Review and Approve Results in Empower

Data, Meta Data and Audit Trails

- Systematic "story" of the data from creation, through interpretation and final assessment and reporting

- Easily confused as : Log of everything that happens in my system"

  - Recent quote: "We switched on audit trails of everything at the beginning"   and.......

Process Understanding

- Key to determine the true audit trail
  - How is data recorded, where and when
  - What additional records are created along the way
  - How are these connected and what traceability is there between them
  - If records are not editable, do you need a traditional audit trail functionality?
  - Can you create a paper audit trail / change control?
- Using the answers to these questions the criticality of the audit trail can be determined and a sensible review process designed.

Critical Audit trails

| Standard Solution and Sample Preparation | Instrument fit for us (Maintenance and calibration records) | Training records of operators | Raw Data | Methods for interpretation | Processed results | Reported data |

- At each step, where are records created?
- Can they be modified? By whom? And how is this traced
- How is data passed from one system to another?
  - Automatically and validated
  - Manually and Four eyes checked?

Annex 11: Prompting the question of audit trail review

Four new key areas in Annex 11

- Supplier Audits: including the requirement to share a summary of your assessment

  - Be sure this is agreed in your vendor NDA agreement

- Qualification of IT Infrastructure

  - And a formal agreement with IT departments

- Inclusion of Risk Management

  - In Regulation rather than in Guidance

- Review of Audit Trails

  - Specifically mentioned

Accurate and Traceable Data Entry
- Audit Trails

- Annex 11§9
  - Based on Risk
    - o Record of all GMP relevant changes and deletions
    - o Reasons should be included
    - o Convertible to human readable form **and regularly reviewed.**
- Additionally 11§8.2
  - ..ability to " generate printouts indicating if any data changed since original entry"

Review of Audit Trails

- **Audit trails** need to be available and convertible to a generally intelligible form and **regularly reviewed.** (A11§9)
  - Part 11 " agency review"
- From a NIST publication*
  - Audit trails are a technical mechanism that **help managers maintain individual accountability**. ..Users are less likely to attempt to circumvent security policy if they know that their actions will be recorded in an audit log.
  - "Determine how much review of audit trail records is necessary"
- Increased appearance of Warning Letter observations

* Introduction to Computer Security: The NIST Handbook

US FDA Audit Trail Review Warning Letters

- Gulf Pharmaceutical Industries Feb 2012
  - We also note that **your SOP does not have provisions for any audit trail reviews to ensure that deletions and/or modifications do not occur**.

- Banner Pharmacaps Sept 2006:
  - A second person must review these audit trails, particularly given the lack of controls for preventing data manipulation. **Such an audit may well have detected the data manipulation which was occurring at your facility**.

- Sunrise Jan 2010:
  - In addition, your firm's **review of laboratory data does not include a review of an audit trail** or revision history to determine if unapproved changes have been made.

Product /Batch Number	Lack of Complete Data
Products and batches listed in FDA-483, point # 2	OOS results not documented in laboratory records. Unreported OOS results found in electronic data files.
Propoxyphene Napsylate and APAP Tablets, 100/650mg Batch 303110A	Changed chromatogram headers by cutting and pasting, so during review all sample injections would appear to be in sequence, for Dissolution Testing of Tablets D1 and D5.
Propoxyphene Napsylate and APAP Tablets, 100/650mg Batch 104026B Validation Batch	Original Sample Weights not recorded in notebook. Sample weights were changed by the analyst until a passing result was obtained for Assay (A2)
Acetaminophen & Codeine Phosphate Tablets, 300/30mg Batch 407148	Processing methods changed by analyst until the processing method resulted in a passing result. Original processing method not recorded in laboratory notebook.

Empower Compliance Features:
Audit Trails

Biggest Compliance feature in Empower??

- The built in Empower Database
  - Enables every object to be uniquely referenced
  - Can never overwrite data
  - Can never mistake which data went with which method
  - Ensures easy and accurate data review

- Automatic versioning for results / methods
  - With full computer generated audit trail
  - WHO changed WHAT (before and after values) WHEN.... And WHY?)

