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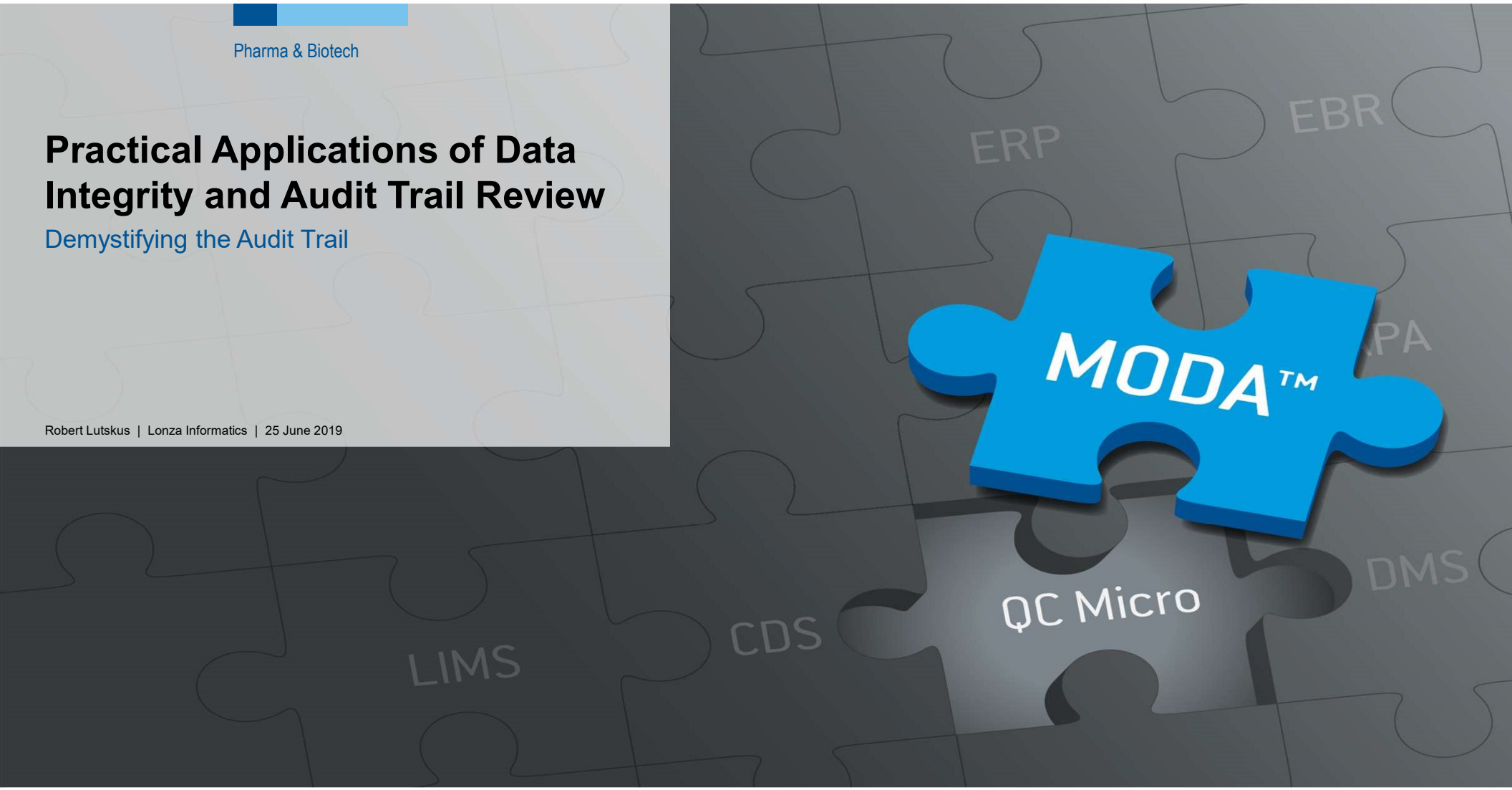
Pharma & Biotech

Practical Applications of Data Integrity and Audit Trail Review

Demystifying the Audit Trail

Robert Lutskus | Lonza Informatics | 25 June 2019



Agenda

- Regulatory requirements
  - ALCOA +
  - Current Guidance
  - What does it look like on paper
  - Is this new?
- Today's Expectations
  - Regulatory Requirements
- Types of Audit Trails
  - Types of audit trails (Data and System)
  - Understand what is in the application audit trail
  - Examples of Good, Bad and Ugly Audit Trails
  - System Selection considerations
- How to Review
  - Critical Audit Trail Data
  - Risk Assessment
  - Periodic Review
  - Documentation

