

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......





- 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.

Standard

Solution and

Sample

Preparation

Critical Audit trails

Instrument fit

for us

(Maintenance

and calibration

records)

At each step, where are records created?

Training

records of

operators

Can they be modified? By whom? And how is this traced

Raw Data

Methods for

interpretation

Processed

results

- How is data passed from one system to another?
 - Automatically and validated
 - Manually and Four eyes checked?

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Reported data

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Annex 11: Prompting the question of audit trail review

5

- 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

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



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- 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

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.

Recent Cases of Deliberate Fraud Using e-Records...

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



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Empower Compliance Features: Audit Trails

Biggest Compliance feature in Empower??

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- 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 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

▲▶	Sample Sets Injections Channels Methods Result Sets Results Peaks Fi								
Ē	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			

- Raw Data မြှော်ရာ ID's
 - Missing numbers from mbers
 Channel assigned to
 Assigned to aligettion
 - Assigned tondial.1142,
 - 1143, 1144,

ers

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1145, 1146?

IDs assigned to Cal Curve in Peak View

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▲▶	Sample Sets Injections Channels Methods Result Sets Results Peaks Fractions Sign Offs Curves View Filters Custom Fields											
Ē	SampleName	Vial	Vial ld (Result)	Injection	Injection Id	Channel Id	Result Id	Calibration Id	Name	Curve ld	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	



💽 Inform2012_Tutorial2_Process as Employee_00789/Administrator - QuickStart - [Find Data]									
File Edit View Tools	File Edit View Tools Database Manage Help								
Edit View Update Ma									
Run Samples	▲▶	Sample Sets Injections C	hannels Methods	Result Sets Results Frag	tione Sign Offe	Curvee			
Sample Queue	È.	. Method Name	Method Type	Method Date	Method Version	Method Id	Method Locked		
Control Panel	1	Analgesics	Method Set	4/19/2012 10:40:05 AM CEST	3	1136			
	2	Analgesics_2	Processing	4/19/2012 10:39:31 AM CEST	3	1135			
Browse Project	3	Analgesics	Processing	4/19/2012 10:38:22 AM CEST	2	1134			
	4	Sample Audit Report	Report	4/19/2012 10:36:28 AM CEST	1	1130			
	5	Zeroed Baseline Report	Report	4/19/2012 10:36:28 AM CEST	1	1132			
View Data	6	Sample Summary Table	Report	4/19/2012 10:36:28 AM CEST	1	1131			

Result Audit Trail... more than a table of changes

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- 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

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- 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

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- 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

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	🗢 Alliance UV System in Pharmaceutical_Projectas CWeis/Manager - QuickStart - [Find Data]												
	File Edit View Tools Database M	Manage Help											
	💦 🔤 🔤 🐚 Sample(s) in Pharmaceutical_Project as CWeis/Manager - Alter Sample												
	File Edit View Help												
	Kun Sampies	Sa 🗗 💕 🖬 🖓 🖶	18 IS X 🖻 🖻	N?									
	Control Panel Method Set (
	Sample Histor		Sample Type III	or No. 1. Samplen:	ame i	2 X thod	1	V	Phari				
	Browse Pr File Help	· /					1	Γ	P iari				
							1	◄	Phari				
	View Data		Sample History				1		Phari				
		nois Date: 5/3/2002 12:49:1	6 AM Reason: All sample	e information not kr	now at time of analysis	s	1	L	Phari				
		ed Vial(Lot_No): ≺No Value	> -> SS 4Comp				1		Phari				
	View Metho Method Set 3 User: TBrow	wn Date: 5/3/2002 12:52:31	I AM Reason: Wrong wie	eght values entered	at time of analysis.		1	Γ	Phari				
		ed Vial(SampleVVeight): 1.00)000 -> 23.40000					Γ	Phari				
	Processing						1	\searrow	Phari				
									Phari				
;	User: TBrown Date:	5/3/2002 12:52:3	1 AM Reason:	Wrong wei	ght values ent	ered at time	ofan	nalysi	s.				
	Modified Vial(SampleWeight): 1.00000 -> 23.40000												
	40 3	system suitability 554	Hide Column	standard	Friday, November 3	<u>30, 2001 3:20:10 PI</u>	Ŵ		Phar				
	View Acquisition	SystemSuitability SS 4	Show All Columns	Standard	Friday, November 3	30, 2001 3:17:21 PI	М		Phari				
	50 S	SystemSuitability SS 4	Print Table	Standard	Friday, November 3	30, 2001 3:14:26 PI	M		Phari 🧹				
	<		Table Properties						>				
	For Help, press F1		Column Properties										