Empower Audit Trails ID numbers

- Empower is built into an Oracle Database
- This database gives each object or result a Unique Identifier for tracking the values and records
- This identifier is unique within each project.
- Modification of any data base object results in a NEW record with NEW identifiers

- Many users of Empower use these ID number to prove and identify results to auditors
  - Also to track for their own purposes

Assigns Unique ID # for All Entries

	SampleName	Vial	Vial Id (Result)	Injection	Injection Id	Channel Id
1	System Suitability test	1:A,1	1062	1	1064	1065
2	System Suitability test	1:A,1	1062	2	1069	1070
3	System Suitability test	1:A,1	1062	3	1071	1072
4	System Suitability test	1:A,1	1062	4	1073	1074
5	System Suitability test	1:A,1	1062	5	1075	1076
6	AG Standard 1	1:A,2	1077	1	1078	1079
7	AG Standard 2	1:A,3	1080	1	1081	1082
8	AG Standard 3	1:A,4	1083	1	1084	1085
9	AG Standard 4	1:A,5	1086	1	1087	1088
10	AG Standard 5	1:A,6	1089	1	1090	1091
11	AG Sample 1	1:A,7	1092	1	1093	1094
12	AG Sample 2	1:A,8	1095	1	1096	1097
13	AG Sample 3	1:B,1	1098	1	1099	1100
14	AG Sample 4	1:B,2	1101	1	1102	1103
15	AG Sample 5	1:B,3	1104	1	1105	1106
16	AG Sample 6	1:B,4	1107	1	1108	1109
17	AG Sample 7	1:B,5	1110	1	1111	1112
18	AG Sample 8	1:B,6	1113	1	1114	1115
19	AG Sample 9	1:B,7	1116	1	1117	1118

(Tabs: Sample Sets | Injections | Channels | Methods | Result Sets | **Results** | Peaks | Fr...)

- Raw Data ID's
  - Missing numbers from Channel
    - Assigned to Injection
    - Assigned to Vial.

- Result ID's
  - Missing numbers assigned to Calibration
  - And...1142, 1143, 1144, 1145, 1146?

IDs assigned to Cal Curve in Peak View

Sample Sets | Injections | Channels | Methods | Result Sets | Results | **Peaks** | Fractions | Sign Offs | Curves | View Filters | Custom Fields

	SampleName	Vial	Vial Id (Result)	Injection	Injection Id	Channel Id	Result Id	Calibration Id	Name	Curve Id	Retention Time (min)	Area (µV*sec)
1	System Suitability test	1:A,1	1062	1	1064	1065	1147	1141	Acetaminophen	1142	0.871	68955
2	System Suitability test	1:A,1	1062	1	1064	1065	1147	1141			1.213	90121
3	System Suitability test	1:A,1	1062	1	1064	1065	1147	1141			1.499	99000
4	System Suitability test	1:A,1	1062	1	1064	1065	1147	1141	Caffeine	1143	1.664	109067
5	System Suitability test	1:A,1	1062	1	1064	1065	1147	1141	Acetanilide	1144	2.098	39798
6	System Suitability test	1:A,1	1062	1	1064	1065	1147	1141	Acetylsalicylic Acid	1145	2.785	59302
7	System Suitability test	1:A,1	1062	1	1064	1065	1147	1141			2.829	89074
8	System Suitability test	1:A,1	1062	1	1064	1065	1147	1141	Phenacetin	1146	3.102	63820
9	System Suitability test	1:A,1	1062	2	1069	1070	1148	1141	Acetaminophen	1142	0.871	69341
10	System Suitability test	1:A,1	1062	2	1069	1070	1148	1141			1.211	90589
11	System Suitability test	1:A,1	1062	2	1069	1070	1148	1141			1.497	99962
12	System Suitability test	1:A,1	1062	2	1069	1070	1148	1141	Caffeine	1143	1.664	110371
13	System Suitability test	1:A,1	1062	2	1069	1070	1148	1141	Acetanilide	1144	2.098	40193
14	System Suitability test	1:A,1	1062	2	1069	1070	1148	1141	Acetylsalicylic Acid	1145	2.788	61222
15	System Suitability test	1:A,1	1062	2	1069	1070	1148	1141			2.831	89512
16	System Suitability test	1:A,1	1062	2	1069	1070	1148	1141	Phenacetin	1146	3.106	65476
17	System Suitability test	1:A,1	1062	3	1071	1072	1149	1141			2.938	60289
18	System Suitability test	1:A,1	1062	3	1071	1072	1149	1141	Phenacetin	1146	3.064	88351
19	System Suitability test	1:A,1	1062	3	1071	1072	1149	1141			3.225	65641
20	System Suitability test	1:A,1	1062	3	1071	1072	1149	1141	Acetaminophen		0.869	