Regulatory Requirements

Regulatory Requirements

ALCOA + Refresher

- **Attributable**
  - Data must be recorded so that it can be linked to the unique individual who produced it. Every piece of data entered into the record must be capable of being traced back to the time it was taken and to the individual who entered it.
- **Legible**
  - Data must be traceable, permanent, readable, and understandable by anyone reviewing the record. This is expanded to include any metadata pertaining to the record.
- **Contemporaneous**
  - Data are data that are summarily entered into the record at the time they are generated.
- **Original**
  - Data, or the source data, is the record medium in which the data was first recorded. An original data record should include the first data entered and all successive data entries required to fully detail the scope of the project.
- **Accurate**
  - Data are correct, truthful, complete, valid, and reliable. Controls put in place to assure the accuracy of data should be implemented on a risk-based structure.
- **Complete**
  - Data including any repeat or reanalysis performed on the sample.
- **Consistent**
  - All elements of the analysis such as the sequence of events follow on and are date or time stamped in the expected sequence.
- **Enduring**
  - Not recorded on the back of envelopes, cigarette packets, sticky notes, or the sleeves of a coat but in notebooks or electronic media in the data systems of instruments.
- **Available**
  - Data can be accessed for review and audit or inspection over the lifetime of the record.

Regulatory Requirements

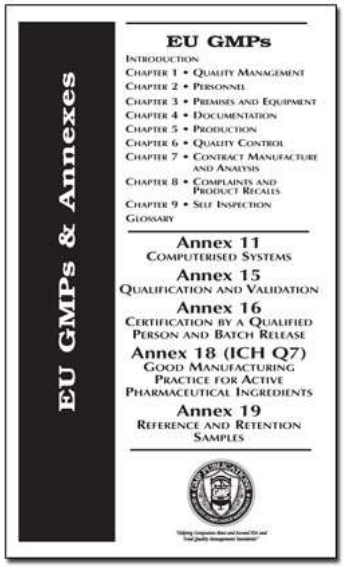
- **Core purpose for the audit trail?**

Regulatory Requirements

- 21 CFR Part 11 Subpart B Sec 11.10 Controls for Closed Systems
- *Use of secure, computer-generated, time-stamped audit trails to independently record the date and time of operator entries and actions that create, modify, or delete electronic records. Record changes shall not obscure previously recorded information. Such audit trail documentation shall be retained for a period at least as long as that required for the subject electronic records and shall be available for agency review and copying*

Regulatory Requirements

- EudraLex Volume 4 Annex 11: Computerised Systems
- *"Consideration should be given, based on a risk assessment, to building into the system the creation of a record of all GMP-relevant changes and deletions (a system generated "audit trail"). For change or deletion of GMP-relevant data the reason should be documented. Audit trails need to be available and convertible to a generally intelligible form and regularly reviewed."*



Regulatory Requirements

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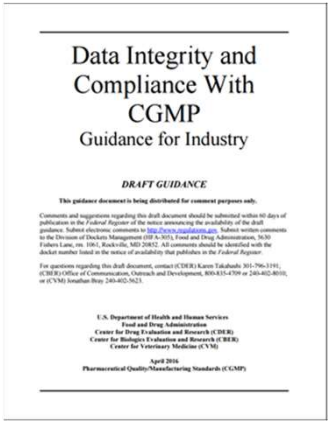
- PIC/S Good Practices for Data Management and Integrity in Regulated GMP/GDP Environments
- *"Where available, audit trail functionalities for electronic-based systems should be configured properly to capture general system events as well as any activities relating to the acquisition, deletion, overwriting of and changes to data for audit purposes."*
- *"Audit trails should be verified during validation of the system."*
- *"Companies should implement procedures that outline their policy and processes for the review of audit trails in accordance with risk management principles"*

Regulatory Requirements

System Audit Trail

- FDA Data Integrity and Compliance with CGMP
- *"Regarding audits, FDA recommends that audit trails that capture changes to critical data be reviewed with each record and before final approval of the record. Audit trails subject to regular review should include, but are not limited to, the following: the change history of finished product test results, changes to sample run sequences, changes to sample identification, and changes to critical process parameters. FDA recommends routine scheduled audit trail review based on the complexity of the system and its intended use."*



Data Integrity and Compliance With CGMP

Guidance for Industry

DRAFT GUIDANCE

This guidance document is being distributed for comment purposes only.