Method Properties and Audit Trail

Method Prop	perties			
Type: Pr	ethamphetamine 2 rocessing ified By: Employe Locked By	:		
∟ ⊢ Method His	story		Audit	Trail - Methamphetamine 2
	thod Date	Method Modified Use	File	Help
1 2013 8 2 1/2013 3 1/2013 4 1/2013	8:10:38 AM EDT 3 9:12:47 AM EDT	Employee_00789 HLongden HLongden HLongden	1 2 3 4 5 €	A Version 5 5/2/2013 8:10:38 AM EDT User Employee_00789 forgot peak label Version 4 4/24/2013 9:12:47 AM EDT User System Method (WVaters-s4lehz1\Pharmaceutical\PharmDev Version 4 24/01/2003 16:23:50 User HLongden Method (\Hlongden\PharmaceuticalQA : 1282) copied in Version 4 23/01/2003 15:59:13 User HLongden Method (\Hlongden\Sales_Project : 1363) copied into project. Version 4 7/16/2002 11:16:42 AM User SSmith Method (\Armadam700\TEST : 1446) copied into project. Version 4 7/16/2002 11:11:11 AM User SSmith Method (\Armadam700\TEST : 1446) copied into project.
Differen	nces Print Met	hods Print Histor	у	Save As Current Audit Trail
	ОК	Cancel		Help

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Method Differences

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	Nethod Differences			
File	Edit View Help			
		•		
	Group	Value Name	lethod (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 Creat	
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	

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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 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?

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- 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
(GXP) Image: Final state in the stat
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

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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



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Report methods for electronic Signatures

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



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Signing reports

- Report is viewed as normal
- Signature table is displayed



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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

Sign Off Resu	Sign Off Results							
	There is 1 result available for sign off.							
Sign Off 1								
<u>U</u> ser: de	demouser							
Password:	Password:							
R <u>e</u> ason: 🔼	R <u>e</u> ason: Authorship							
	<u>S</u> ign Off							
Sign Off 2								
Use <u>r</u> :								
P <u>a</u> ssword:								
Reaso <u>n</u> :	•							
	Lock channels after Sign Off							
	Sign Off							
	<u>C</u> lose <u>H</u> elp							

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Report now contains sign off information

Default Individual	Sign Off in Pharr	naceutical\De	faults on EM	POWER3.WORI	LD as demouser/Ac	lministrator 🗖 🗖	
- 	x 🖻 🛍			ad da		u 🔽 🖉	
	Empower2			Defa	ult Individual S	ign Off	
		SAM	PLE IN	FORMATI	O N		
	Sample Name: Samole Tvoe: Vial: Injection #: Injection Volume: Run Time:	PQ Std 5.0x Standard 2 1 20.00 ul 6.0 Minutes		Acquired By: Sample Set Name Acc. Method Set Processing Method Channel Name: Proc. Chnl. Descr.:	LC Demo Method Set LC PQ ApexTrack 488		
	Date Accuired: Date Processed:	Wednesdav. Seo Thursdav. Mav 1		7 5:03:14 PM EDT AM EDT			
	0.050 0.000 0.000 0.000 0.000 0.000 0.000 0.000 0.000	Arctions - 1 - 440	<u>Arthrithmone - 2-152</u>	00000000000000000000000000000000000000	Butyophenone - 4.782		
	0.000	1.00 150	200 250	300 350	400 450 500		
	Г	PeakName	RT Area	Minutes	Amount		
	1 2 3	Aceto ne Aceto pheno ne Propiopheno ne	1.249 394015 2.132 390990 3.110 310316		1875.000 5.000 5.000		
	4	P-1	4.7 02 014 000				
(SampleName Result Id	Sgn Of Full Name	Result Sid	Sign Off Date	Sign Off Reason		
	1 P2 Std 50x 2315 Reported by User. De	Demonstration User (d			ED T Sign Off Level 1, Reason A		
	Report Method: Defa Report Method II250 Page: 1 of 1	ult Individual Sig		,	l Thursday, A	Date Printed: April 18, 2013 M US/Eastern	
real of 1					During	t. Dharmacoutical\I	Defeul

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





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Individual Reports or Summary?





