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Qualification & Maintenance for LC System

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USP 1058 Terminology

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According to USP 1058…..

- Instruments are QUALIFIED , Was the instrument built right?
- Processes are VALIDATED , Was the right instrument built?
- AIQ (Analytical Instrument Qualification)
  - *"AIQ Is documented evidence that an instrument performs suitably for its intended purpose and that it is properly maintained and calibrated"*
  - Does not include people (training), processes performed on instruments (analytical methods)
  - Helps to justify the continued use of instrument, but it alone does not ensure quality of the data
- It is easiest to qualify instruments using standardized tests
- Procedures and methods are validated for each specific analysis

Performing AIQ

- **Recommended set of parameters for AIQ:**
  - Design Qualification (DQ)
  - Installation Qualification (IQ)
  - Operational Qualification (OQ)
  - Performance Qualification (PQ)
  - Change Control

- Chosen because they are the most widely understood terms

Operational Qualification - Current

- OQ Parameters: Test operation of instrument as per specifications in the user's environment
  - Test critical parameters to assure required performance
  - Parameters based on manufacturer's recommendation and on user's intended use
  - Secure data storage, backup and archive process

- Performance of OQ
  - Use non-method specific testing
  - Repeat relevant OQ tests when instrument undergoes major repairs or modifications
  - Repeat tests on a regular basis

Operational Qualification – Proposed

- OQ Parameters additions
  - Parameters to qualify described in the general chapters for the analytical technique used
  - Test critical functions under actual operating conditions
  - Demonstrate that the entire system, including software, works as intended
- Performance of OQ addition
  - OQ performed using the same software configuration as that used for routine analysis
- The best and easiest way to meet this requirement is using SystemsQT

Performance Qualification - Current

- PQ tests are performed on a periodic basis to ensure that the instrument remains in qualified state after IQ/OQ
  - Run tests to check and verify satisfactory performance of the instrument
  - These tests can verify suitability of the instrument for your specific intended use and configuration
- Performance of PQ
  - Perform at specified intervals
    - Tests based on good science
    - Tests reflect general use of the instrument
    - Same tests can be used repeatedly to generate history of instrument performance
  - Specifications for PQ tests can be different than for OQ if required
  - Perform after repairs and maintenance
  - Maintain an SOP for operation/calibration/maintenance

Performance Qualification - Proposed

- Instrumentation that fails must be investigated and an explanation provided with the reason for failure
- Addition of periodic review for critical instruments and computer systems

Change Control

- Changes are inevitable as new features are added and corrections are made
- Follow DQ/IQ/OQ/PQ classification process
  - DQ: Review the change; adopt only useful or necessary changes
    - Not making changes for too long can also cause problems
    - Ex: Running unsupported versions of software or firmware
  - IQ: Install the changes
    - Log any changes in the system log
  - OQ/PQ:
    - Revise tests and specifications if necessitated by the change
    - Change SOPs as necessary
    - Perform changed OQ or PQ tests

Pre-use Qualification

Installation Qualification
For each module in the system, enter any requested information into the IQ, and complete any procedures as directed.

↓

Maintenance Procedures
Maintenance is not performed during pre-use qualification. Maintenance Procedures are provided for these purposes:
• *To provide a maintenance log, in which you record all maintenance, repair and qualification performed after startup*
•*.To meet the requirements for instituting standard operating procedures for future maintenance*

↓

Operational (or Module) Qualification
For individually qualified modules, follow the applicable steps..

↓

Vendor Performance (or System) Qualification
For your complete system, use the applicable qualification procedures to verify proper system performance.

Guideline for HPLC Qualification

- Waters System Qualification Tools (SQT) take these guidelines into account

edqm European Directorate for the Quality of Medicines & HealthCare

COUNCIL OF EUROPE CONSEIL DE L'EUROPE

OMCL Network of the Council of Europe
QUALITY MANAGEMENT DOCUMENT

PA/PH/OMCL (11) 04

QUALIFICATION OF EQUIPMENT
ANNEX 1: QUALIFICATION OF HPLC EQUIPMENT

OMCL Checks Identified by Levels

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Level I – Selection of instruments and suppliers
- Best carried out by the user
- Define user requirements
- Assess ability of vendor to train, repair, test etc

Level II – Installation and release for use
- The instrument vendor can perform these steps
- Knowledgeable on proper installation and commissioning practices

Level III – Periodic and motivated instrument checks
- The instrument vendor can assist the user in complying with this guidelines
- Most knowledgeable on design of the instrument

Level IV – In-use instrument checks
- Best carried out by the user
- Most knowledgeable on design of the application or method

Annex 1 Specification Examples

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Examples of requirements for HPLC instruments and detectors

Instrument module	Parameter to be checked	Typical tolerance limits
Solvent delivery system	• Flow rate • Proportioning accuracy and precision (gradient test) • Proportioning ripple	• ± 5 % • ± 2 • ≤ 0,2 %
Injector	• Volume precision • Carry-over	• RSD ≤ 1.0 % • see Annex I
Autosampler	• Thermostatting accuracy and precision	• ± 3 °C
Oven or cooling device	• Thermostatting accuracy	• ± 2 °C
UV/DAD detector	• Linearity • Wavelength accuracy	• $r^2 \geq 0.999$ • ± 2 nm
Fluorescence detector	• Wavelength accuracy excitation • Wavelength accuracy emission • Sensitivity	• ± 3 nm • ± 3 nm • see Annex I
Electrochemical detector	• Accuracy of the signal • Stability of the signal	• see Annex I • see Annex I
RID detector	• Signal/Noise ratio • Drift over time	• see Annex I • ± 0.1 mV/min

Typical Qualification Tests for LC system

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- Solvent Delivery System
  - Flow rate accuracy
  - Flow rate precision
  - Flow rate linearity
- Injector System
  - Injection accuracy
  - Injection linearity
  - Injector precision
  - Injector carryover
  - Sample position accuracy
- Detector System
  - Detector wavelength accuracy
  - Detector absorbance linearity
  - Detector noise and drift

Example 1 - HPLC Flow Linearity and Accuracy

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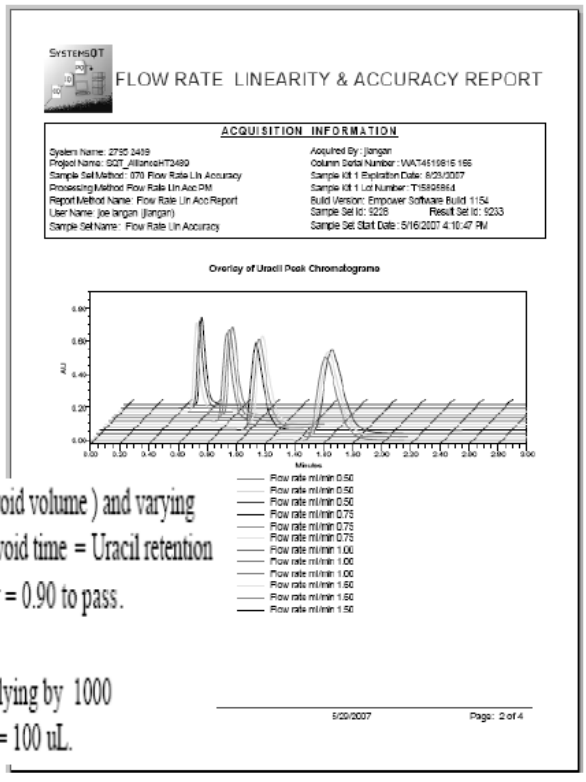
Uracil Flow Rate Linearity & Accuracy Results Table

	Linearity R^2 Specification	Linearity R^2	Linearity R^2 Pass Fail	Accuracy Specification	Accuracy	Accuracy Pass Fail
1	R^2 > or = 0.90	1.00	PASS	< or = 100 ul	1	PASS

Accuracy Calculation : Flow rate Accuracy = |Y intercept/Slope| * 1000

Y intercept = -0.001423 Slope = 1.240509

Flow rate Accuracy = |-0.001423 / 1.240509 | * 1000 = 1.1


FLOW RATE LINEARITY & ACCURACY REPORT

ACQUISITION INFORMATION

Overlay of Uracil Peak Chromatograms

Flow rate linearity is determined by injecting a Uracil solution (which elutes in the void volume) and varying the flow rate. The plot generated is the plot of 1/void time versus flow rate (where void time = Uracil retention time). The flow rate linearity coefficient of determination (R^2) must be R^2 > or = 0.90 to pass.

