

Introduction

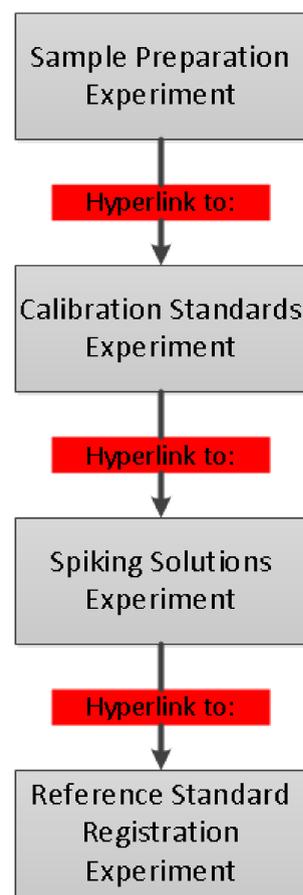
Auditing in an Electronic Laboratory Notebook environment has three key tools: **hyperlinks, queries, and audit trails**. The days of sorting through numerous notebook pages and paper forms are in our past. We now have electronic tools that allow auditors to drastically reduce the amount of time spent reviewing a study.

- Hyperlinks are electronic links that provide direct access from one place to another. They allow the auditor to view critical pieces of study information in seconds.
- Querying is a search used to retrieve information from a database. Queries can be used to show a particular piece of data in seconds.
- Audit trails are chronological records, or set of records, that show operations performed. These trails are essential to determine how data evolves during the execution of work.

Hyperlinks

The workflow shown below depicts each experiment completed by the laboratory. Links from the sample preparation method show the information for where the calibration standards, quality controls, and spiking solutions were prepared. From the spiking solutions, the links show where the reference standard was registered including the certificate of analysis for that particular standard (circled in red). All these preparations can be viewed with a mouse click.

Workflow



Example

Reference Standard Query Results	
COA ID	REFSTD-CS-Oxycodone-FE092910-02-004506
CoA Sponsor Number	0010
COA_Compounds	Oxycodone
COA_Expiration Date	30-Sep-2015
Concentration (mg/mL)	1
COA Regulation Status	Regulated
COA Hyperlink	/Root/AIT Bioscience/Sponsor Node/0010/Sponsor Specific Template Lifecycle Library/4_ Executed Reference Standard Experiments/REFSTD-CS-Oxycodone-FE092910-02-004506 (v3)



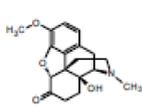
Certificate of Analysis

Oxycodone
4,5-Epoxy-14-hydroxy-3-methoxy-17-methylmorphinan-6-one

Catalog Number: O-002
Solution Lot: FE092910-02
Expiration Date: September 2015
Solvent: Methanol
Volume per Ampule: Not less than 1 mL
Storage: Protect from air and light, refrigerate or freeze.
Intended Use: For laboratory use only. Not suitable for human or animal consumption.
Regulatory: USDEA Exempt | Canadian TK # 61-51

Cardinal Quality
ISO GUIDE 34
ISO/IEC 17025
ISO 9001:2008

Safety: Flammable, Poison



Queries

When a query is conducted, a particular piece of information or data can be found in seconds; rather than sorting through boxes of paper which could take hours or days, or may even be impossible to find. Queries can be as broad or as specific as the end user needs. Three examples of queries are shown below.

Examples

1. Show me the quarterly reverification experiments for pipette (BEQ.1020) in 2012.

Search Results

Title (Experiment)	Last Modified At (Experiment)
EQM-BEQ.1020-18-Sep-2012-006-C-R	Sep 18, 2012 1:52:02 PM
EQM-BEQ.1020-07-Dec-2012-003-C-R	Dec 7, 2012 1:43:11 PM
EQM-BEQ.1020-28-Jun-2012-004-C-R	Jul 2, 2012 1:14:23 PM
EQM-BEQ.1020-27-Jan-2012-006	Jan 31, 2012 7:46:35 AM
EQM-BEQ.1020-12-Apr-2012-005	Apr 27, 2012 12:00:12 PM

The query results indicate that the quarterly reverification did occur for pipette (BEQ.1020) in 2012.

By clicking on the Experiment Title-the maintenance experiment can be viewed in seconds.