- Maters
- 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?

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- 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





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



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- 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	Mai	hj#	Run Time (Minutes)	hjedion Volume (ul)	Acquistion Mictited Set	Sample Weight	Processel Channel Descr.	injection (d
1	PQ Std 25x	Sandard	1	-	6.00	20.00	LC Deno Method Set	1.00000	254mm	1007
2	PQ Std 5.0x	Sandard	2	1	6.00	20.00	LC Derro Method Set	1.00000	254nm	1023
3	PQ Std 10x	Sandard	3	1	6.00	20.00	LC Derro Michool Set	1.00000	254mm	1027
4	PQ Unk. 1	Unknown	4	1	6.00	20.00	LC Deno Method Set	1.00000	254mm	1081
5	FQ Unk.2	Unknown	5	1	6.00	20.00	LC Derro Method Set	1.00000	254nm	1085
6	FQ Unk.3	Unknown	6	1	6.00	20.00	LC Derro Michool Set	1.00000	254mm	1035
7	PQ Unk. 4	Unknown	7	1	6.00	20.00	LC Derro Method Set	1.0000	254mm	1043



- Result Information
 - Samples... Standards... Controls... Blanks... None
 - Some... All...

– ID

- Result Set Name
- Result Set ID
- Altered
- Manual
- Peak Codes

				Sampler		2 Slu. 2.5X				
	PeakName	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: PO Std. 2.5v

SampleName: PQ Std 5.0x

	PeakName	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

	PeakName	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

Waters

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

– ID



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- 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?

- VVOTECS
- 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
 - Sampling / solution creation/ standard creation
 - No true recording of activity

How to review data in Empower

- THE SCIENCE OF WHAT'S POSSIBLE."
- Use the Empower project name to open the correct Empower project
- In the result or result set tab search for the ID

Pharmaceutical\Acetam	inophen on EMPOWER3.WORLD as demou	ıser/Administrator - Proje	ct		
File Edit View Tools	Database NuGenesis 8 ELN Help				
	5 # N III @ <u>D</u> <u>D</u>				Select Result Set using Select Result Set ID
					Result Set Id =1667
Filter By: Select Result Set ID	Edit View	Jpdate Max Rows: 1000			
Sample Sets Injection	ons Channels Methods Result Sets Re	sults Peaks Fractions	Sign Offs Curves View Filters Cu	stom Fields	
E Result Set Name	Result Set Date	Sample Set Name	Sample Set Start Date	Sample Set N	
1 Acetaminophen ID_Assay	Monday, February 22, 2010 11:22:50 PM EST	Acetaminophen ID_Assay	Sunday, July 14, 2002 2:50:33 PM EDT	8536_02 071	Complete view filter selection criteria.
					Reset OK Help
					_
1 total					

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

Pharmaceutical/Acetaminophen on EMPOWER3.WORLD as demouser/Administrator - Project Edit View Tools Database NuGenesis 8 ELN Help													
			1										
a 2 2 4 4													
Iter By: Select Result Set ID	Edit View	<u>U</u> pdate	Max Rows: 100										
Sample Sets Injections Chann		-											
Result Set Name	Result Set Date		mple Set Name	Sample Set Start Date	Sample Set Method	System Name	Node	System Comments					
New Method	bruary 22, 2010 11:22:50 PM EST	Acetan	ninophen ID_Assay	Sunday, July 14, 2002 2:50:33 PM	EDT 8536_02 071402	B101R319_Waters1	Lacen101r319a		1667				
Review													
Preview/Publisher													
Process													
Print													
Export													
Run Samples													
Copy To Project													
Lock													
nlock Channel													
View As	Sample Sets	- F											
Delete Row(s)	Results												
	Peaks	۱ H							+				
Copy Paste	Processing Methods												
	Instrument Methods												
Hide Column	Sample Set Methods	∕⊦											
Show All Columns	Audit Records								+				
Print Table													
Taule Properties													
Column Projecties													
		+							<u> </u>				
		+							+				



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......