Flow rate accuracy is calculated by dividing the y -intercept by the slope and multiplying by 1000 (to convert from mL to uL). The flow rate accuracy passes when the result is < or = 100 uL.

Example 2 - System Precision

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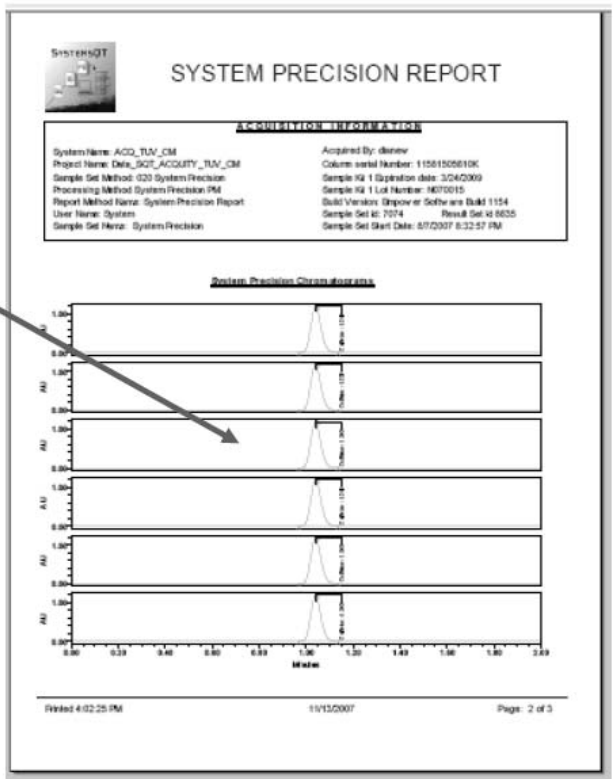
%RSD of
6 Replicate
Injections


SYSTEM PRECISION REPORT

ACQUISITION INFORMATION

System Name: ACQ_TUV_CM
Project Name: Beta_SQT_ACQUITY_TUV_CM
Sample Set Method: 020 System Precision
Processing Method: System Precision PM
Report Method Name: System Precision Report
User Name: System
Sample Set Name: System Precision

Acquired By: dlanew
Column serial Number: 115615056101K
Sample Kit 1 Expiration date: 3/24/2009
Sample Kit 1 Lot Number: N070015
Build Version: Empower Software Build 1154
Sample Set Id: 7074 Result Set Id 8635
Sample Set Start Date: 8/7/2007 8:32:57 PM

System Precision Chromatograms

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UV Caffeine Area and Height Results Table

	Area %RSD Specification	Area %RSD	Area %RSD Pass Fail	Height %RSD Specification	Height %RSD	Height %RSD Pass Fail
1	%RSD < or = 0.5	0.2	PASS	%RSD < or = 1.1	0.2	PASS

UV Caffeine Retention Time (RTsec) Results Table

	Retention Time (sec) Standard Deviation Specification	Retention Time (sec) Standard Deviation	Retention Time (sec) Standard Deviation Pass Fail
1	SD RT < or = 1.0sec	0.0	PASS

Example 3 - Gradient Performance

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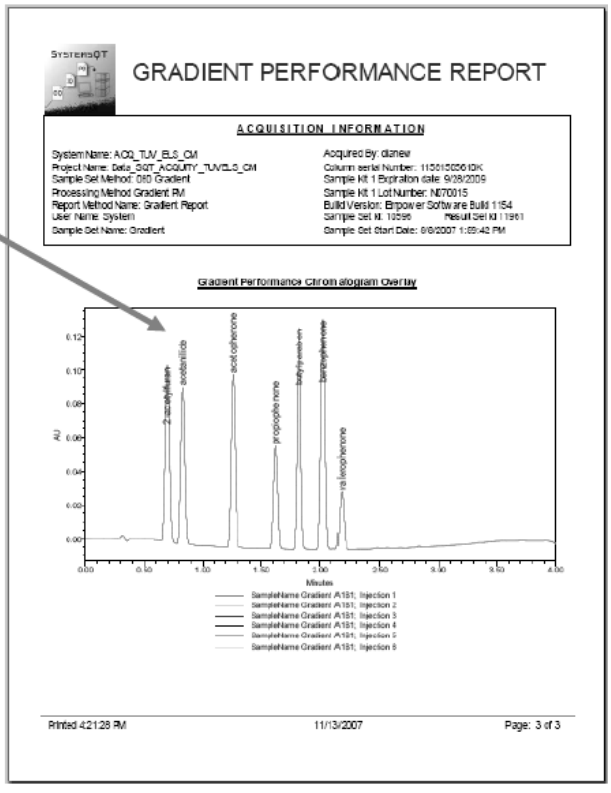
SD of Retention
Time from each
of 7 Peaks over
Six Injections

SD must be < or = 1.0 sec


GRADIENT PERFORMANCE REPORT

ACQUISITION INFORMATION

System Name: ACQ_TUV_ELS_CM
Project Name: Beta_SQT_ACQUITY_TUVELS_CM
Sample Set Method: 080 Gradient
Processing Method: Gradient PM
Report Method Name: Gradient Report
User Name: System
Sample Set Name: Gradient

Acquired By: dlanew
Column serial Number: 115615056101K
Sample Kit 1 Expiration date: 9/28/2009
Sample Kit 1 Lot Number: N070015
Build Version: Empower Software Build 1154
Sample Set Id: 10596 Result Set Id 11961
Sample Set Start Date: 9/6/2007 1:59:42 PM

Gradient Performance Chromatogram Overlay

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Note: In this UPLC case, there are two high pressure pumps.

Example 4 - Compositional Accuracy

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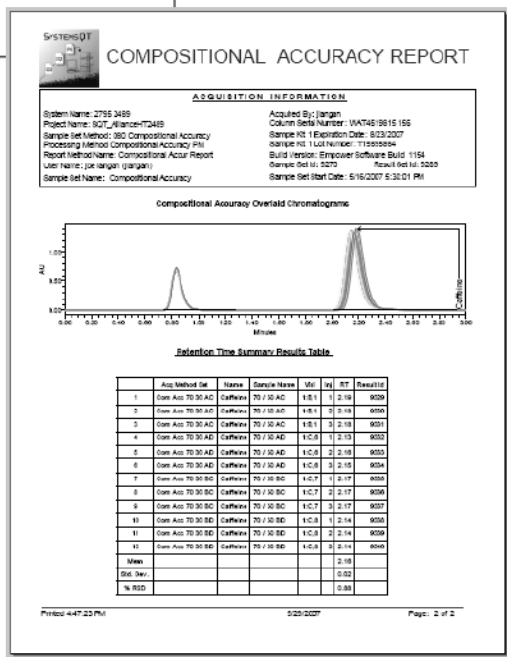
The compositional accuracy test determines that the solvent management system can deliver a solvent mixture within acceptable criteria . The same sample is injected and eluted using different combinations of solvent reservoirs . If the proportioning valves are working properly , there should be very little variation in the caffeine retention time . The compositional accuracy test passes if the %RSD of the caffeine retention time is < or = 3.0 %.