Method ID, Version and 'Locked'

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Sample Sets

Standards used for Calibration

Processing Method

Calibration

Original Processing Method

Calibration Curves

Instrument Method

Original Instrument Method

Unchanged Raw Data File

Unique Result

E-cord information

LC/GC System Used

EU04000000439

Product Code/ Stage Reagent LIMS ID

Who Collected
Who Processed
Who Reviewed
Who Approved

When
What
Why

- It is not possible to create, manipulate, modify or delete data inside Empower without creating an audit trail entry
- All user actions are logged in various audit trails and associated with the logged in USERNAME
  - Assumes all users have unique User Account
- Multiple "modes" of audit trail
  - Silent
  - Full – Includes the requirement to enter a reason "Why?"
    - With free form reasons
    - With predefined reasons only (Default Strings)
  - Reauthentication (re entry of password to confirm identity)
- Empower Audit trails are not editable or modifiable by ANY USER

Empower Audit Trails

- Sample Audit Trail
  - Tracks changes to entered data about each sample
- Result Audit Trail
  - Links results to instruments, samplesets, methods, calibration curves and standards used in calibration.
  - Also traces any manual manipulation of data
- Method Audit Trail
  - Keeps all versions of method for recreation of results
  - Audit Trail monitors each change, before and after values, who when and why
  - Different versions can be compared to identify the differences

Empower Audit Trails

- Project Audit Trail
  - Gives overview of all changes in a project
  - Includes details of method / data deletion

- System Audit Trail
  - shows changes to system objects and system policies
  - details archive activity
  - notes all changes to security (users, user types etc)
  - documents all successful and unsuccessful logins
    - you have a history of who was logged into the application at any time
    - you have information about system break in attempts
    - includes the client the login/login attempt occurred at

Empower Sample Audit Trail

Method Properties and Audit Trail

Method Differences

Method Differences

File   Edit   View   Help

	Group	Value Name	Method (Methamphetamine 2 : 5/2/2013 8:10:38 AM EDT (Ver. 5)	Method (Methamphetamine 2 : 4/24/2013 9:12:47 AM EDT (Ver. 4)
11		*Method Revision*	*Version 4 23/01/2003 15:59:13 User HLongden Meth*	*Version 4 7/16/2002 11:16:42 AM User SSmith Method*
12		*Method Revision*	*Version 4 7/16/2002 11:16:42 AM User SSmith Meth*	*Version 4 7/16/2002 11:11:11 AM User SSmith*
13		*Method Revision*	*Version 4 7/16/2002 11:11:11 AM User SSmith*	*Version 3 7/16/2002 11:09:56 AM User SSmith*
14		*Method Revision*	*Version 3 7/16/2002 11:09:56 AM User SSmith*	*Version 2 7/16/2002 11:02:38 AM User SSmith*
15		*Method Revision*	*Version 2 7/16/2002 11:02:38 AM User SSmith*	*Version 1 7/14/2002 10:48:19 AM User SSmith Created*
16		*Method Revision*	*Version 1 7/14/2002 10:48:19 AM User SSmith Crea*	
17	< Expected Mass >			
18		*Component Name*	*Methamphetamine*	
19		*Retention Time*	*8.658*	
20		*Expected Mass 1*		
21		*Expected Intensity 1*		
22		*Expected Mass 2*		
23		*Expected Intensity 2*		
24		*Expected Mass 3*		
25		*Expected Intensity 3*		
26		*Expected Mass 4*		
27		*Expected Intensity 4*		
28		*Expected Mass 5*		
29		*Expected Intensity 5*		
30	< Component >			
31		*Peak Label*	*MethA*	

How to Review Audit Trails

- Purpose
  - To uncover possible cases of fraudulent behaviour
    - Multiple processing data
    - Altering metadata to make results pass
    - Hiding or altering meta data on reports sent to QA
    - Uncovering persistent suspicious behaviour around security of data
    - Ensuring only authorised users have access to certain functionality
    - Deletion of data
    - Altering system policies /configuration / settings without change control procedures
- How?
  - Two possible procedures:
    - Review of relevant audit trails as part of data review
    - Periodic review of system level audit trails by admin

Review of Audit trails

- Review audit trails as part of data review process
  - Find anomalies before batch release
  - Focus of user behaviour that affect results
  - Peer Review / Manager review / QA review?
- Periodic Review of overall Audit trails
  - Looking for system level activity without correct documentation, change control, testing or approval
    - Eg changing system policies, user access or deletion of data

- Biggest issue: Audit trails are often more a log of all activity (to comply) and not designed for easy review
  - But it is expected that inspectors will look at the audit trails

How to Review Audit Trails in Empower?