U.S. Department of Health and Human Services
Food and Drug Administration
Center for Drug Evaluation and Research (CDER)
Center for Biologics Evaluation and Research (CBER)
Center for Veterinary Medicine (CVM)

April 2016
Pharmaceutical Quality/Manufacturing Standards (CGMP)

Regulatory Requirements

System Audit Trail

- MHRA
- *"An audit trail provides for secure recording of life-cycle details such as creation, additions, deletions or alterations of information in a record, either paper or electronic, without obscuring or overwriting the original record. An audit trail facilitates the reconstruction of the history of such events relating to the record regardless of its medium, including the "who, what, when and why" of the action."*
- *"Routine data review should include a documented audit trail review where this is determined by a risk assessment."*

Regulatory Requirements

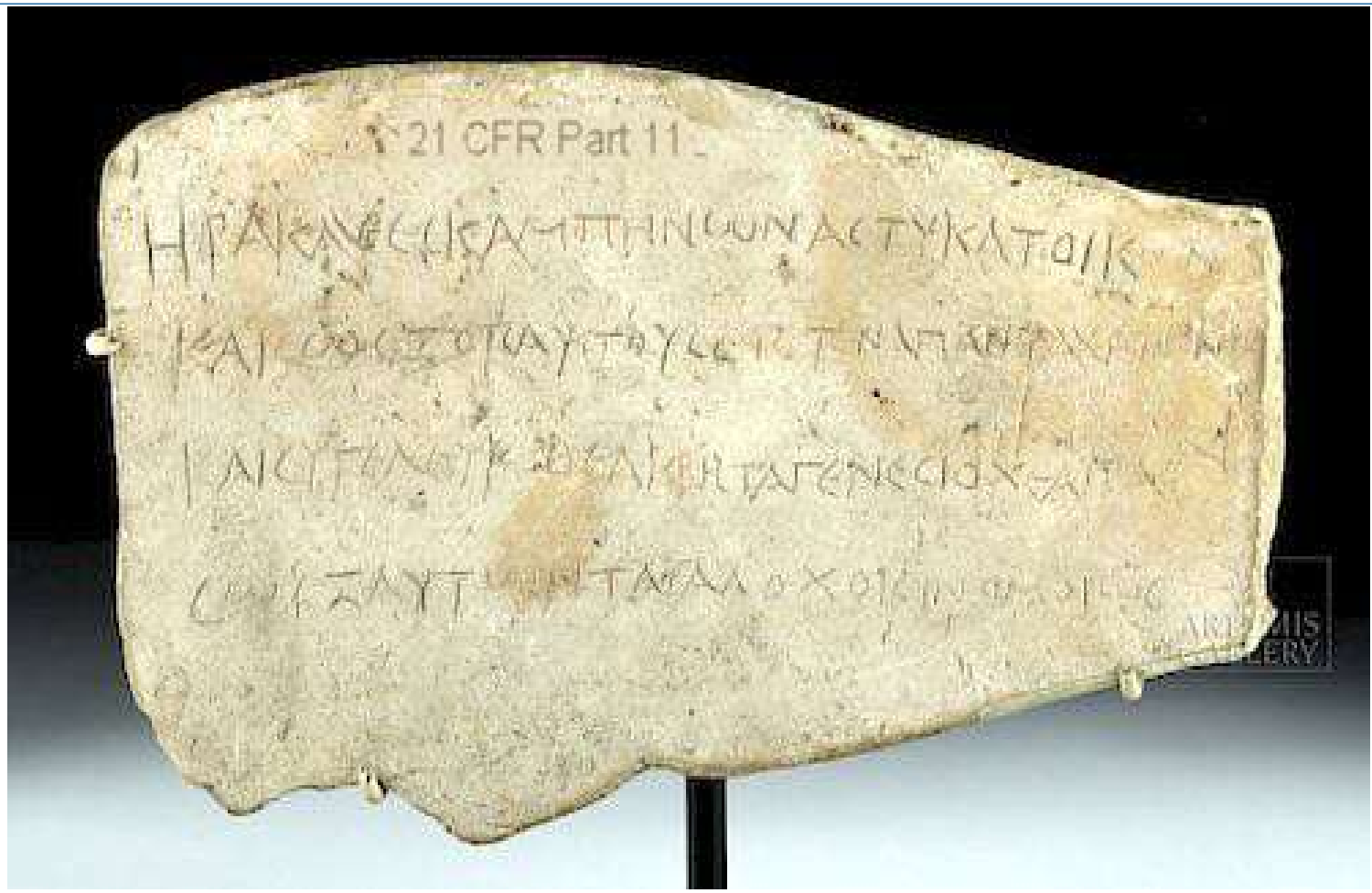
Paper Audit Trail

Step	Test description	Actual Result	Tester Sign / Date
1.	Record Equipment number and Temperature	Equipment Number ~~INC~~ ~~INCOT~~ INC02 Temperature ~~95~~ ~~35.0~~ 35	RL 26Feb2019