Caffeine Compositional Accuracy Results Table

	Compositional Accuracy Specification Caffeine Retention Time %RSD	Caffeine Retention Time %RSD	Compositional Accuracy Pass Fail
1	RT %RSD < or = 3.0	0.9	PASS


COMPOSITIONAL ACCURACY REPORT

ACQUISITION INFORMATION

Compositional Accuracy Overlaid Chromatograms

Retention Time Summary Results Table

Note: In this case, we are testing one pump with low pressure mixing capability of 4 solvents

Example 5 - Injector Linearity and Accuracy

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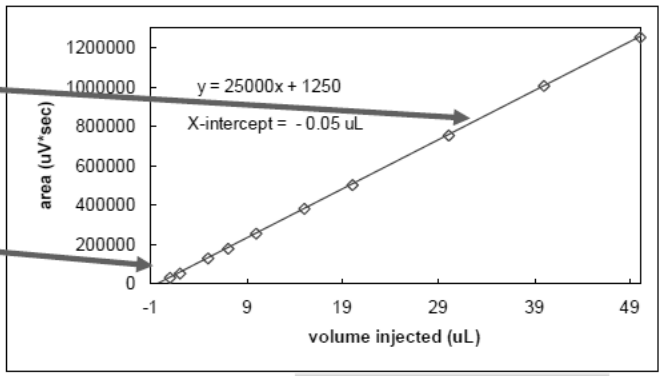
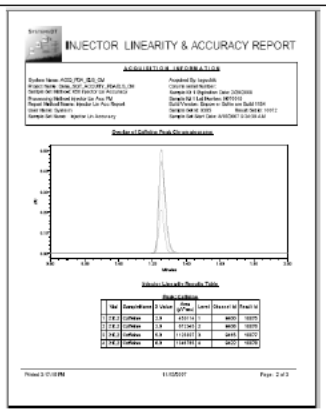
Linearity = R^2 of curve

Accuracy = X Intercept



Caffeine Injector Linearity & Accuracy Results Table

	Linearity R^2 Specification	Linearity R^2	Linearity R^2 Pass Fail	Injection Accuracy Specification	Injection Accuracy	Injection Accuracy Pass Fail
1	R^2 > or = 0.9990	1.0000	PASS	< or = 0.2 ul	0.0	PASS


INJECTOR LINEARITY & ACCURACY REPORT

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Example 6 - Wavelength Accuracy

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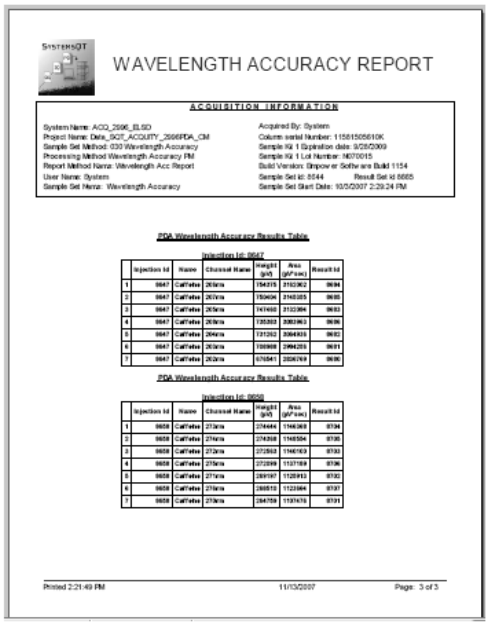
λ Max' For Caffeine



WAVELENGTH ACCURACY REPORT

ACQUISITION INFORMATION

PDA Wavelength Accuracy Results Table

	Injection Id	Name	Channel Name	Height (µV)	Area (µV*sec)	Result Id
1	8647	Caffeine	205nm	1764375	31923621	8694
2	8647	Caffeine	207nm	1594294	31403355	8695
3	8647	Caffeine	207nm	1674490	31523894	8693
4	8647	Caffeine	205nm	1753203	32023463	8696
5	8647	Caffeine	204nm	1731263	32044335	8692
6	8647	Caffeine	203nm	1709908	31942255	8691
7	8647	Caffeine	202nm	1705841	31936769	8696

PDA Wavelength Accuracy Results Table

	Injection Id	Name	Channel Name	Height (µV)	Area (µV*sec)	Result Id
1	8658	Caffeine	273nm	2744444	51463363	8704
2	8658	Caffeine	274nm	2743369	51465364	8705
3	8658	Caffeine	272nm	2725853	51461433	8703
4	8658	Caffeine	275nm	2722998	51371769	8706
5	8658	Caffeine	271nm	2691597	51259153	8702
6	8658	Caffeine	276nm	2685515	51231664	8707
7	8658	Caffeine	270nm	2647581	51074176	8701

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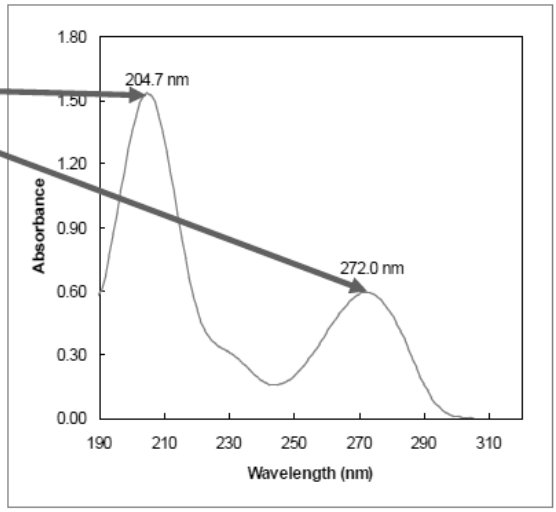

Wavelength Accuracy Results

	Specification 1	Lambda Max	Lambda Max Pass Fail
1	203nm-207nm	206	PASS

	Specification 2	Lambda Max	Lambda Max Pass Fail
1	271nm-275nm	273	PASS

Example 7 - Detector Linearity and Sensitivity

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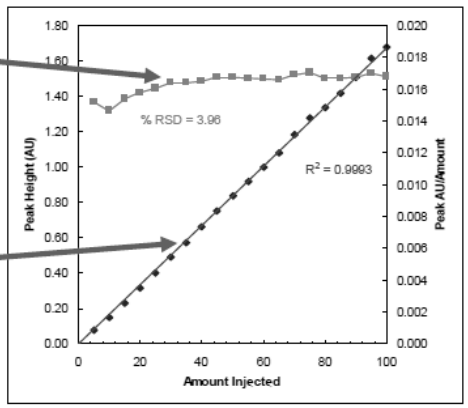
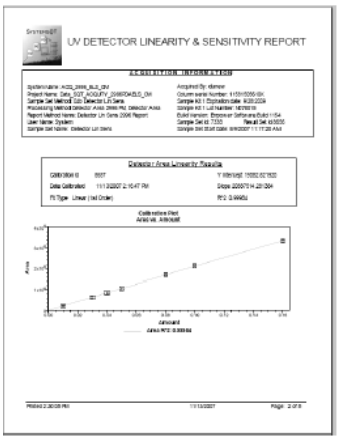
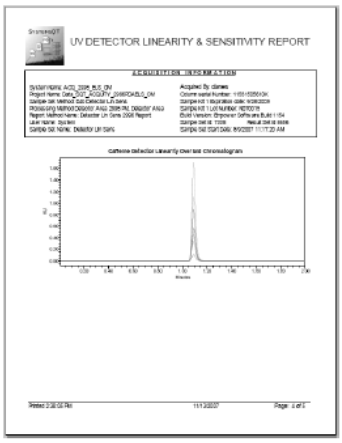
Sensitivity is %RSD Of Peak Heights / Amounts

Linearity is R^2 of curve





UV DETECTOR LINEARITY & SENSITIVITY REPORT



UV DETECTOR LINEARITY & SENSITIVITY REPORT

Detector Area Linearity

	Area Linearity Curve R2 Specification	Area Linearity Curve R2	Area Linearity Curve R2 Pass Fail
1	R^2 > or = 0.9990	0.9998	PASS

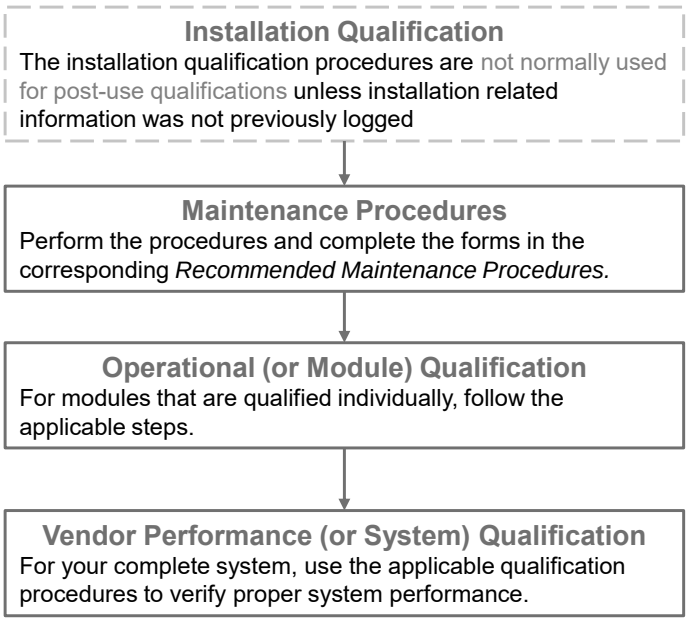
Detector Area Sensitivity

	Area Sensitivity %RSD Specification	Area Sensitivity %RSD	Area Sensitivity %RSD Pass Fail
1	%RSD < or = 3.5	0.8	PASS

What do really know after these tests?

