The IR-4 National Education Conference

eQA Reporting System
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New Orleans, LA
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Historical Background

IR-4 has attempted to enter the electronic records arena previously.

- Expensive
- Take large IT budgets to support
- Require large development costs
- None were found implementable
• Three years ago QA was given a challenge by Management
  – Identify the needs for electronic capture and distribution of QA reports
  – Identify plausible systems and report back to management
Objectives

• Significantly reduce copying and snail mail
• Web based system
• Contain an electronic signature and audit trail
Objectives

• Allow for system generated notifications and reminders
• Searchable for online viewing
Objectives

- System to provide QA reports from a single location
- Relationally based system for monitoring compliance trends
- Reasonably priced
Historical Background

• 2011

– 3 plausible electronic Quality Reporting system were identified:
  • Master Control - >$$$$$$
  • Intelex - >$$$
  • QSI - <$$

One stood out as the best potential system for the price

Action – investigate QSI, set up evaluation webinars for HQ, The IR-4 QAU and the IR-4 Regional Personnel
• Webinar based previews of the QSI system were conducted July 2011 through Feb. 2012

• Proposal submitted to the IR-4 Project Management Committee in March of 2012 - APPROVED

• Purchase approved by Rutgers May 15, 2012
Welcome to IR-4 eQA
Implementation

• Timeline:

  • Software was purchased and installed on Rutgers servers June 21, 2012

  • QSI provided training to high level users on July 24-26, 2012 at IR-4 HQ

  • The three implementation teams met via webinars to discuss the generation of the workflows for each of the new QA forms and to test the draft forms as they are generated. This occurred from September 2012 through December 2012.
• Timeline, cont.:

  • The conversion teams were expanded at end of October of 2012 in order to further educate IR-4 personnel on the use of the system.

  • Entry of users, permission groups and location specifics into eQA software progressed in January and February of 2013 in order to establish our privacy goals.
Implementation Teams

• Team 1 - Field Forms Conversion Team
  – David Studstill, Dan Heider, Maury Craig, Rebecca Sisco, Stephan Flanagan, Ray Leonard, Jane Forder and Robin Adkins

• Team 2 - Lab Forms Conversion Team
  – Wlodek Borejsza-Wysocki, Tom Hendricks, Matt Hengel, Debbie Carpenter, Sherita Normington and Michael Chen

• Team 3 – “Other” Forms Conversion Team
  – Van Starner, Marija Arsenovic, Martin Beran, Juliet Thompson and Tammy Barkalow
Overview of eQA

- eQA system is a QA report/QA document generation, communication and access system
- No one receives an audit via eQA, they receive notice that a new audit has been generated and is available for activities
- QA generates an audit using standardized forms
- Users read, respond, attach and communicate their activity to the next identified recipient via the system
Specific activities/notifications are assigned with in a packet

Standard progression of a packet:

a) QA writes an audit using the standard form in eQA
b) QA electronically signs the audit and it goes to the next step
c) The Testing Facility Management (TFM) is notified of a new audit and must acknowledge the audit. Once acknowledged it goes to the next step
d) The FRD/LRD and/or SD is assigned an activity. (The RQAC and/orRFC/RLC is notified that that the audit can be read but do not receive an activity)
e. The FRD and the SD respond to QA findings using an internal word processor which saves their responses into the database.

f. If corrected pages are generated as part of the corrective action to a QA finding or memos are created that are to be added to the data those documents are attached by the FRD or SD in their response section
g. Once all actions and responses are completed the response section is closed when both the FRD and the SD select the electronic “finished with responses” button

h. The SD then is assigned the activity to review all responses and acknowledge the completion

i. The SD approves the finished audit with responses using an e-signature
j. The TFM is notified that they have an activity to approve the completed audit report and responses.

k. Once approved, the TFM finishes their activity by e-signing the packet.

l. The QA who generated the packet is then notified by email that the audit is complete and must login to the system and acknowledge its completion by selecting an electronic button.
Overview

• If you have permissions you can view a packet at any time (But you cannot alter it in anyway)

• Field Research Directors (FRDs) and LRDs typically will only be able to view packets for their sites

• RF Coordinators and RL Coordinators will be able to view the packets of cooperators in their region
It is important that all IR-4 participants understand and support the policy that user logon and passwords are to be kept confidential and are not to be used by multiple persons in the course of generating or responding to QA audits. While not data, these records containing e-signatures and audit logs are legally required documents and the integrity of the e-signature should not be compromised.
• Password selection form available
• If you are not a user, you will not have a login and password
• Users will be determined by FRD designation in the protocol or provided on the website password protected spreadsheet that will identify special needs sites
• **eQA** – this is the software system that allows us to generate, communicate, respond to and retain QA inspection reports.

• **Packet** – A packet is the electronic file that is the QA report.

• **Sections** – within each packet there are typically 5 sections that comprise the QA inspection report.