- Use the Preview and Sign off tools
  - Inform regulatory bodies that electronic signatures are being used in your company
  - Set up system policies to control signature processes
  - Create reports including all relevant meta data and include hte Sign Off property
    - Sample Set, Method details, All versions of Results and all Audit trails
  - Review all pages of report
  - Sign report

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Using Reports and E-Signatures to review and approve results

Selecting policies for GXP and eSigs

- Result Sign off tab
  - Sign off Inactivity delay
  - Clear password
  - Enforce single logon
  - Allow lock channels
  - Save report image as pdf
  - Multiple sign off behavior
  - Enforce sign off 1 before sign off 2

System Policies

User Account | New Project | System Audit Trail | Data Processing | Other | Result Sign Off | E-Mail

Result Sign Off Policies

(ES) ☑ Sign Off Inactivity Delay: 10 minutes
(ES) ☑ Clear password after Sign Off
(ES) ☑ Enforce Single Logon for Sign Off
(GXP) ☑ Allow 'Lock Channels' after Sign Off 2
(GXP) ☑ Save report image (as PDF) after Sign Off
☐ Require Sign Off 1 and Sign Off 2 by Different Users

(GXP) Multiple signoff behavior: Allow the Same Reasons

Valid Sign Off 1 Reason(s):
(GXP) ☑ Enforce Sign Off 1 before Sign Off 2
☐ Data Rejected - all result versions for t
☐ Data rejected - one result only
☐ Authorship
☐ Responsibility

If you are working in a regulated environment, Waters recommends setting the options marked with GXPs and ER. If you are implementing Electronic Signatures, add the option settings marked ES.

Warning: By selecting "cancel", changes made in ALL tabs, including changes made to the LDAP domains, will be undone.

OK | Cancel | Help

Report methods for electronic Signatures

- Report methods to be used for electronic signatures must have 'Allow this method to be used in sign off' checked

- If the content of the method is changed this check box will be automatically deselected and must be selected again before the method can be used for electronic signatures

Report methods for electronic Signatures

- Viewing sign off information in the report
- Add the sign off table to the method

Signing reports

- Report is viewed as normal
- Signature table is displayed

Signing reports

- Review the report and if suitable

- Click the sign off button

- Note

    - Sign off button is greyed out until all the pages of the report have been displayed

Signing reports

- Sign off dialogue box is displayed
- Enter
  - User name
  - Password
  - Reason
- Click sign off
- If signing of for 'Sign off 2'
  - Can lock channels

- Report now contains sign off information

What should be included in an Electronic Signature report

What should be included in an Electronic Signature report

- Should I use a report to review data
- What should go on that report
  - As much as possible
  - Only what is essential

What is essential?

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- ■ Individual Reports or Summary?

- Individual: Each result is signed individual date/ time
  - Can reject one result out of a batch
- Summary: One signature applies to each individual result
  - Same date and time
  - Simplify the signature box on reports with single signing action

- What to do with results which are not signed?
  - Are they superseded results?
  - Do you need to sign as "rejected"?
  - What will you say to an auditor who asks about these results?

What should be included in an Electronic Signature report

- **Chromatogram**
  - One... Some... All... None
  - Full
  - Expanded base line
  - Thumb nail

- **How useful is this for scientific review?**
  - No zoom on integration

- **Could annotations have obscured data?**
  - Only show up on printed reports, not electronic reports

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What should be included in an Electronic Signature report

- Method data
  - Processing... Instrument... Method Set... Sample Set... None
  - Some... All...
  - History
  - ID
  - Version
- Compare Methods
- Train reviewer on Empower traceability

What should be included in an Electronic Signature report

- Sample Set Method?

- Sample Set?