6	Pharmaceutical\Acetaminophen on EMPOWER3.WORLD as demouser/Administrator - Project														
File	File Edit View Tools Database NuGenesis 8 ELN Help														
Г															
Filb	ilter By: All by Date Proc. (Detailed)														
∎	Sample Sets Injections Channels Methods Result Sets Results Peaks Fractions Sign Offs Curves View Filters Custom Fields Audit Trails														
E	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	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 t	otal														

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

a#			3		*a Fa 🔏 🖻 6	Apply Table Pr	eferences	Alter Sample		•					
V	'ial	lnj Vol (uL)	# of Injs	Label	SampleName	Sample Type	Level	Function	Method Set / Report Method	Label Reference	Processing	SampleWeight	Dilutio	on	AI
1		20.0	1		blank	Unknown		Inject Samples	8536_02_MS		Normal	1.00000	1.00	000	t
1		20.0	1	B1	blank	Unknown		Inject Samples	8536_02_MS		Normal	1.00000	1.00	00	
2		20.0	1	X1	Sys Suit	Unknown		Inject Samples	8536_02_MS		Normal	1.00000	1.00	000	
								Clear Calibration	8536_02_MS		Normal				
3		0.0	2	S0101	Stanou, 14	Standard	1	Inject Standards	8536_02_MS		Normal	1.00000	100.0	000	
		20.0	2	00100		Standard	1	Inject Standards	8536_02_MS		Normal	1.00000	100.0	000	
				History		hknown		Inject Samples	8536_02_MS		Don't Process or Report	1.00000	2500.0	000	
	Vi	iew Sa	mple	Set Met	hod History	Unhown		Inject Samples	8536_02_MS		Don't Process or Report	1.00000	2500.0	000	
	Vi	iew A	s Sam	ple Sets		Unkrown		Inject Samples	8536_02_MS		Don't Process or Report	1.00000	2500.0	000	
			s Injec			Unkrown		Inject Samples	8536_02_MS		Don't Process or Report	1.00000	2500.0	000	
			s Char			St idard	1	Inject Standards	8536_02_MS		Normal	1.00000	100.0	000	
			s Resu			standard	1	Inject Standards	8536_02_MS		Normal	1.00000	100.0	000	
	V	IEW A	s nesu	its		Unknown		Inject Samples	8536_02_MS		Don't Process or Report	1.00000	1000.00	000	
	A	da ne				Unknown		Inject Samples	8536_02_MS		Don't Process or Report	1.00000	1000.00	00	
	In	isert R	low			Standard	1	Inject Standards	8536_02_MS		Normal	1.00000	100.00	Di DO	
	D	elete	Row(s)		Standard	1	Inject Standards	8536_02_MS		Normal	1.00000	100.00	0 00	
								Quantitate	8536_02_MS	U*	Normal				
	C							Summarize Custom Fields			Normal				
	C	ору													N
	Pa	aste				L									
	н	ide C	olumr	1		L									
	SI	how A		umns		L									
						L							<u> </u>		
	P	rint Ta	able			L							<u> </u>		-
	Т	able P	roper	ties		L									
				erties		L							<u> </u>		-
-	-			1									<u> </u>		-
															L

Sample History

- Who
- What
- When
- Why

l	_
History	-
e> A2 (Vial): 0.000 Scatte	
Value> A2 (Vial): 0.000 S	
Value> A2 (Vial): 0.000 S	Ξ
No Value> A2 (Vial): 0.000	
4	
	Close

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How to review data in Empower

- VVOIES
- SampleSet/Instrument/Processing Method History
 - Name
 - Date
 - ID
 - Version
 - Audit Trail
 - Check differences between version