2. Show me what experiments utilized the following pipette (BEQ.1020) in April of 2013.

Search Results

Title (Experiment)	Last Modified At (Experiment)
CS_QC-BAM.0130-03-Apr-2013-008151	Apr 12, 2013 12:13:50 PM
SS-Comparison-02-Apr-2013-012434	Apr 2, 2013 3:01:32 PM
SS-General Spiking-03-Apr-2013-012454	Apr 3, 2013 11:18:21 AM
SS-Internal Standard-03-Apr-2013-012474	Apr 3, 2013 11:26:12 AM
Water-MeOH-HAc, 50-50-1-02Apr2013-012209	Apr 2, 2013 2:55:28 PM

The results show exactly which experiments were executed using pipette (BEQ.1020) in April of 2013. This search is invaluable when a pipette reverification fails during a quarterly maintenance event so that a thorough and accurate investigation can be completed.

3. Show me every stock stability experiment for Bioanalytical Method #: BAM.0130.

Search Results

Title (Experiment)	Last Modified At (Experiment)
Stock Comparison and Stability-BAM.0130-0010-1181-21	Apr 3, 2013 2:04:44 PM
Stock Comparison-BAM.0130-3644	Feb 20, 2013 4:32:34 PM
Stock Stability-BAM.0130-3645	Feb 20, 2013 4:30:14 PM
Stock Stability-BAM.0130-3704	Feb 27, 2013 1:28:32 PM

The query shows every stock stability experiment executed in the laboratory for BAM.0130. Now by clicking on any of these experiments, the days of stability established for this method can be reviewed in seconds.

Audit Logs

Most electronic systems provide audit trails at both the system level and the study level. Each level should be reviewed on a routine basis allowing an auditor to determine who made changes and when the changes were made. Reviewing audit trails is imperative in order to review the conduct of work. An example audit trail for the preparation of a spiking solution is shown below.

Example

The first two columns of the example audit trail below show the **Date** and **Time** that each entry or change was made to the experiment. The third column shows the **User**, which is indicated by a unique user ID.

The **Type** column indicates the nature of the change. The QA Staff browse the audit trails for key words or verbs. For example, when a 'Data Changed' reason is utilized, a comment must be added to indicate why the change was made. See the green circles in the **Comments** column as examples.

Description column will describe exactly what information was added or changed to any cell in the experiment.

See the active hyperlinks in the **Source** column (red outlines). These hyperlinks show where the recorded data entry or change resides.

Audit Log

	Date	Time	User	Type	Description	Source	Comment
1	Apr 16, 2013	11:08:39 AM	roachj	Document Created	Document created from template '/Root/AIT Bioscience/Template Lifecycle Library/Approved Primary Templates Folder/Spiking Solutions_v5' version: 2		
2	Apr 16, 2013	11:08:39 AM	roachj	Map Variables	Variable(s) mapped to catalog		
3	Apr 16, 2013	11:08:58 AM	roachj	Data Changed	System updated Experiment Properties from E-WorkBook		
4	Apr 16, 2013	11:09:08 AM	roachj	Data Added	Values "BEQ.1020, 41327, Maxipettor 4720, 41417" added to cells Pipette:Pipette 1, Date of Last Calibration:Pipette 1, Model:Pipette 1, Verification Due Date:Pipette 1	Pipettes	
5	Apr 16, 2013	11:09:20 AM	roachj	Data Changed	Values changed from "BEQ.1020, Maxipettor 4720" to "BEQ.1022, Reference Series 2000 Adjustable 10 - 100 µL" in cells Pipette:Pipette 1, Model:Pipette 1	Pipettes	Wrong dropdown selection- Wrong pipette selected
6	Apr 16, 2013	11:10:03 AM	roachj	Data Added	Values "BEQ.1061, Refrigerator, 49090" added to cells Equipment:'1', Equipment Name:'1', Calibration Expiration Date:'1'	Equipment Used	
7	Apr 16, 2013	11:10:19 AM	roachj	Searches Changed	Saved changes to associated searches		
8	Apr 16, 2013	11:10:19 AM	roachj	Search Run	Associated searches run		
9	Apr 16, 2013	11:10:43 AM	roachj	Data Changed	Values changed from "BEQ.1061, Refrigerator, 49090" to "BEQ.1062, Biomedical Freezer (-20C), 49239" in cells Equipment:'1', Equipment Name:'1', Calibration Expiration Date:'1'	Equipment Used	Wrong dropdown selection- Wrong storage location chosen.

Conclusion

The hyperlinks, querying, and audit trails presented here have practical advantages over traditional paper-based laboratory auditing. These three types of electronic tools give QA Auditors the ability to review a study more quickly and efficiently.