- Channel Information (is it complete? Test injections?)
  - Samples... Standards... Controls... Blanks... None
  - Some... All...
  - Sequence, ID, Channel name

	SampleName	Sample Type	Vial	InJ#	Run Time (Minutes)	Injection Volume (uJ)	Acquisition Method Set	Sample Weight	Processed Channel Descr.	Injection Id
1	PQ Std 2.5x	Standard	1	1	6.00	20.00	LC Demo Method Set	1.00000	254nm	1007
2	PQ Std 5.0x	Standard	2	1	6.00	20.00	LC Demo Method Set	1.00000	254nm	1023
3	PQ Std 10x	Standard	3	1	6.00	20.00	LC Demo Method Set	1.00000	254nm	1027
4	PQ Unk. 1	Unknown	4	1	6.00	20.00	LC Demo Method Set	1.00000	254nm	1031
5	PQ Unk. 2	Unknown	5	1	6.00	20.00	LC Demo Method Set	1.00000	254nm	1035
6	PQ Unk. 3	Unknown	6	1	6.00	20.00	LC Demo Method Set	1.00000	254nm	1039
7	PQ Unk. 4	Unknown	7	1	6.00	20.00	LC Demo Method Set	1.00000	254nm	1043

What should be included in an Electronic Signature report

- Result Information
  - Samples... Standards... Controls... Blanks... None
  - Some... All...
  - ID
  - Result Set Name
  - Result Set ID
  - Altered
  - Manual
  - Peak Codes

SampleName: PQ Std. 2.5x

	Peak Name	RT	Area	Amount	Result #	# Results Stored	Manual	Int Type	Altered	Result Id
1	Butyrophenone	4.781	155794	2.500	26	26	No	BB	Yes	1015
2	Propiophenone	3.110	153589	2.500	26	26	No	BB	Yes	1015
3	Acetophenone	2.132	194108	2.500	26	26	No	BB	Yes	1015
4	Acetone	1.249	194656	937.500	26	26	No	BB	Yes	1015

SampleName: PQ Std 5.0x

	Peak Name	RT	Area	Amount	Result #	# Results Stored	Manual	Int Type	Altered	Result Id
1	Butyrophenone	4.782	314968	5.000	25	25	No	BB	Yes	1025
2	Propiophenone	3.110	310316	5.000	25	25	No	BB	Yes	1025
3	Acetone	1.249	394015	1875.000	25	25	No	BB	Yes	1025
4	Acetophenone	2.132	390990	5.000	25	25	No	BB	Yes	1025

SampleName: PQ Std 10x

	Peak Name	RT	Area	Amount	Result #	# Results Stored	Manual	Int Type	Altered	Result Id
1	Butyrophenone	4.782	626000	10.000	25	25	No	BB	Yes	1029
2	Acetophenone	2.132	771815	10.000	25	25	No	BB	Yes	1029
3	Propiophenone	3.111	614622	10.000	25	25	No	BB	Yes	1029
4	Acetone	1.248	781448	3750.000	25	25	No	BB	Yes	1029

What should be included in an Electronic Signature report

- Calibration information
  - One... Some... All... None
  - Curve plot
  - Equation
  - Calculations
  - ID

What should be included in an Electronic Signature report

- Audit trails
  - Samples... Standards... Controls... Blanks... None
  - Some... All...
  - Sample History
  - Method History
  - Method Versions

How to Review Audit Trails in Preview and Reports?

- Advantage: Evidence of "review"
- Issues:
  - Just because they are on the reports and you looked at the at page, did you actually see anything irregular?
  - Can you pick out " normal" audit records from " non normal"?
  - What real value does this bring to the review process?
  - Creating huge reports for each run, effectively a new " copy" of the electronic data.

How to Review Audit Trails in Empower?

- Review chromatograms, methods and relevant Audit Trails in Empower application

  - Sign a report to document that you have followed the review SOP

    I sign this data to attest that I performed/ reviewed / approved this data according to SOP 12345
    This includes review of all manual entry of meta data (eg weights, dilution and other factors and also the relevant audit trails.)

  - Mimics the review of many other aspects of a method execution

    o Sampling / solution creation/ standard creation

    - No true recording of activity

How to review data in Empower

- Use the Empower project name to open the correct Empower project
- In the result or result set tab search for the ID

- Use right click "View as..." to select
  - Sample Sets
  - Results
  - Peaks
  - Processing methods
  - Instrument Methods
  - Sample Set methods
  - Audit Records

How to review data in Empower

- ## In Results tab
  - Result ID, Processed Manually, number of results for channel, result number, processed by, processed date, Processing method, date acquired, channel, vial, injection, system, label, sampleset id, run time, custom fields, faults, blank, comments, peak codes, number of sign offs, sample name.......

