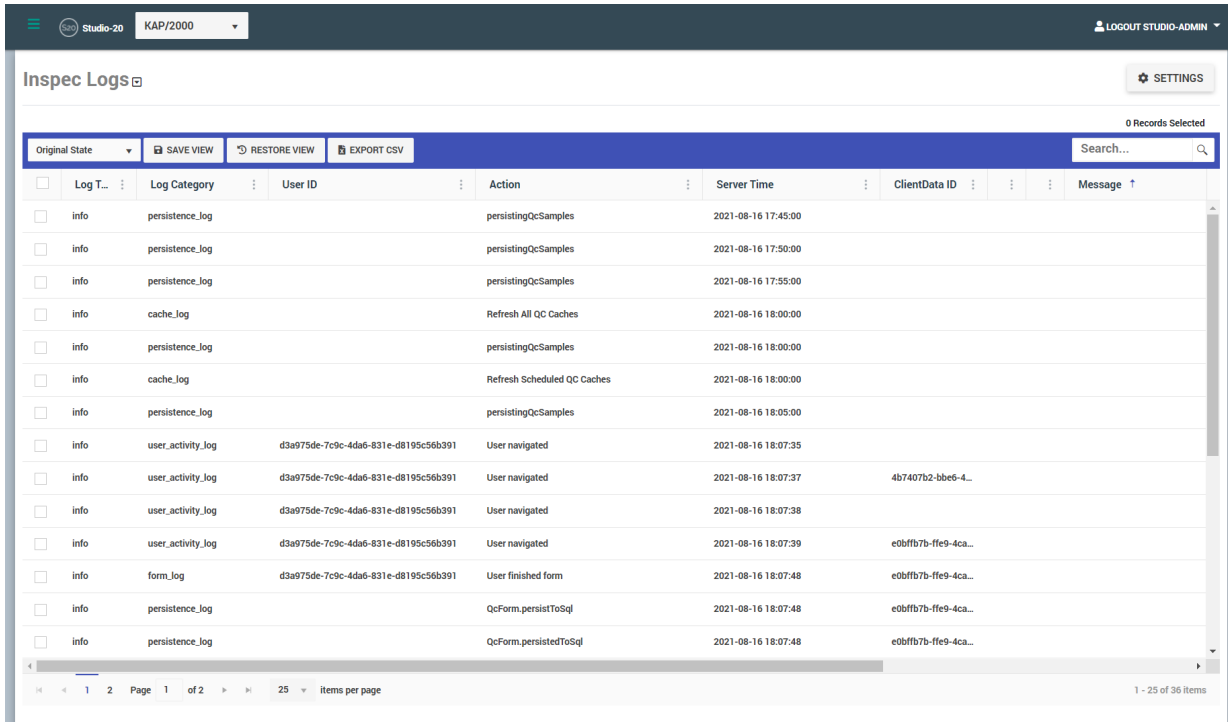


The screenshot displays the 'USER MAINTENANCE' interface. At the top, there are navigation tabs: 'Editing User Maintenance', 'Edit User Context Maintenance', 'Edit User Enrollment', and 'Edit Kiosks'. Below the tabs, there are buttons for 'ADD USER' and 'IMPORT NEW USERS'. The main section is titled 'Local Users' and features a table with the following columns: Username, Full Name, Email, and Notifications. The table contains 10 rows of user data, each with a set of action buttons: 'Edit User', 'Remove', 'Reset Password', 'Send Enrollment Email', 'Change Context/Roles', and 'Make Kiosk'. The 'Remove' button is highlighted in red. A pagination control at the top right of the table shows 'Show 25 rows per page' and page numbers 1 and 2.

Username	Full Name	Email	Notifications	Actions
a1	a1		🔔 🔕 🔊	Edit User Remove Reset Password Send Enrollment Email Change Context/Roles Make Kiosk
a10	a 10		🔊	Edit User Remove Reset Password Send Enrollment Email Change Context/Roles Make Kiosk
a11	a11		🔊	Edit User Remove Reset Password Send Enrollment Email Change Context/Roles Make Kiosk
a2	a2		🔊	Edit User Remove Reset Password Send Enrollment Email Change Context/Roles Make Kiosk
a3	a3		🔊	Edit User Remove Reset Password Send Enrollment Email Change Context/Roles Make Kiosk
a4	a4		🔔 🔕 🔊	Edit User Remove Reset Password Send Enrollment Email Change Context/Roles Make Kiosk
a5	a 5		🔔 🔕 🔊	Edit User Remove Reset Password Send Enrollment Email Change Context/Roles Make Kiosk
a6	a 6		🔊	Edit User Remove Reset Password Send Enrollment Email Change Context/Roles Make Kiosk
a7	a 7		🔊	Edit User Remove Reset Password Send Enrollment Email Change Context/Roles Make Kiosk
a8	a 8		🔊	Edit User Remove Reset Password Send Enrollment Email Change Context/Roles Make Kiosk
a9	a 9		🔔 🔕 🔊	Edit User Remove Reset Password Send Enrollment Email Change Context/Roles Make Kiosk

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

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



The screenshot displays the 'Inspec Logs' interface. At the top, there's a navigation bar with 'Studio-20' and 'KAP/2000'. Below that, the 'Inspec Logs' title is visible along with a 'SETTINGS' button. A search bar is present with the text '0 Records Selected'. Below the search bar are buttons for 'Original State', 'SAVE VIEW', 'RESTORE VIEW', and 'EXPORT CSV'. The main area is a table with the following columns: Log T..., Log Category, User ID, Action, Server Time, ClientData ID, and Message. The table contains 14 rows of log entries. The last two rows show 'User navigated' and 'User finished form' actions.

Log T...	Log Category	User ID	Action	Server Time	ClientData ID	Message
info	persistence_log		persistingQcSamples	2021-08-16 17:45:00		
info	persistence_log		persistingQcSamples	2021-08-16 17:50:00		
info	persistence_log		persistingQcSamples	2021-08-16 17:55:00		
info	cache_log		Refresh All QC Caches	2021-08-16 18:00:00		
info	persistence_log		persistingQcSamples	2021-08-16 18:00:00		
info	cache_log		Refresh Scheduled QC Caches	2021-08-16 18:00:00		
info	persistence_log		persistingQcSamples	2021-08-16 18:05:00		
info	user_activity_log	d3a975de-7c9c-4da6-831e-d8195c56b391	User navigated	2021-08-16 18:07:35		
info	user_activity_log	d3a975de-7c9c-4da6-831e-d8195c56b391	User navigated	2021-08-16 18:07:37	4b7407b2-bbe6-4...	
info	user_activity_log	d3a975de-7c9c-4da6-831e-d8195c56b391	User navigated	2021-08-16 18:07:38		
info	user_activity_log	d3a975de-7c9c-4da6-831e-d8195c56b391	User navigated	2021-08-16 18:07:39	e0bfb7b-ffe9-4ca...	
info	form_log	d3a975de-7c9c-4da6-831e-d8195c56b391	User finished form	2021-08-16 18:07:48	e0bfb7b-ffe9-4ca...	
info	persistence_log		QcForm.persistToSql	2021-08-16 18:07:48	e0bfb7b-ffe9-4ca...	
info	persistence_log		QcForm.persistedToSql	2021-08-16 18:07:48	e0bfb7b-ffe9-4ca...	

At the bottom of the table, there is a pagination bar showing 'Page 1 of 2' and '25 items per page'. The total number of items is '1 - 25 of 36 items'.

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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