- Solvent Delivery System
  - motors work correctly
  - The gradient are working properly and the mixing valve (low pressure mixing) all actuate without sticking
- Injector System
  - syringe drive motors, valves and gears all work as intended.
- Detector System
  - gratings, mirrors, cell and lamp are functioning as intended in terms of directing light through the cell and that the correct wavelengths are used

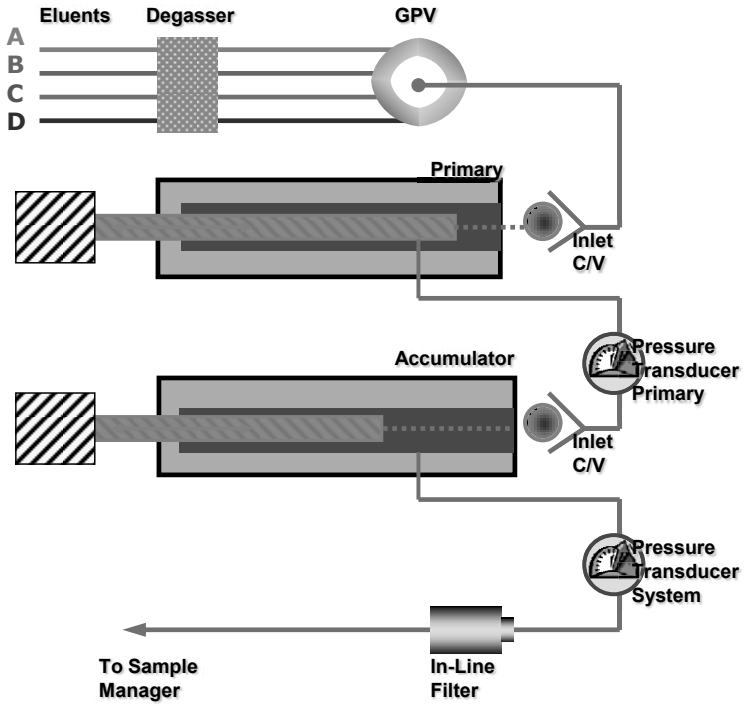
Post-use Qualification

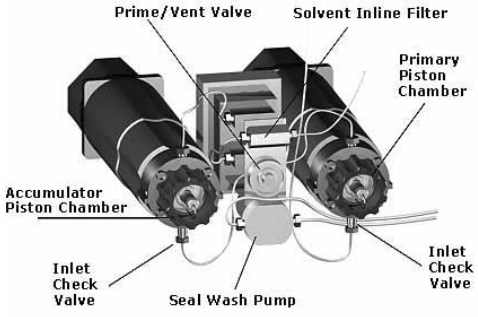


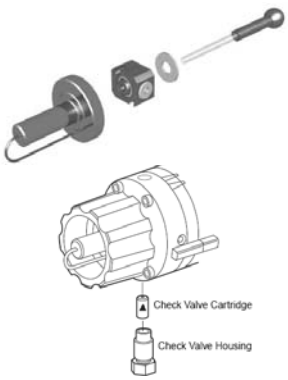
Recommended Qualification Procedure - Pump

Repair Type and Affected Device	Procedure
Major repair • Pump motor driver PCBs • Gears • Piston drives • Pump castings • Pump control modules	Requalify each parts
Minor repair • Check valves • Check valve cartridges • Plungers • Seals • Pressure transducer • Gradient proportioning valves • Column heater • Column heater/cooler	 Static leak test Static leak test Static leak test Static leak test Verify proper zero and pressure increase Verify gradient valve proportioning or gradient operation Verify temperature accuracy Verify temperature accuracy

Solvent Management Schematic Alliance e2695 as an example



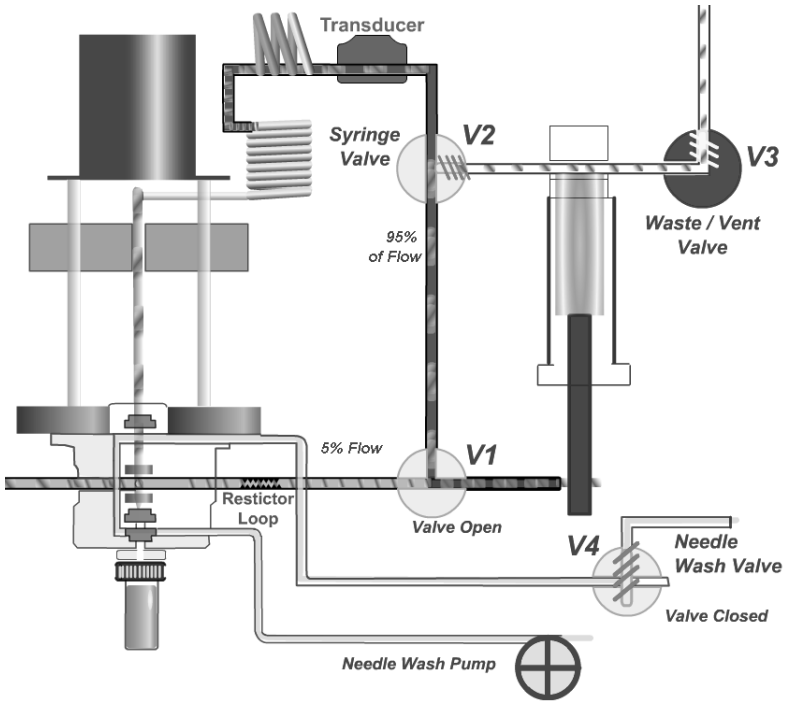


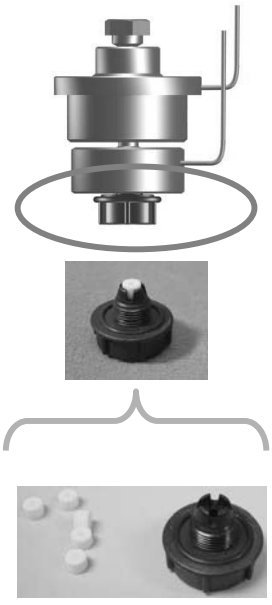


Recommended Qualification Procedure - Injector

Repair Type and Affected Device	Procedure
Major repair • Injector/valve driver PCBs • Injector assemblies • Valve assemblies	Requalify each parts
Minor repair • Sample positioning drives • Pressure transducers • Seal pack and needle • Valve seals • Sample heater/cooler • Column heater • Column heater/cooler	 Verify sample positioing accuracy Verify zero and deflection at pressure Verify injector accuracy Verify injector accuracy Verify temperature accuracy Verify temperature accuracy Verify temperature accuracy

Sample Management Schematic Alliance e2695 as an example





Recommended Qualification Procedure – Optical detectors

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Repair Type and Affected Device	Procedure
Major repair • Cell assembliers • Analog PCBs • Preamp PDBs • Photodiodes • Optics benches • Gratings • Grating drive devices • Mirrors • Beam splitters • Photodiode arrays • Photomultiplier tubes • Optical slits • Filter wheel replacement • Drift tube • Nebulizer • Nebulizer heater/cooler	Requalify each parts
Minor repair • Lamps • Cell windows	Verify lamp calibration via start-up diagnostics Verify lamp calibration via start-up diagnostics