Pharmaceutical\Acetaminophen on EMPOWER3.WORLD as demouser/Administrator - Project

File   Edit   View   Tools   Database   NuGenesis 8 ELN   Help

Filter By: All by Date Proc. (Detailed)   Edit View   Update   Max Rows: 1000

Sample Sets | Injections | Channels | Methods | Result Sets | **Results** | Peaks | Fractions | Sign Offs | Curves | View Filters | Custom Fields | Audit Trails

	SampleName	Vial	Injection	Sample Type	Channel	Processed Channel Descr.	Date Acquired	Date Processed	Processing Method	Processed By	Result #	# of Results Stored	Manual	Faults	Result Id
1	200906485-N99048_2	12	1	Unknown	2487Channel 1		Monday, July 15, 2002 5:15:54 AM EDT	Monday, February 22, 2010 11:22:52 PM EST	Acetaminophen PM	demouser/Administrator	21	21			1690
2	200906485-N99048_1	11	1	Unknown	2487Channel 1		Monday, July 15, 2002 4:14:16 AM EDT	Monday, February 22, 2010 11:22:52 PM EST	Acetaminophen PM	demouser/Administrator	21	21			1689
3	200906483-N99043_2	8	1	Unknown	2487Channel 1		Monday, July 15, 2002 1:09:12 AM EDT	Monday, February 22, 2010 11:22:52 PM EST	Acetaminophen PM	demouser/Administrator	21	21			1688
4	200906483-N99043_1	7	1	Unknown	2487Channel 1		Monday, July 15, 2002 12:07:35 AM EDT	Monday, February 22, 2010 11:22:52 PM EST	Acetaminophen PM	demouser/Administrator	20	20			1687
5	200906484-N99047_2	6	1	Unknown	2487Channel 1		Sunday, July 14, 2002 11:05:57 PM EDT	Monday, February 22, 2010 11:22:52 PM EST	Acetaminophen PM	demouser/Administrator	21	21			1686
6	200906484-N99047_1	5	1	Unknown	2487Channel 1		Sunday, July 14, 2002 10:04:06 PM EDT	Monday, February 22, 2010 11:22:52 PM EST	Acetaminophen PM	demouser/Administrator	19	19			1685
7	Standard 2	14	1	Standard	2487Channel 1		Monday, July 15, 2002 7:19:31 AM EDT	Monday, February 22, 2010 11:22:52 PM EST	Acetaminophen PM	demouser/Administrator	18	18			1684
8	Standard 1	13	1	Standard	2487Channel 1		Monday, July 15, 2002 6:17:34 AM EDT	Monday, February 22, 2010 11:22:52 PM EST	Acetaminophen PM	demouser/Administrator	18	18			1683
9	Standard 2	10	1	Standard	2487Channel 1		Monday, July 15, 2002 3:12:33 AM EDT	Monday, February 22, 2010 11:22:52 PM EST	Acetaminophen PM	demouser/Administrator	18	18			1682
10	Standard 1	9	1	Standard	2487Channel 1		Monday, July 15, 2002 2:10:54 AM EDT	Monday, February 22, 2010 11:22:51 PM EST	Acetaminophen PM	demouser/Administrator	18	18			1681
11	Standard 2	4	2	Standard	2487Channel 1		Sunday, July 14, 2002 9:02:26 PM EDT	Monday, February 22, 2010 11:22:51 PM EST	Acetaminophen PM	demouser/Administrator	18	18			1680
12	Standard 2	4	1	Standard	2487Channel 1		Sunday, July 14, 2002 8:00:50 PM EDT	Monday, February 22, 2010 11:22:51 PM EST	Acetaminophen PM	demouser/Administrator	18	18			1679
13	Standard 1	3	2	Standard	2487Channel 1		Sunday, July 14, 2002 6:59:08 PM EDT	Monday, February 22, 2010 11:22:51 PM EST	Acetaminophen PM	demouser/Administrator	18	18			1678
14	Standard 1	3	1	Standard	2487Channel 1		Sunday, July 14, 2002 5:57:34 PM EDT	Monday, February 22, 2010 11:22:51 PM EST	Acetaminophen PM	demouser/Administrator	18	18			1677
15	Sys Suit	2	1	Unknown	2487Channel 1		Sunday, July 14, 2002 4:55:53 PM EDT	Monday, February 22, 2010 11:22:51 PM EST	Acetaminophen PM	demouser/Administrator	18	18			1672
16	blank	1	1	Unknown	2487Channel 1		Sunday, July 14, 2002 3:54:16 PM EDT	Monday, February 22, 2010 11:22:51 PM EST	Acetaminophen PM	demouser/Administrator	18	18			1671
17	blank	1	1	Unknown	2487Channel 1		Sunday, July 14, 2002 2:52:17 PM EDT	Monday, February 22, 2010 11:22:51 PM EST	Acetaminophen PM	demouser/Administrator	18	18			1670