① Wrong Measurement 26 Feb 2019 RL
② Incorrect Rounding 26 Feb 2019 RL
③ Write over 26 Feb 2019 RL
④ Incorrect Equipment ID 26 Feb 2019 RL

Regulatory Requirements

- Dated requirements
  - 21 CFR Part 11 – 1997 (2003)
  - Annex 11 – 2011
- Recent Guidance
  - PIC/S - 2016
  - FDA- 2018
  - MHRA – 2018



Regulatory Requirements

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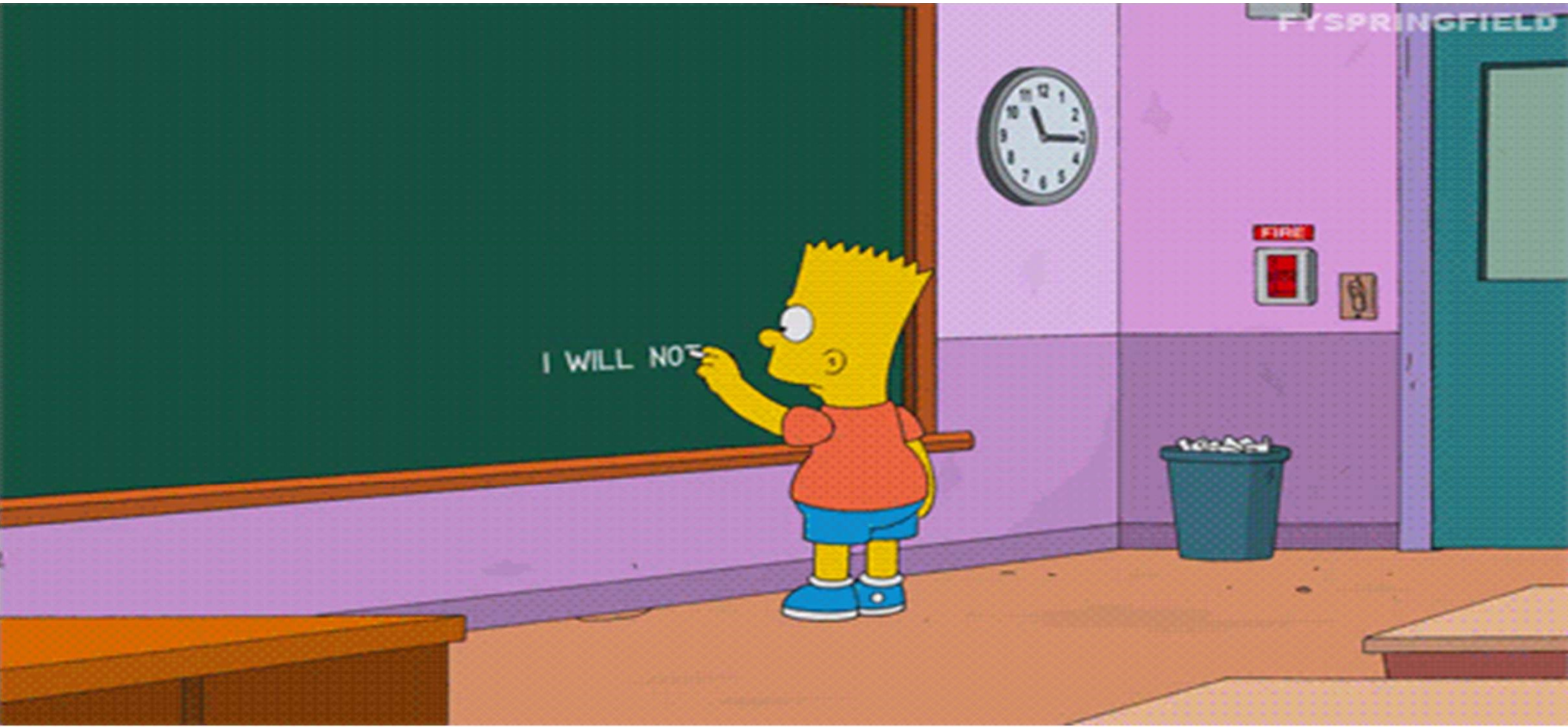
- Systems User Requirements Specification
- Previous Audit Focus