Metho	Method Properties													
	hod Information me: 8536_02.0714	02												
Тур	e: Sample Set													
Las	st Modified By: de	mouser												
	Lock Lock	ed By:												
	Clear Being Edited By: demouser													
Meth	hod History													
E	Method Name	Method Type	Method Date	^										
1	8536_02 071402	Sample Set	Monday, February 22, 2010 11:22:34 PM EST											
2														
3														
4	8536_02 071402	Sample Set	Friday, February 05, 2010 5:20:16 PM EST											
5	8536_02 071402	Sample Set	Friday, February 05, 2010 5:17:30 PM EST											
6	8536_02 071402	Sample Set	Friday, February 05, 2010 5:13:46 PM EST											
7	8536_02 071402	Sample Set	Friday, February 05, 2010 5:13:29 PM EST											
8	8536_02 071402	Sample Set	Friday, February 05, 2010 5:05:15 PM EST											
9	8536 02 071402	Sample Set	Friday February 05: 2010 5:03:31 PM EST											
•	▲													
D	Differences Print Methods Print History Save As Current Audit Trail													
	OK Cancel Help													

How to Review Audit Trails in Empower?

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- 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

The Review Tool

- 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



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Reviewing Audit Trails: A New tool in FR2

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- 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)

■ Waters

Inform2012_Tutorial2_Process as Empl File Edit View Tools Plot Proces												
Preview Saved R Alter Sample Run Sample Result Audit Vie	lesults	2.4	12 CA 22 CA	88 <u>68</u>	≝ ¥ <u>⊡</u> [⊾] 7.000			\[2		
Sample Queue	System Suitat			n 1n-I	- F		. 784					
Browse Project	¥ File V ¥ 🙀 🕅	- /iew Hel	nform2012_Tutorial2 p	2_Process	as Employee_0078	9/Admir	iistrator - Kes	uit Audit	viewer			_
View Data							Result	s				_
View Method		Result Id	Sample Name	Manual	Result Comments	Faults	Summary Faults	Result #	Result Superseded			
Method Set	X 8	1160 /	AG Standard 3			Г		10		Injection Volume = 2.00	Acetaminophen Value = 31.250000	0
Brocossing	🖋 9	1161 /	AG Standard 4					10		Injection Volume = 2.00	Acetaminophen Value = 34.400000	0
📋 🗄 🖞 👘	AI 10		\G Standard 5					10		Injection Volume = 2.00	Acetaminophen Value = 37.500000	0 -
	A(A(Result	III t History	Result Differences Pr	rocessing f	Method Sample Set	Method	Instrument N	1ethod M		fter This Date: 1/ 9)/2000 🔽 Upda	ate
Show Me						Reas	on User		Date	Action Type	Source	
📋 👘 🛱 .	Al 1 u	to Addition:	s: Injection Id : 1087	Instrume	nt Method Id : 1063	N/A	System	7/25/201	11 2:21:45 PM C	EST N/A	Acquistion Log	
View Acquisition							System		11 2:28:35 PM	N/A	Sample Set Method Properties	
	3					_	System		11 1:50:32 PM	N/A	Instrument Method Properties	-11
	4					_	Rune Rune		11 7:57:13 AM	N/A N/A	Processing Method Properties Method Set Properties	$- \ $
	6						Rune		11 11:07:47 AM	N/A	Processing Method Properties	$- \parallel$
	7						Rune		11 10:08:34 AM	N/A	Processing Method Properties	$- \parallel$
,	8						Rune	6/16/20	I1 10:01:33 AM	N/A	Instrument Method Properties	
	9						System	6/15/201	11 3:15:36 PM	N/A	Processing Method Properties	

- Waters THE SCIENCE OF WHAT'S POSSIBLE."
- 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