17 total

- In Sample Set use alter sample
- See if a sample has been altered then right click and Select view
  - Sample History
  - SampleSet method History

How to review data in Empower

- **Sample History**
  - Who
  - What
  - When
  - Why

How to review data in Empower

- SampleSet/Instrument/Processing Method History

  - Name
  - Date
  - ID
  - Version
  - Audit Trail
  - Check differences between version

How to Review Audit Trails in Empower?

- **Concerns**
  - Difficult to FIND all audit records in Empower
  - Complicated SOP to follow
    - Even for experienced Empower users
    - Difficult for non/ new/ infrequent users like QA
  - No automatic documentation of the review process

- Access to integrated chromatograms /results
  - All integration positions
  - Ability to zoom in to examine without reprocessing
- Peak and Result level values
- Instrument Method
- Processing Method
- Calibration Curves
- NOW Direct access Sample Set
- All that was missing was the audit trails

Sample Sets

Standards used for Calibration

Original Processing Method

Calibration Curves

Original Instrument Method

Unchanged Raw Data File

Unique Result

E-cord information

LC/GC System Used

Product Code/ Stage Reagent UMS ID

Who Collected
Who Processed
Who Reviewed
Who Approved

When What Why

Reviewing Audit Trails:
A New tool in FR2

- Designed to make the requirement to review Audit trails simpler
  - Annex 11 and various warning letters
- Launched from Review
  - Where a manager would be looking at Results
- Brings into one window audit records from
  - Project window
  - Manual results
  - Method changes
    - Processing, Instrument, Sample Set (alter sample) and Method Set
    - Allows multiple methods to be compares
- Compares results from superceded results
  - Where results have been reprocessed
  - Compares Areas, RT, Amount etc between two results

Enhanced Data Review
New Result Audit Viewer(RAV)

Result History Table

- Searches the multiple Audit trails for data related to the selected injection
  - Acquisition Log
  - Injection Log
  - Sample Set History (Includes sample set level history, sample level history and method changes)
  - Sample History
  - Method History
  - Audit Trail Records
- Merges data, with different columns and information, into one easy to search table..
  - Some logs are missing ACTION REASON or type... So a N/A is entered
  - Blank columns really were not populated

Result History

Result Differences

- Middle table show all superseded results that are stored in the CURRENT result set
  - Individual results can be selected and brought into review to see " lone results or across result sets
- Selecting these results will compare to the most recent result
  - Selected in the top table
- Select a peak to see peak values and compare across results
  - Faults are still highlighted
  - Differences can be highlighted
  - Can select to ONLY show differences
    - All can be saved as preferences, along with column selection and order

Result Differences

Result Audit Viewer

Differences in the results are in blue. Results outside limits are in red

Manual integration noted in Integration Type field

- Selecting a result in the TOP table will search and display the associated methods in the middle table

- For each type of method an entire method history can be displayed in the middle table

  – Although easier to see in Review graphically

- The bottom table displays the contents of the method version selected

- Selecting two method versions allows methods to be compared

  – Uses the regular "Method Differences" functionality

    o Show Only or Highlight differences

  – Can only compare two methods at one time

  – NB for details of change, use the Result History tab

Result Audit Viewer

Methods differences shown in separate tab

Differences have text search

Questions How would you use this?

- As part of Chromatogram review for all chromatograms?
- Only to investigate where odd integration is seen,
    - Where Manual integration is done?
    - Where data faults or is close to a fault?
- On a random number of samples?

- Would you update SOPs to use this tool?
    - Would you test them
    - And that they were being followed?

- Would you want more information in here?
- How would you document that Audit trail review was done?
- Could we add more tools?