Today's Expectations



Regulatory Requirements

Expectations today for the Audit Trail – GAMP 5 Guidance

- Automated
  - The audit trail entries must be automatically captured by the computer system whenever an electronic record is created, modified or deleted.
- Secure
  - Audit trail data must be stored in a secure manner and must not be editable by any user.
- Contemporaneous
  - Each audit trail entry must be time stamped according to a controlled clock which cannot be altered. The time should either be based on central server time or a local time, so long as it is clear in which time zone the entry was performed.
- Traceable
  - Each audit trail entry must be attributable to the individual responsible for the direct data input. Updates made to data records must not obscure previous values and where required by regulation the reason for changing the data must also be recorded.
- Archived
  - The audit trail must be retained as long as the electronic record is required to be stored.
- Available
  - The audit trail must be available for agency review and copying

Regulatory Requirements

Expectations today for Audit Trail Entries - GAMP 5 Guidance

- Identification of the User making the entry
  - This is needed to ensure traceability. This could be a user's unique ID, however there should be a way of correlating this ID to the person.
- Date and Time Stamp
  - This is a critical element in documenting a sequence of events and vital to establishing an electronic record's trustworthiness and reliability. It can also be effective deterrent to records falsification.
- Link to Record
  - This is needed to ensure traceability. This could be the record's unique ID.
- Original Value - New Value
  - This is needed in order to be able to have a complete history and to be able reconstruct the sequence of events
- Reason for Change
  - This is only required if stipulated by the regulations pertaining to the audit trailed record.

Types of Audit Trails

Types of Audit Trails

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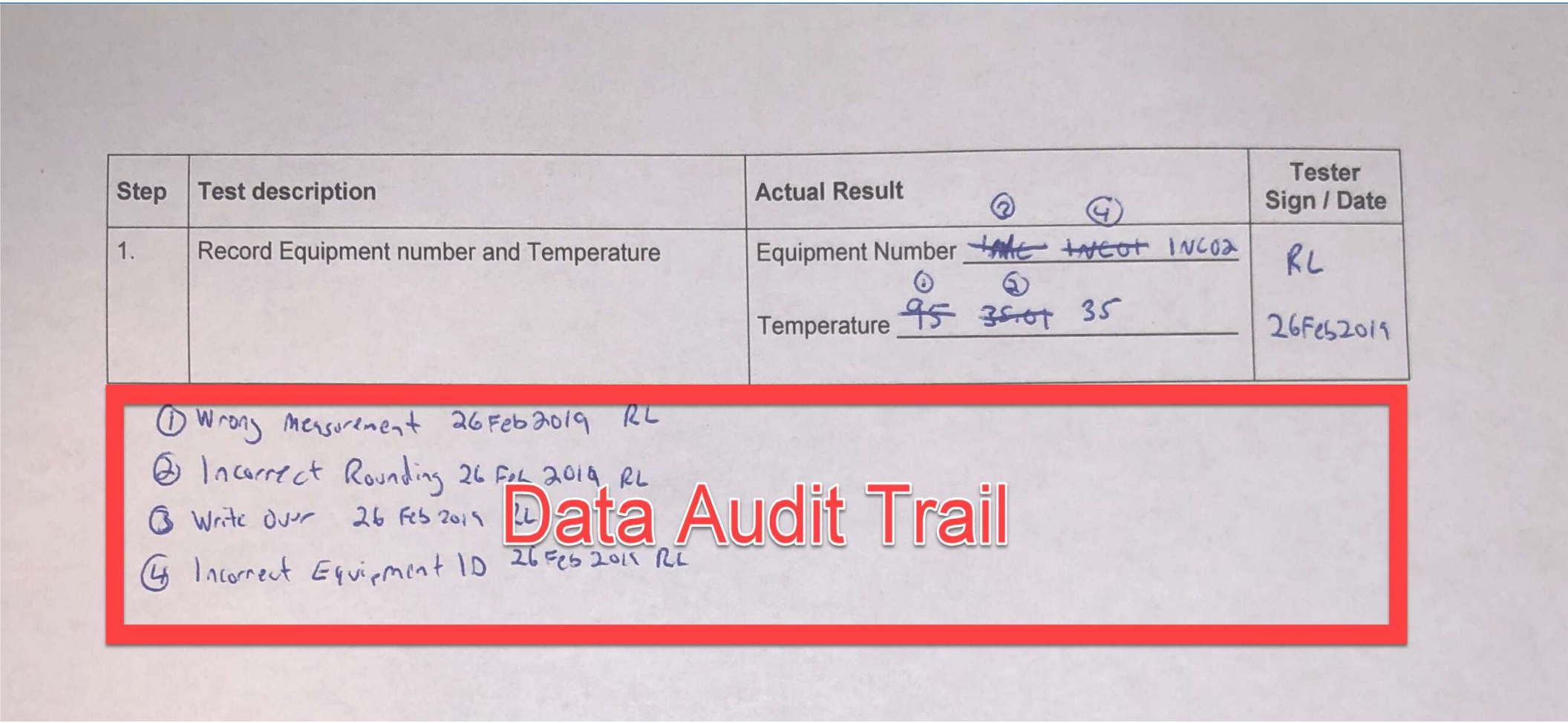
- **Data Audit Trail**
  - Applied to data i.e. electronic records/results
  - Reviewed as part of regular review