• **Activity** – this is an assignment to an individual that their attention is required (need to respond to findings, acknowledge receipt, etc)
Definitions

- **Notification email** – this is an email alerting the recipient that they have a packet that can be viewed (they do not have an activity assigned to them)

- **Activity email** – this is an email that alerts the recipients that their attention is needed for a specific packet.
Electronic QA Reporting System

E mail notification
Logon to system
Open packet
Read findings
Respond to findings
Attach any memos to file, corrected pages or new data pages/report pages
Finish only when you are positive all actions needed have been completed.
Mail any originals to HQ QA
Basic Steps for Users of eQA

- E
- L
- O
- R
- A
- F
- M
- Elephant, Landed, On, Rump, Running,
- Away, From, Mouse
Audit has been completed. Please open and select button for finalizing
Due Date: 2/23/2013 12:00:00 AM

Packet: LCPI-000045
   LCPI Cyazofamid/tomato (GH) 10656.11CAR05

Form: SD/TFM Approval Page

Click Here To View Form

Click Here To Add to Outlook Calendar
Logon

Everyone will have a logon that is unique to the individual
User Name= cits\twhite
Password= XXXXXXX

Windows Security

The server ir4devel.rutgers.edu at ir4devel.rutgers.edu requires a username and password.

Warning: This server is requesting that your username and password be sent in an insecure manner (basic authentication without a secure connection).

User name
Password

Remember my credentials

OK  Cancel
**Menu**
(Scott Chapman)

- Main Menu
- My Activities
- Document List
- Document Search
- Forms Module
- TMS Help
- About TMS

**eQA**

**My Activities**

<table>
<thead>
<tr>
<th>Due Date</th>
<th>Activity For</th>
<th>Recv'd</th>
<th>Comp'd</th>
<th>Activity Type</th>
<th>Document / Form</th>
<th>Title</th>
<th>Recip. Notes</th>
</tr>
</thead>
<tbody>
<tr>
<td>3/8/2013</td>
<td>Scott Chapman</td>
<td>☐</td>
<td>☐</td>
<td>Please see QA findings and add responses</td>
<td>FCP-000085</td>
<td>Diquat/Onion 09986.12-W101</td>
<td>N/A</td>
</tr>
</tbody>
</table>

**Receive All Activities**
• There are five sections to each QA audit report (packet)

1. Cover Sheet
2. QA Checklist
3. QA Findings/Recommendations
4. Response to QA Findings
5. SD/TFM Approval Page
Electronic QA Reporting - Packet Detail Section 1, Cover Sheet

Form Group: Field Raw Data Audit
Packet ID: FDB:009980
Audit Type Chem/Crop/PR#(ID): FDB Quinoxyfen/squash 08673.12-OR13
Location: Western Field Oregon
Date: 2/13/2013 14:17:04 PM
Closed: 

Study Title: Quinoxyfen/squash
Field ID Number: 08673.12-OR13
Origin of Audit: Internal
Inspection Date #: 2/13/2013
FRD and SD Notification of Activity:
- Bill Barney
- Gina Kosekola

RFC and RQAC Notification (read only):
- Debbie Carpenter
- Tammy Barklow

Quality Assurance Inspector:
- Tammy Barklow

Study Director:
- Bill Barney

Please select Van Stauer as TFM

Testing Facility Management:
- Tammy Barklow
Electronic QA Reporting - Section 2 - QA Checklist

Form Detail
Field Raw Data Audit

Show Activities / Workflow Status Page
Show Audit Trail Page
Go To Bottom

Field Raw Data Checklist

Form Group: Field Raw Data Audit
Packet ID: FDE-00000050
Audit Type: Chem/Crop/PR#(ID): FDE Quinoxyfen/squash 08673.12-OR13
Location: Western Field-Oregon
Date: 9/13/2013 1:41:16 PM
Closed: ☑

Study Title: Quinoxyfen/squash
Field ID Number: 08673.12-OR13

A. General

1. Protocol and applicable amendments(s)/deviation(s) present and approved: Yes
2. Pages identified with field ID #: Yes
3. Study personnel signatures complete: Yes
4. Training documents sufficient: Yes
5. All in use pages/entries signed and dated: Yes
6. Data changes GLP compliant as per SOP: Yes
7. Notes with sufficient detail: Yes
Electronic QA Reporting – Section 3-QA Findings/Recommendations

QA Findings/Recommendations

Form Group: Field Raw Data Audit
Packet ID: FDE-000005
Audit Type Chem/Crop/PR#(ID): FDE Quinoxylen/squash o8673.12-OR13
Location: Western Field-Oregon
Date: 2/13/2013 1:41:16 PM
Closed: No

Findings for Field Research Director:
This is a test of the attachment function. Can you open and view both attachments?

1. What is attachment #1?

2. What is attachment #2?

Findings for Study Director:
Comments from Quality Assurance:

Attachments #1:
multi gerbers 2.jpg

Attachments #2:
FDE o8673.12-OR13 test.docx

Signature of QA:
Tammy Barkalow (QA HQ Assist. Director)
Signed By:
Signature Date: 2/26/2013 6:13:24 PM

Menu
(Gina Koskela)
FDB Quinoxyfen/squash 08673.12-OR13

Please initial and date after each response.