Advantages of using CDS Managed Qualification

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- Accurate Qualification Testing and Analysis
  - Less opportunity for human error
  - Measures peak areas, peak heights and retention times accurately and consistently
  - Custom field calculations and regression analysis
  - Testing consistent from system to system
  - Reduces time that system is off-line by about half
  - Multiple systems can be qualified at once
  - Qualifies software and systems in their analytical configuration
  - Qualifies using same peak processing and quantitation algorithms as during use on CDS system of record
  - Demonstrates system level fitness for chromatographic use

Empower SQT (System Qualification Tool)

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- Built into Empower
- Secure and Auditable Qualification Data
  - 21 CFR Part 11 Compliant Ready Qualification Data
  - All of your data is maintained on your CDS
  - On-Line Qualification Documentation for Easy Inspection
  - Easy tracking and trending of qualification results
  - Audit trails and method change control part of the data system
  - No need for external spreadsheets or third party software
  - Secure data environment
  - On-line review and approval available

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Empower 3 Audit Trial Overview

Michelle Ho
Informatics BD Manager – APAC
June 2017

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Empower Audit Trails

- Understand the Information in the Audit Trails and what causes an entry to be made in these Audit Trails
- Differentiate between the various Audit Trails
  - System
  - Project
  - Method
  - Sample
  - Sample Set
  - Result

  System Audit Trail=specific to installation to Empower

  All data related Audit Trails are in the project

Empower Audit Trails ID numbers

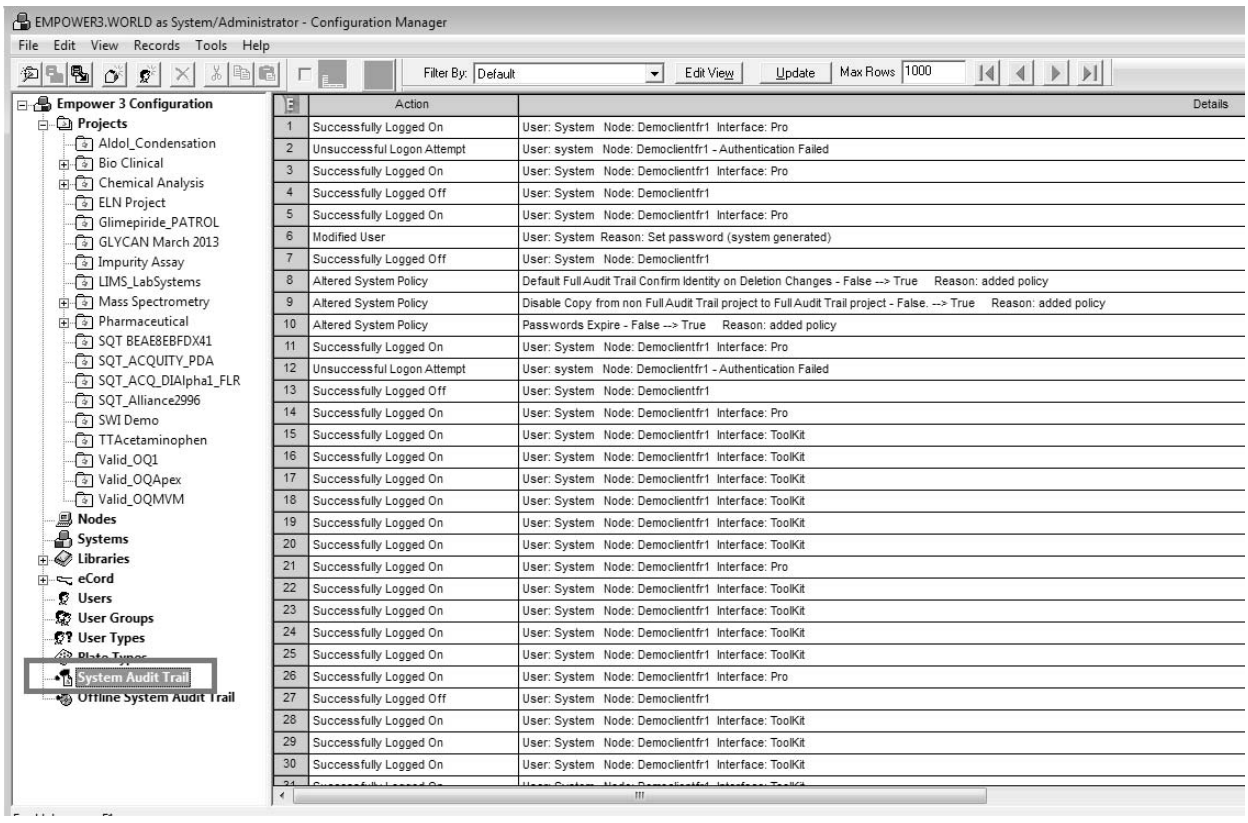
- Empower is built into an Oracle Database
- This database gives each object or result a Unique Identifier for tracking the values and records
- This identifier is unique within each project.
- Modification of any data base object results in a NEW record with NEW identifiers (Nothing is ever over written but versioned)
- Many users of Empower use these ID number to prove and identify results to auditors
  - Also to track for their own purposes

Empower Audit Trail

- 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?)

Audit Trail – System Audit Trail



What is System Audit Trail

- System Audit Trail keeps track of actions taken at the system level.
- The audit trail is divided into the following fields:
  - Action
  - Details
  - Date and time stamp as the when the action took place
  - User – Who took the action
- The 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

System Audit Trail examples…

	Action	
1	Successfully Logged On	User: System Node: Democlientfr1 Interface: Pro
2	Unsuccessful Logon Attempt	User: system Node: Democlientfr1 - Authentication Failed
3	Successfully Logged On	User: System Node: Democlientfr1 Interface: Pro
4	Successfully Logged Off	User: System Node: Democlientfr1
5	Successfully Logged On	User: System Node: Democlientfr1 Interface: Pro
6	Modified User	User: System Reason: Set password (system generated)
7	Successfully Logged Off	User: System Node: Democlientfr1
8	Altered System Policy	Default Full Audit Trail Confirm Identity on Deletion Changes - False --> True Reason: added policy
9	Altered System Policy	Disable Copy from non Full Audit Trail project to Full Audit Trail project - False. --> True Reason: added policy
10	Altered System Policy	Passwords Expire - False --> True Reason: added policy
11	Successfully Logged On	User: System Node: Democlientfr1 Interface: Pro
12	Unsuccessful Logon Attempt	User: system Node: Democlientfr1 - Authentication Failed
13	Successfully Logged Off	User: System Node: Democlientfr1
14	Successfully Logged On	User: System Node: Democlientfr1 Interface: Pro
15	Successfully Logged On	User: System Node: Democlientfr1 Interface: ToolKit
16	Successfully Logged On	User: System Node: Democlientfr1 Interface: ToolKit
17	Successfully Logged On	User: System Node: Democlientfr1 Interface: ToolKit