- **System Audit Trail**
  - Applied to system settings or actions
  - Reviewed periodically based on risk

Types of Audit Trails

Data Audit Trail



Step	Test description	Actual Result	Tester Sign / Date
1.	Record Equipment number and Temperature	Equipment Number ~~INC~~ ~~INC0~~ INC02 (②, ④) Temperature ~~95~~ ~~35.01~~ 35 (①, ③)	RL 26Feb2019

① Wrong Measurement 26 Feb 2019 RL
② Incorrect Rounding 26 Feb 2019 RL
③ Write over 26 Feb 2019 RL
④ Incorrect Equipment ID 26 Feb 2019 RL

Data Audit Trail

Types of Audit Trails

System Audit Trail

Date	Operation (*)	Item/ order no.	Batch designation/ batch expiration date	Facility-specific area	Time from - to		Cause/measure/comments	SOP no.	carried out by	Control/ approval
23.02.2000	P	Test production/	4711/	4000 packages	9.25	11.35			Maier	Müller
		230456	23.02.2003							
23.02.2000	RE				11.35	13.30	Malfunction:			
							Product feed clogged/			
							Measure: feed equipment			
							removed, feed rails			
							polished, aligned and refitted.			
							Machine readjusted.		Huber	Müller
23.02.2000	P	Test production/	4711/							
		230456	23.02.2003	5670 packages	13.30	16.15			Maier	Müller
24.02.2000	C				6.50	16.00			Schwarz	Müller
25.02.2000	CH				6.50	11.00	Changeover to 20 bowl blisters	1234-UM-4	Huber	Müller
25.02.2000	P	Verum/789456	3336/25.02.02	20,000 packages	11.00	16.00			Maier	Müller