Enhanced Data Review New Result Audit Viewer

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Result History

	Soft Drink Analysis in Reviewer Training\Reviewer as System/Administrator - Result Audit Viewer le View Help																
_			1														
												R	esults				
)	Result Id	Vial Id (Result)	Sample Set Id (Result)	Sample Name	Vial	Injection	Dati Proces		Processing Method	Result Codes	Result Type	Channe	l Name	Processed Channel Descr.	Integration Algorithm	Software Version	Source SMV Info Integr (Result) System
1	2189	1066	2121	Blank	1:A,1	1	1/22/2013 9:31	1:07 PM EST	Soft Drink Assay	S02	LC	ACQUITY	TUV ChA	ACQUITY TUV ChA 214nm	ApexTrack	Empower 3	Empower 3 Software Build 3471 SPs Installed: Feature Release 2 DB ID: 2288045534
2	2190	1069	2121	Reference	1:A,2	1	1/22/2013 9:31		Soft Drink Assay	S02	LC	ACQUITY		ACQUITY TUV ChA 214nm	ApexTrack	Empower 3	Empower 3 Software Build 3471 SPs Installed: Feature Release 2 DB ID: 2288045534
3	2191	1072	2121	Sys Suit	1:A,3	1	1/22/2013 9:31	1:08 PM EST	Soft Drink Assay	S02	LC	ACQUITY	TUV ChA	ACQUITY TUV ChA 214nm	ApexTrack	Empower 3	Empower 3 Software Build 3471 SPs Installed: Feature Release 2 DB ID: 2288045534
																	4
Re	Result History 12 vVonderwoman/Administrator Audit Trail Record Attered Sample Set																
	Image: System/ 13 Belle Processing Method Properties N/A Optimized integration																
	1 System/ 14 Belle Processing Method Properties N/A Optimized integration																
4		15	Belle					Samp	le Set Me	thod Pro	perties		N/A				Modified Sample Name/Amount/Values
6	-	1 10	Belle					Samp	le Set Me	thod Pro	perties		N/A				Corrected bracketing
8		- 17	Belle					Samp	le Set His	tory			N/A				Corrected bracketing
10	_	118	Belle					Samp	ole Set Me	thod Pro	perties		N/A				Corrected bracketing
1:	_	19	Belle					Metho	od Set Pro	operties			N/A				Added processing method
14	Belle	20	Belle					Proce	essing Me	thod Pro	perties		N/A				Optimized Integration
18	_			nple Set Method F	Propertie				Corrected	-						5 4/7/2008 3:16:58 P	
17				nple Set History nple Set Method F	ropertie	N/A			Corrected	-	_					elle Date: 4/7/2008 3:1 4 4/7/2008 3:16:18 P	16:18 PM EDT Reason: Corrected bracketing Modified Sample Set(HPLC_Column) <no belle="" bracketing<="" corrected="" edt="" m="" td="" user="" val=""></no>
19				hod Set Propertie		N/A				cessing method						2 4/7/2008 3:08:58 F	
20	Belle		Pro	cessing Method F	ropertie	s N/A	.		Optimized I	ntegration					Version	3 4/7/2008 3:08:53 P	M EDT User Belle Optimized Integration
•		(m							•
For H	elp, press F	1															

VVOTECS

- 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

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	B0mg_Content Uniformity in Audit Trail Project1 as System/Administrator - Result Audit Viewer File View Help																					
	Results																					
	Ē	Result Id		Sample Nar	ne Manual		Result Comments Faults						Summar Faults	·	Resu Superse					Date Processed		
	15	2481	50120)6-80m	g-CU5 🛛 🗹	requir	red to catch th	ne end of	the tail	for peal	<			38		9	,	1 4/24	/2013 9	:29:55 AN	MEDT I	Meth
	16	2470		νο-ουπί	J-COO -	кеци	neureproces	sing aite	акепп	y samp	ie miorma			36		10		1 4/24	/2013 9	:17:24 AN	MEDT I	Meth +
	After This Date: 12/31/2012 Update Result History Result Differences Processing Method Sample Set Method Instrument Method Set																					
	Superseded Results																					
	È.	Selected	Result Id	s	Sample Name	Manual	I Result Comments				Faults	Summary Faults	Result #	Result Vial Injection Date Processed								
	1	~	2480	50120	06-80mg-CU5	~	integration improved manually					37	~	9	1	1 4/24/2013 9:23:43 AM ED		EDT				
	2	v	2474	50120	06-80mg-CU5		Required re	processii	ng after	altering	sample ir	nformation			36	~	9	1	1 4/24/2013 9:17:24 AM EDT			EDT
l	. ∢ Peak																					- F
		namphetam	hine Dia	Result Id	Name		Area (µV*sec)	Amount	Int Type	Curve Id	Re: Peak Label	sult Difference: Retention Time (min)	s % Area	Height (µ∀)	Units	Peak Type	Re	elative RT (min)	RT Ratio	Start Time (min)	End Time (min)	Baselir (m
			1	2481	Methampheta	mine	10115635	98.112	bb	2465		8.649	100.00	542880		Found				7.700	11.283	
			2	2480	Methamphet	amine	10100090	97.962	Bb	2465		8.649	100.00	542805	;	Found				7.867	9.917	
			3	2474	Methamphet	amine	10086680	97.832	BB	2465		8.649	100.00	542697		Found				7.867	9.525	7
	For Help, press F1																					