Empower Project Audit Trails

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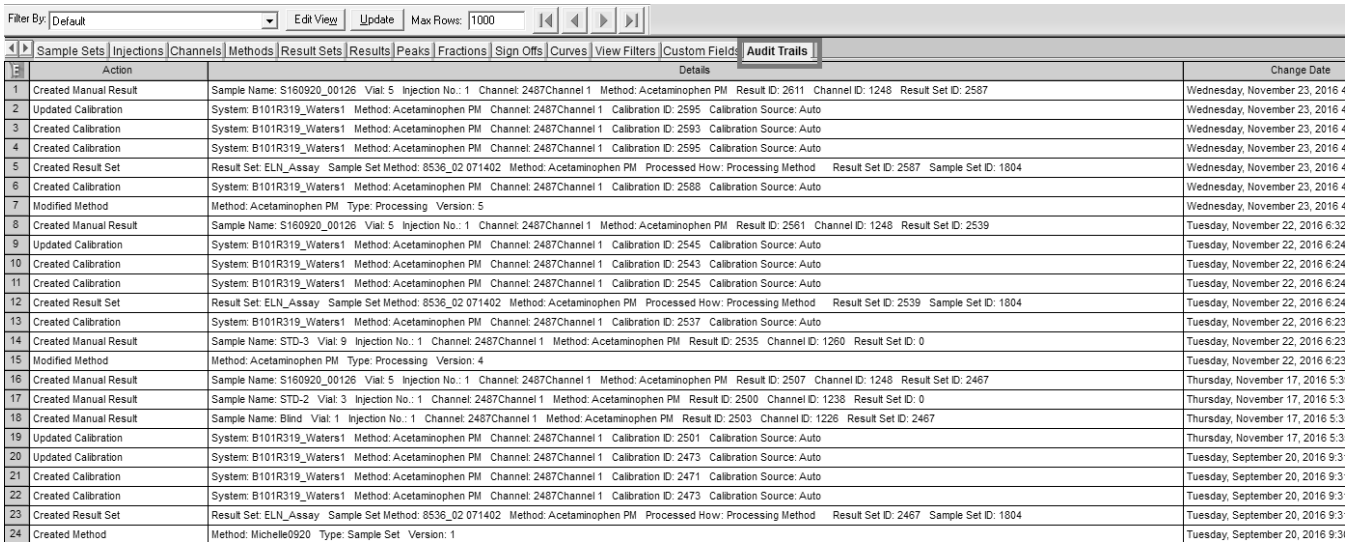
- The Project audit trail keeps track of action taken within the project. Each project has its own unique audit trail.



	Action	Details	Change Date
1	Created Manual Result	Sample Name: S160920_00126 Vial: 5 Injection No.: 1 Channel: 2487Channel 1 Method: Acetaminophen PM Result ID: 2611 Channel ID: 1248 Result Set ID: 2587	Wednesday, November 23, 2016 4
2	Updated Calibration	System: B101R319_Waters1 Method: Acetaminophen PM Channel: 2487Channel 1 Calibration ID: 2595 Calibration Source: Auto	Wednesday, November 23, 2016 4
3	Created Calibration	System: B101R319_Waters1 Method: Acetaminophen PM Channel: 2487Channel 1 Calibration ID: 2593 Calibration Source: Auto	Wednesday, November 23, 2016 4
4	Created Calibration	System: B101R319_Waters1 Method: Acetaminophen PM Channel: 2487Channel 1 Calibration ID: 2595 Calibration Source: Auto	Wednesday, November 23, 2016 4
5	Created Result Set	Result Set: ELN_Assay Sample Set Method: 8536_02 071402 Method: Acetaminophen PM Processed How: Processing Method Result Set ID: 2587 Sample Set ID: 1804	Wednesday, November 23, 2016 4
6	Created Calibration	System: B101R319_Waters1 Method: Acetaminophen PM Channel: 2487Channel 1 Calibration ID: 2588 Calibration Source: Auto	Wednesday, November 23, 2016 4
7	Modified Method	Method: Acetaminophen PM Type: Processing Version: 5	Wednesday, November 23, 2016 4
8	Created Manual Result	Sample Name: S160920_00126 Vial: 5 Injection No.: 1 Channel: 2487Channel 1 Method: Acetaminophen PM Result ID: 2561 Channel ID: 1248 Result Set ID: 2539	Tuesday, November 22, 2016 6:32
9	Updated Calibration	System: B101R319_Waters1 Method: Acetaminophen PM Channel: 2487Channel 1 Calibration ID: 2545 Calibration Source: Auto	Tuesday, November 22, 2016 6:24
10	Created Calibration	System: B101R319_Waters1 Method: Acetaminophen PM Channel: 2487Channel 1 Calibration ID: 2543 Calibration Source: Auto	Tuesday, November 22, 2016 6:24
11	Created Calibration	System: B101R319_Waters1 Method: Acetaminophen PM Channel: 2487Channel 1 Calibration ID: 2545 Calibration Source: Auto	Tuesday, November 22, 2016 6:24
12	Created Result Set	Result Set: ELN_Assay Sample Set Method: 8536_02 071402 Method: Acetaminophen PM Processed How: Processing Method Result Set ID: 2539 Sample Set ID: 1804	Tuesday, November 22, 2016 6:24
13	Created Calibration	System: B101R319_Waters1 Method: Acetaminophen PM Channel: 2487Channel 1 Calibration ID: 2537 Calibration Source: Auto	Tuesday, November 22, 2016 6:23
14	Created Manual Result	Sample Name: STD-3 Vial: 9 Injection No.: 1 Channel: 2487Channel 1 Method: Acetaminophen PM Result ID: 2535 Channel ID: 1260 Result Set ID: 0	Tuesday, November 22, 2016 6:23
15	Modified Method	Method: Acetaminophen PM Type: Processing Version: 4	Tuesday, November 22, 2016 6:23
16	Created Manual Result	Sample Name: S160920_00126 Vial: 5 Injection No.: 1 Channel: 2487Channel 1 Method: Acetaminophen PM Result ID: 2507 Channel ID: 1248 Result Set ID: 2467	Thursday, November 17, 2016 5:3
17	Created Manual Result	Sample Name: STD-2 Vial: 3 Injection No.: 1 Channel: 2487Channel 1 Method: Acetaminophen PM Result ID: 2500 Channel ID: 1238 Result Set ID: 0	Thursday, November 17, 2016 5:3
18	Created Manual Result	Sample Name: Blind Vial: 1 Injection No.: 1 Channel: 2487Channel 1 Method: Acetaminophen PM Result ID: 2503 Channel ID: 1226 Result Set ID: 2467	Thursday, November 17, 2016 5:3
19	Updated Calibration	System: B101R319_Waters1 Method: Acetaminophen PM Channel: 2487Channel 1 Calibration ID: 2501 Calibration Source: Auto	Thursday, November 17, 2016 5:3
20	Updated Calibration	System: B101R319_Waters1 Method: Acetaminophen PM Channel: 2487Channel 1 Calibration ID: 2473 Calibration Source: Auto	Tuesday, September 20, 2016 9:3
21	Created Calibration	System: B101R319_Waters1 Method: Acetaminophen PM Channel: 2487Channel 1 Calibration ID: 2471 Calibration Source: Auto	Tuesday, September 20, 2016 9:3
22	Created Calibration	System: B101R319_Waters1 Method: Acetaminophen PM Channel: 2487Channel 1 Calibration ID: 2473 Calibration Source: Auto	Tuesday, September 20, 2016 9:3
23	Created Result Set	Result Set: ELN_Assay Sample Set Method: 8536_02 071402 Method: Acetaminophen PM Processed How: Processing Method Result Set ID: 2467 Sample Set ID: 1804	Tuesday, September 20, 2016 9:3
24	Created Method	Method: Michelle0920 Type: Sample Set Version: 1	Tuesday, September 20, 2016 9:3