1) This is a test. Please follow all procedures.

2) I’ve attached a .jpg file. Please open the document and attach your own picture as a response in section 4.

3) I attached a word document. Please open the document and attach your own word document as a response.

4) Make sure you finish the report by clicking on the ‘finished with responses” icon. Do not click on that icon until all actions have been completed.

Thanks.
Field Research Director
QA findings for FRD. Please respond. Initial and Date each response.

Hi Maury,

Please answer the following questions. Date and initial each response.

1. How is the weather?

   MEC 10-12-12: Muy bueno, except that it's raining squirrels.

2. What is your favorite movie?

   Hi Maury, can't close the audit without knowing your favorite movie. JC 10/11/2012

   MEC 10-12-12: "Attack of the Killer Tomatoes" Can't beat the all time greats.

3. Can you tell me if the attached c of A is accurate for your test substance?

   Hi Maury, Please check and respond. Thanks. JC 10/11/2012

   MEC 10-12-12: Yes, it is accurate . . . and it sounds DELICIOUS!
Form Group: Field Raw Data Audit
Packet ID: E0000030

Audit Type: Chem/Crop/PR(#ID): FDB BYI/Blueberry 10637.11W104
Location: The IR-4 Project Headquarters
Date: 10/8/2012 12:23:31 PM
Closed: (Van Starner - 10/9/2012 2:06:32 PM) Re-Open Packet

Study Director Signature: Signed By
Marija Arsenovic (Senior Research Scientist) Signature Date
10/9/2012 2:05:48 PM

Testing Facility Management: Signed By
Van Starner (Testing Facility Management) Signature Date
10/9/2012 2:06:32 PM
Electronic QA Reporting

Please sign
You are verifying that you are 'Sherita Normington' and that you have reviewed the audit and are signing your work product. This is equivalent to your wet signature.

Password:

Sign
Cancel
### Workflow Status

**Form Group:** Field Raw Data Audit  
**Packet ID:** E-000033

**Audit Type:** Chem/Crop/PR#(ID): FDB 11/Blueberry 106.37.11W105

**Type:**  
Closed: No
Facilities:

<table>
<thead>
<tr>
<th>Step Status</th>
<th>Step Name</th>
<th>Recipients</th>
<th>Activity Type</th>
<th>Form Name</th>
</tr>
</thead>
<tbody>
<tr>
<td>Completed</td>
<td>Initiator fills out basic information</td>
<td>Tammy Barkalow</td>
<td>Completed On 10/9/2012 4:56:10 PM</td>
<td>Edit Form Data</td>
</tr>
<tr>
<td>Completed</td>
<td>Initiator fills out checklist</td>
<td>Tammy Barkalow</td>
<td>Completed On 10/10/2012 2:40:27 PM</td>
<td>Edit Form Data</td>
</tr>
<tr>
<td>Completed</td>
<td>Complete Findings Page</td>
<td>Tammy Barkalow</td>
<td>Completed On 10/10/2012 2:45:36 PM</td>
<td>Edit Form Data</td>
</tr>
<tr>
<td>Completed</td>
<td>QA signature</td>
<td>Tammy Barkalow</td>
<td>Completed On 10/10/2012 2:45:55 PM</td>
<td>Please sign</td>
</tr>
<tr>
<td>Completed</td>
<td>Group Notification</td>
<td>Dan Heider</td>
<td>Completed On 10/9/2012 4:23:46 PM</td>
<td>Edit Form Data</td>
</tr>
<tr>
<td>Completed</td>
<td>Study Director Review</td>
<td>Raymond Leonard</td>
<td>Completed On 10/10/2012 5:37:38 PM</td>
<td>Edit Form Data</td>
</tr>
<tr>
<td>Completed</td>
<td>Study Director Signature</td>
<td>Raymond Leonard</td>
<td>Completed On 10/10/2012 5:38:00 PM</td>
<td>Please sign</td>
</tr>
<tr>
<td>Rejected</td>
<td>Testing Facility Management review</td>
<td>Van Starner</td>
<td>Rejected On 10/15/2012 3:24:31 PM</td>
<td>View Form Data</td>
</tr>
<tr>
<td>In Progress</td>
<td>Study Director Review</td>
<td>Raymond Leonard</td>
<td>Due Date: 10/15/2012</td>
<td>Edit Form Data</td>
</tr>
<tr>
<td>Not Started</td>
<td>Testing Facility Management signature</td>
<td></td>
<td></td>
<td>Please sign</td>
</tr>
<tr>
<td>Not Started</td>
<td>Notify QA of closed audit</td>
<td></td>
<td></td>
<td>Review Form Packet</td>
</tr>
</tbody>
</table>

**Bullet Points:**
- [ ] Electronic QA Reporting
- [ ] Work flow
Electronic QA Reporting - Work flow

Rejection Details

User Name: Van Storner
User Position / Title: Testing Facility Management
Date of Rejection: 10/15/2012 3:24:31 PM
Reason for Rejection: Still need SD responses
Electronic QA Reporting System

- Packet Demonstrations
Thank You!