Result Audit Viewer

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Naters





- 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
 - Show Only or Highlight differences
 - Can only compare two methods at one time
 - NB for details of change, use the Result History tab

Processing Method Comparison

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	Results																	
Ē	Result Sample Name		Manual	Manual		Result Comments			aults	Summary Faults	Result #	Result Superseded	Vial	Injection		Date Processed		
15	2481 501206-80mg-CU5 🔽 required to catch the end of the tail for peak							38		9	1	4/24/20	13 9:29:55	AM EDT	Meth			
16	2475 5	2475 501206-80mg-CU6 Required reprocessing after altering				r altering sample informa	ation			36		10	1	4/24/20	13 9:17:24	AM EDT	Meth ·	
•																		
													After This Date: 12/31/2012					Update
Resul	t History Re	sult Differences Processing	Method :	Sample Set Meth	od Instrument	Method	Method Set											
	Method History																	
E-	Method Id	Method Id Method Comments		Method Version Metho		ed	Method Date	Meth	Method Modified User		M	Method Name		Method Type		Old Id	Source SA	W Info
1	2183 New Method			4 🗌			4/24/2013 9:12:47 AM EDT	EDT HLongden			Metham	Methamphetamine 2		Processing				
2	2198 New Method			з 🗆		4/24/2013 9:12:47 AM EDT		HLongd	HLongden 1		Metham	Methamphetamine 2		Processing				
3	21	2197 New Method		2		4/24/2013 9:12:47 AM EDT		HLongden		Metham	Methamphetamine 2		Processing					
4	2196 New Method			1			4/24/2013 9:12:47 AM EDT HL		HLongden		Metham	Methamphetamine 2		Processing				
							Method/Differe	ences										
Ē	Group			Value Name			Method (Methamphetamine 2 : 4/24/2013 9:12:47 AM EDT (Ver. 3))				Method (Methamphetamine 2 : 4/24/2013 9:12:47 AM EDT (
12			Netho	Method Revision							Version 1 7/14/2		002 10:-	48:19 AM	User SSmit	h Created n	ethod 'Wethi	amphe
13	-,																	
14			Lower Error Limit (LCL)							98.	98.000							
15	16						98.00					88.444					=	
10				Lower Warning Limit							98.	98.000						
•	4																	

Result Audit Viewer

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QCC	0105_2695_996 in IC	H Impurity Processing as System/A	dministrator - QuickStart - [Review Data Main Window		1			
E		Group	Value Name		Methods			
26	< Integrat	ion Parameters >			differences			
27			Peak Width	2.04	shown in			
28			Detection Threshold	1.400e+002	separate tab			
29	< Compon	ient >						
30			Retention Time	1.761				
31	< System	Suitability Limits >						
32			Field Name	% Adjusted Area				
22		v → L800	Under Connert in it (UCL)	Method Ki Method Comments Method Version Method Locked Method Date Method Modified User A	1			
	Show Me	Find		PM EDT System PM EDT System PM EDT System =	Differences			
Viev	w Acquisition	Find what:		Find PM EDT System	have text			
				PM EDT System	search			
		Any	Case Sensitive					
		Group	me 🔽 Match whole v	Cancel				
				Note: Press F3 to find the next item.				
For Hel	p, press F1							



- 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?