Project Audit Trails

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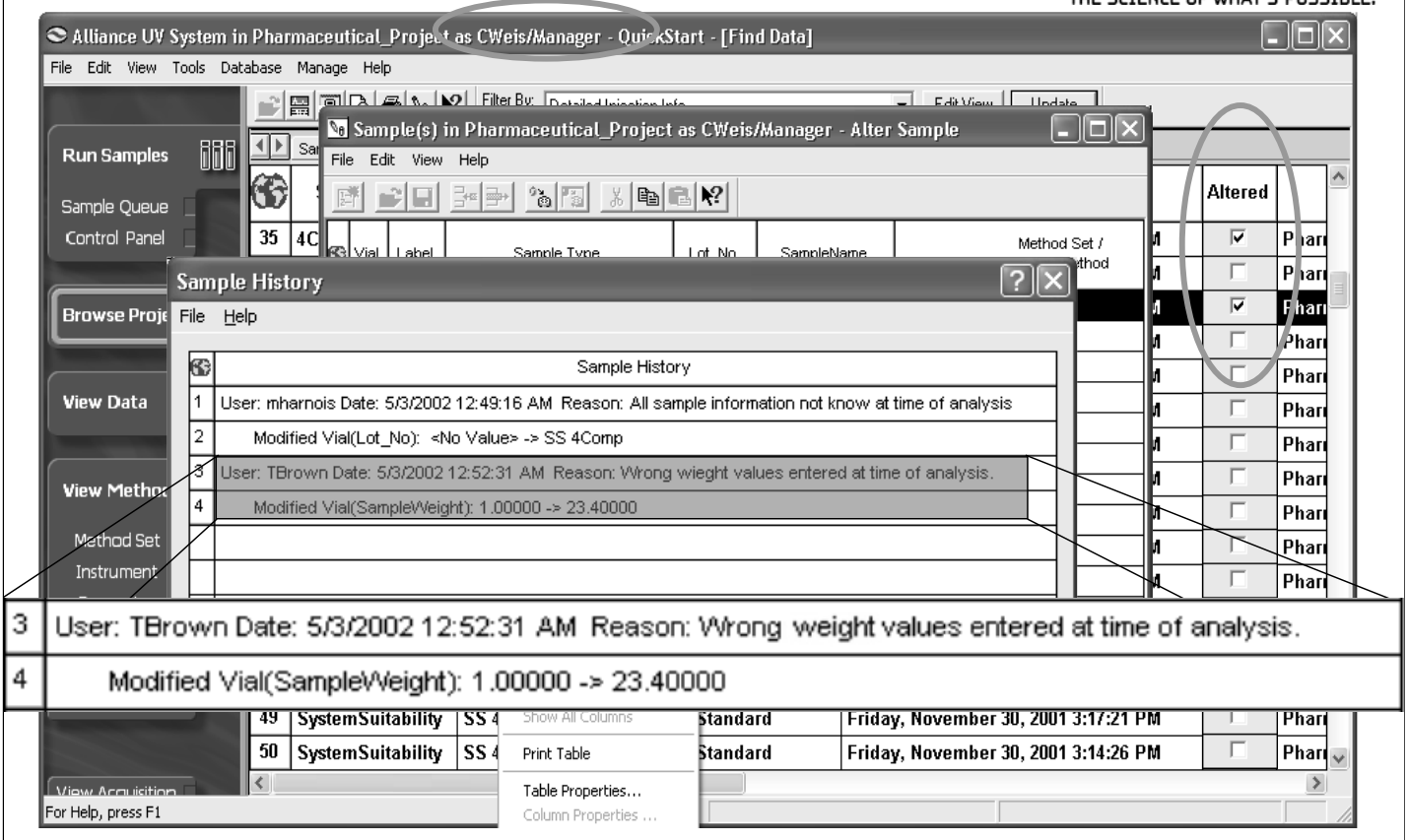
- Sample Audit Trail
  - Tracks changes to entered data about each sample
- Result Audit Trail
  - Links results to instruments, samplesets, methods, calibration curves and standards used in calibration.
  - Also traces any manual manipulation of data
- Method Audit Trail
  - Keeps all versions of method 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

Built in Audit Trails in Empower

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

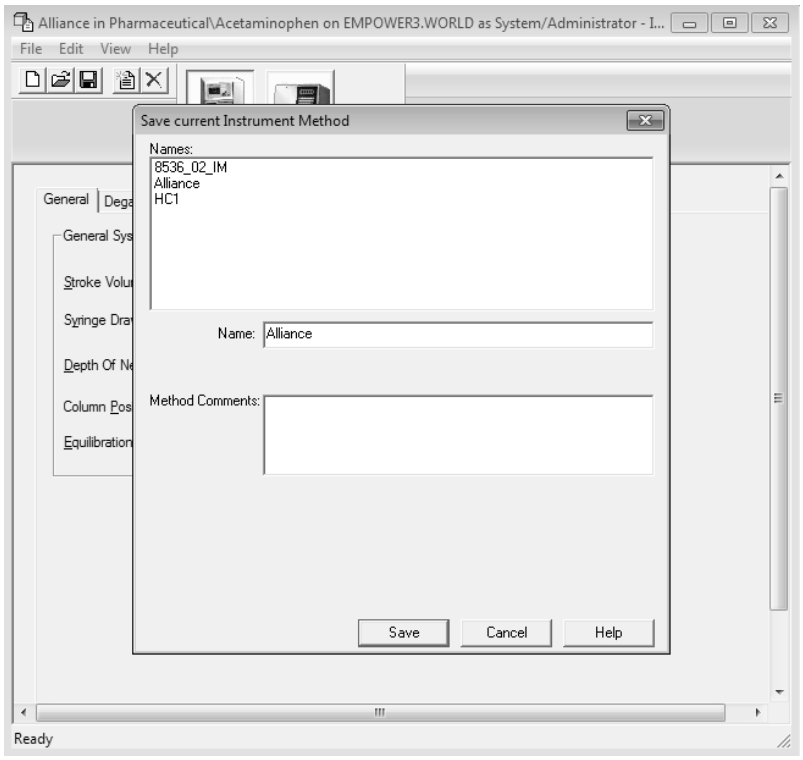
Empower Sample Audit Trail



Audit Trail comments

It is recommended that you enter a comment which reflects why you made a change.

Empower already tracks **what** you changed in the audit trail.



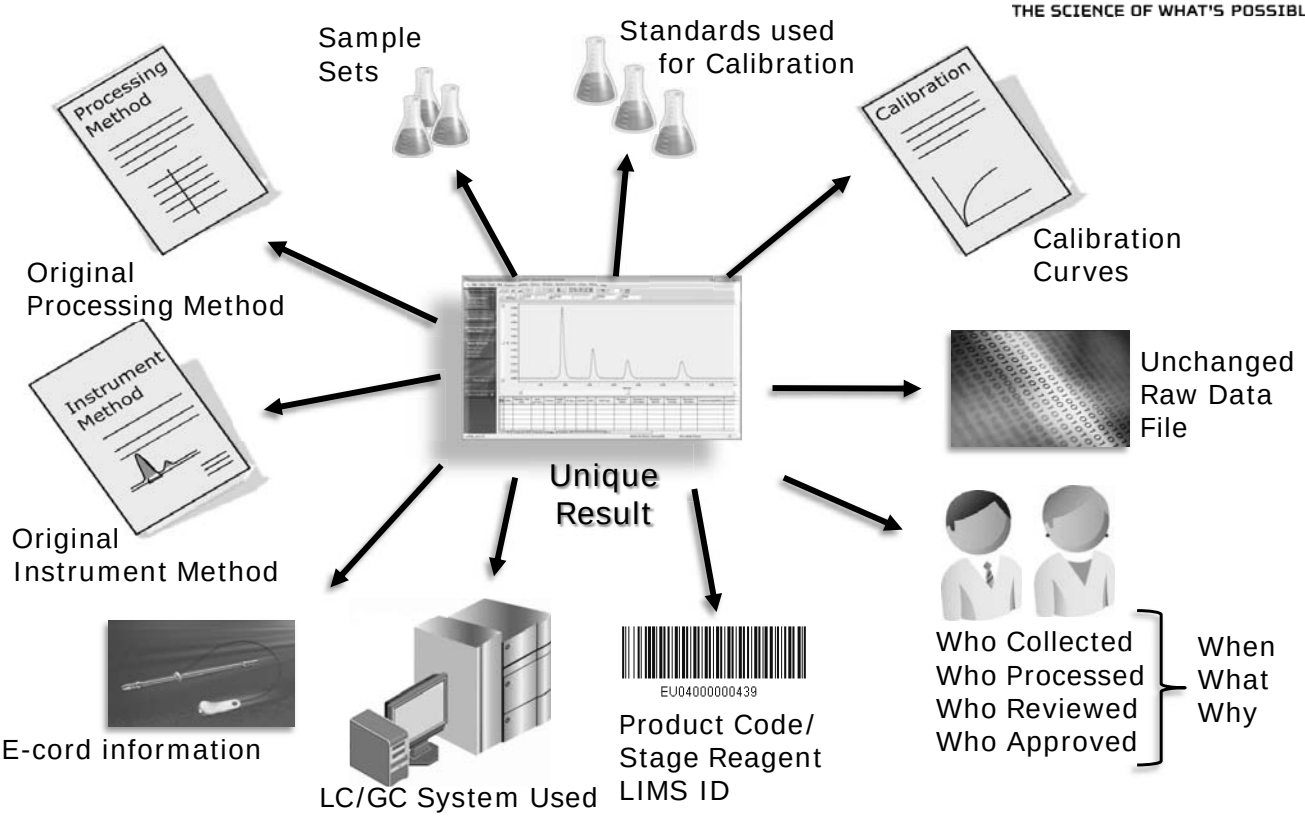
Audit Trial summary

- There are a variety of Audit Trails through out Empower keeping track of critical activities.
- As a Data reviewer it is important to understand the information tracked in these audit trails and what caused entries to be made.
- Comments entered should reflect why a change was made. The audit trails already track what was changed.