Page 3

(*) P = production; C = Cleaning; CH = changeover; RE = repair; MA = maintenance; CA = calibration; Q = qualification; V = validation

```
4/3/2019 9:47:15 AM [Info]   RecordAuditTrailEntry
4/3/2019 9:47:16 AM [Info]   GetUserPrincipal(): expiration is: 57 days 5 hours 14 minutes 9 seconds
4/3/2019 3:48:29 PM [Info]   RecordAuditTrailEntry
4/3/2019 3:48:30 PM [Info]   GetUserPrincipal(): expiration is: 56 days 23 hours 12 minutes 55 seconds
4/3/2019 3:50:58 PM [Info]   RecordAuditTrailEntry
4/3/2019 3:50:58 PM [Info]   GetUserPrincipal(): expiration is: 56 days 23 hours 10 minutes 27 seconds
4/3/2019 3:51:02 PM [Info]   GetLookupData() called with user: MODADMIN and startDateRange: 1/1/0001 12:00:00 AM
4/3/2019 3:51:02 PM [Warn]   ReferenceDataService: startDateRange was NULL.
4/3/2019 3:51:02 PM [Warn]   ReferenceDataService: startDateRange was NULL.
4/3/2019 3:51:02 PM [Debug]  LookupData: GetObjectData() called.
4/3/2019 3:51:02 PM [Debug]  ReferenceDataService.GetLookupData: Elapsed time to get data: 0 min 0 sec
4/3/2019 3:51:03 PM [Info]   RecordAuditTrailEntry
4/3/2019 3:51:03 PM [Info]   GetUserPrincipal(): expiration is: 56 days 23 hours 10 minutes 21 seconds
4/3/2019 3:51:04 PM [Info]   GetTestData() called with user: MODADMIN and startDateRange: 1/1/0001 12:00:00 AM
4/3/2019 3:51:04 PM [Info]   GetSampleData() called with user: MODADMIN and startDateRange: 1/1/0001 12:00:00 AM
4/3/2019 3:51:04 PM [Info]   GetLocationsData() called with user: MODADMIN and startDateRange: 1/1/0001 12:00:00 AM
4/3/2019 3:51:04 PM [Info]   GetResultsData() called with user: MODADMIN and startDateRange: 1/1/0001 12:00:00 AM
4/3/2019 3:51:04 PM [Info]   GetOrganismData() called with user: MODADMIN and startDateRange: 1/1/0001 12:00:00 AM
4/3/2019 3:51:04 PM [Warn]   ReferenceDataService: startDateRange was NULL.
4/3/2019 3:51:04 PM [Warn]   ReferenceDataService: startDateRange was NULL.
4/3/2019 3:51:04 PM [Info]   GetUserData() called with user: MODADMIN and startDateRange: 1/1/0001 12:00:00 AM
4/3/2019 3:51:04 PM [Warn]   ReferenceDataService: startDateRange was NULL.
4/3/2019 3:51:04 PM [Warn]   ReferenceDataService: startDateRange was NULL.
4/3/2019 3:51:04 PM [Warn]   ReferenceDataService: startDateRange was NULL.
4/3/2019 3:51:04 PM [Warn]   ReferenceDataService: startDateRange was NULL.
4/3/2019 3:51:04 PM [Warn]   ReferenceDataService: startDateRange was NULL.
4/3/2019 3:51:04 PM [Debug]  LimitSql.SelectActive: Elapsed time to get data: 0 min 0 sec
4/3/2019 3:51:04 PM [Debug]  ResultsData: GetObjectData() called.
4/3/2019 3:51:04 PM [Debug]  LimitRuleGroupSql.SelectActive: Elapsed time to get data: 0 min 0 sec
4/3/2019 3:51:04 PM [Debug]  ReferenceDataService.GetResultsData: Elapsed time to get data: 0 min 0 sec
4/3/2019 3:51:04 PM [Debug]  LimitRuleSql.SelectActive: Elapsed time to get data: 0 min 0 sec
```