Result Audit Viewer

- Understand how to use the Result Audit Viewer. This tool is designed to help the user review all the history that contributed to the generation of one Empower result.
- Access audit trails information for results in one window.
- As more companies are reviewing data electronically the workflow would be to use the Result audit reviewer before sign offs.
- Electronic Sign-off would be used to confirm that the results had been reviewed.

Result Audit Trail...



Result Audit Viewer Tool

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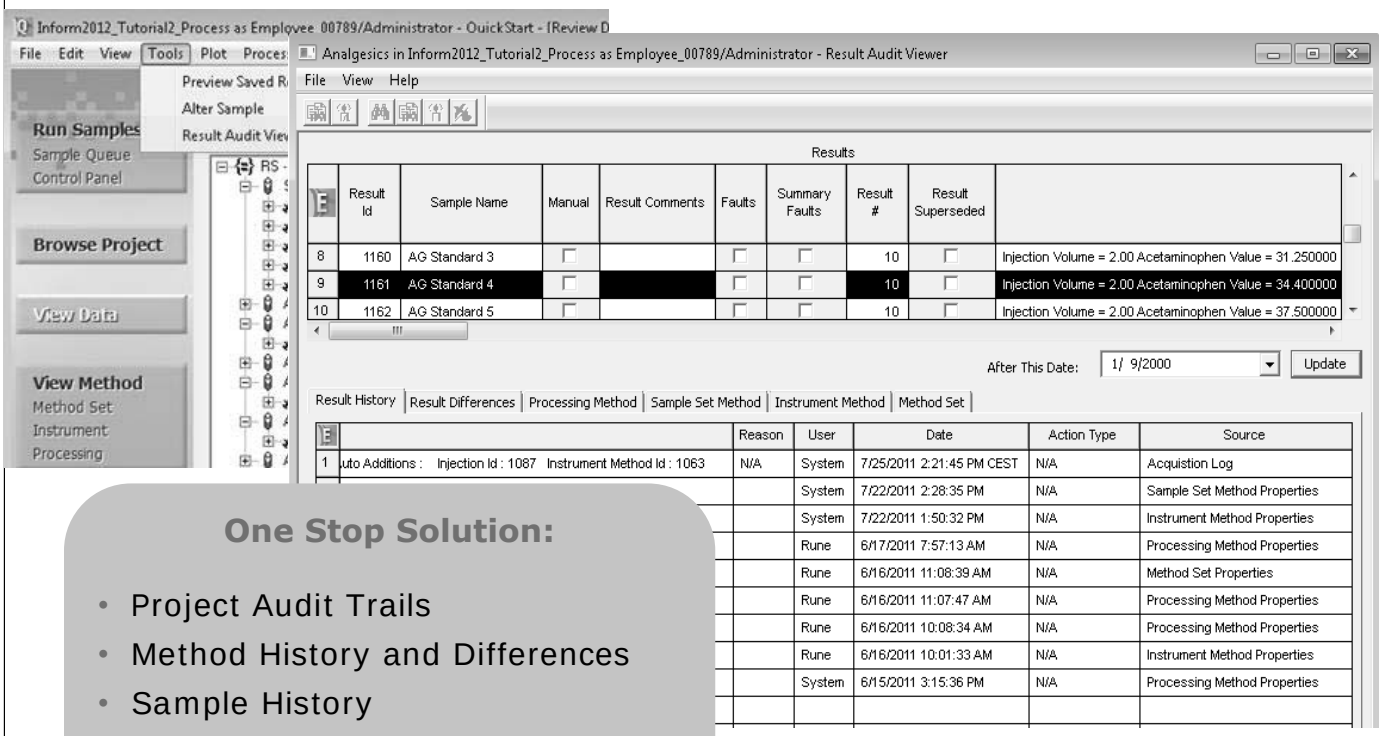

One Stop Solution:

- Project Audit Trails
- Method History and Differences
- Sample History
- Sample Set History
- Acquisition Log
- Injection Log

New in Feature Release 2

Result Audit Viewer

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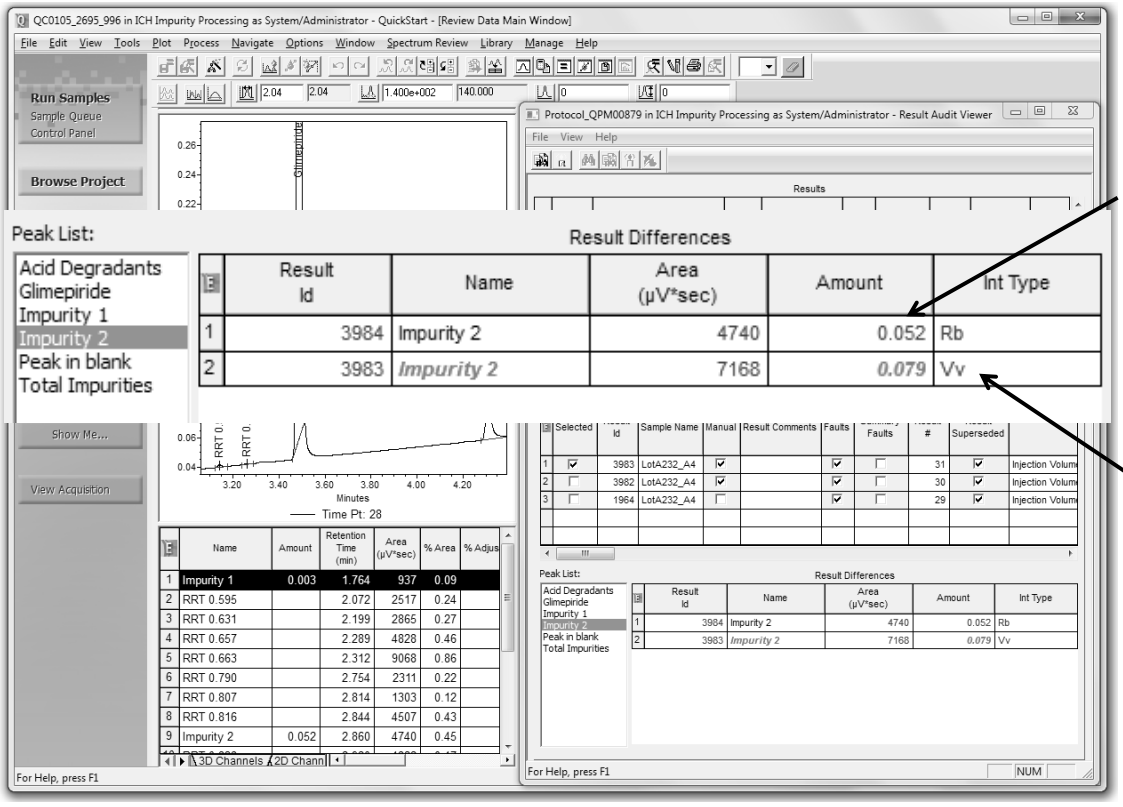

Differences in the results are in blue. Results outside limits are in red

Manual integration noted in Integration Type field

New in Feature Release 2

Result Audit Viewer Summary

- Result Audit Viewer brings together all the audit history related to the result set in view. Audit history is pulled from various locations in the software which were explored in Chapter 4
- Result Audit Viewer additionally aids the user in comparing result changes and identify manual manipulations/faults in a result set.

Questions/Discussion

DEMO

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