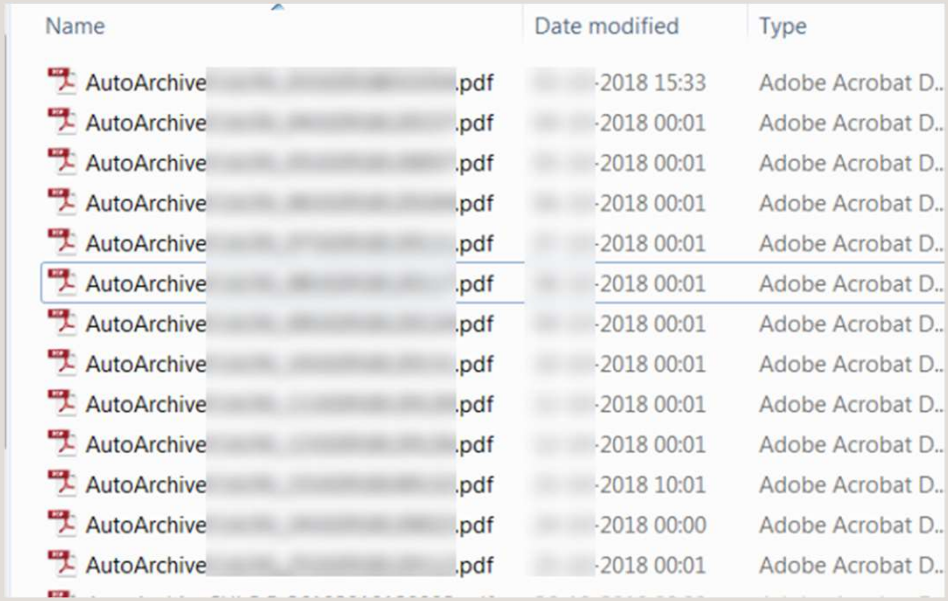
Audit Trail Examples

Audit Trail Examples

Bad

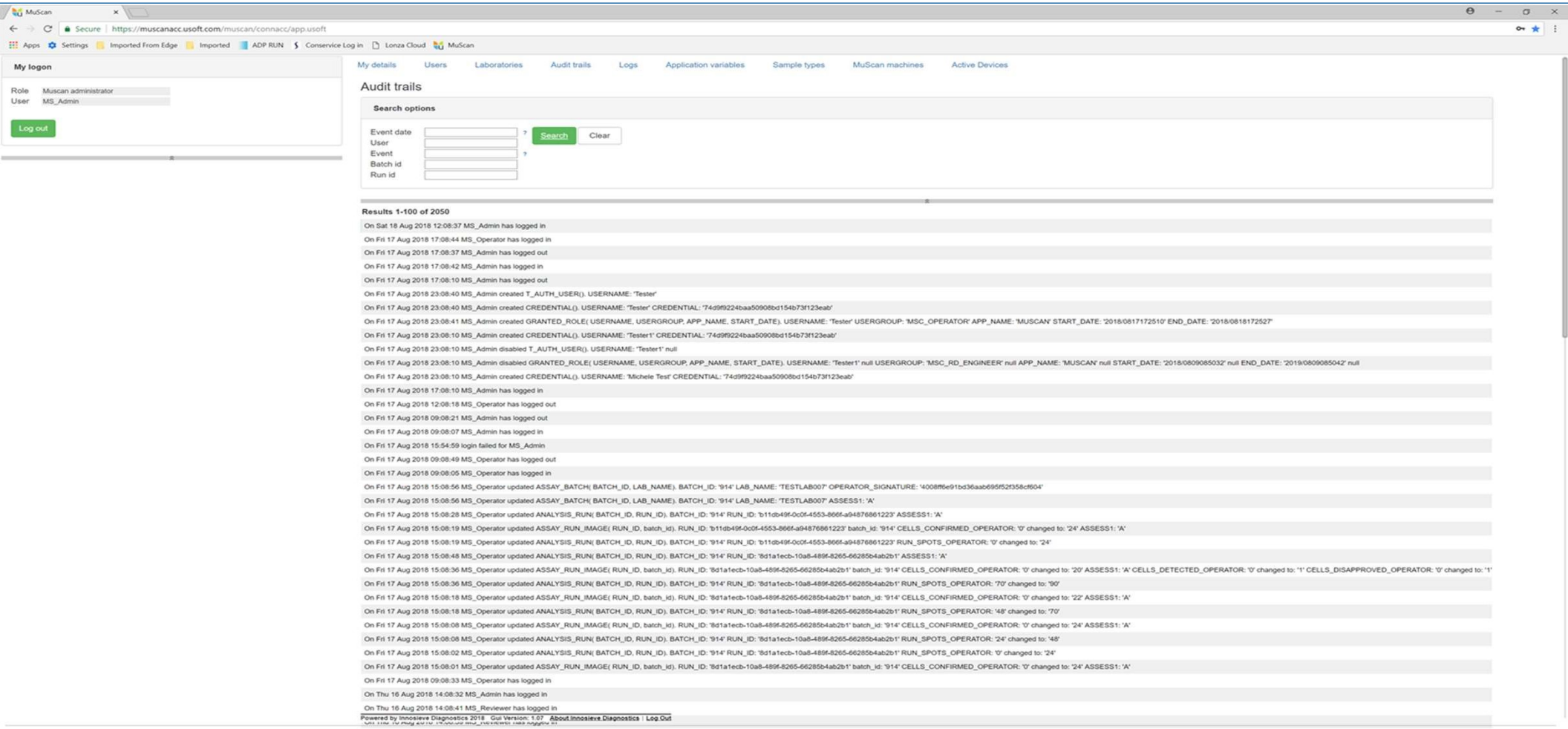
Command Usage Log

Operator	Operator Name	Date / Time	Command
admin	admin	25-10-2018 00:01:17	Auto Archive Log to C:\Temp\Log files auto archive\AutoArchive .pdf
admin	admin	25-10-2018 09:41:15	The user 'admin' logged in to after a login timeout.
admin	admin	25-10-2018 09:43:51	Lab name option changed from nothing to QCA
admin	admin	25-10-2018 09:43:51	AutoName option changed from True to False
admin	admin	25-10-2018 09:43:51	AutoStop option changed from True to False
admin	admin	25-10-2018 09:43:51	AutoPrint option changed from True to False
admin	admin	25-10-2018 10:07:15	timed out due to inactivity.
admin	admin	25-10-2018 11:02:08	The user 'admin' login attempt was successful.
admin	admin	25-10-2018 11:02:08	' application started
admin	admin	25-10-2018 11:02:08	LogoutTime : 15
admin	admin	25-10-2018 11:02:08	UseZero : True
admin	admin	25-10-2018 11:02:08	Reader Type :
admin	admin	25-10-2018 11:02:09	The reader is not responding.
admin	admin	25-10-2018 11:04:46	Changed User Specific from False to True
admin	admin	25-10-2018 11:32:57	Password History Timeout option changed from 0 to 540



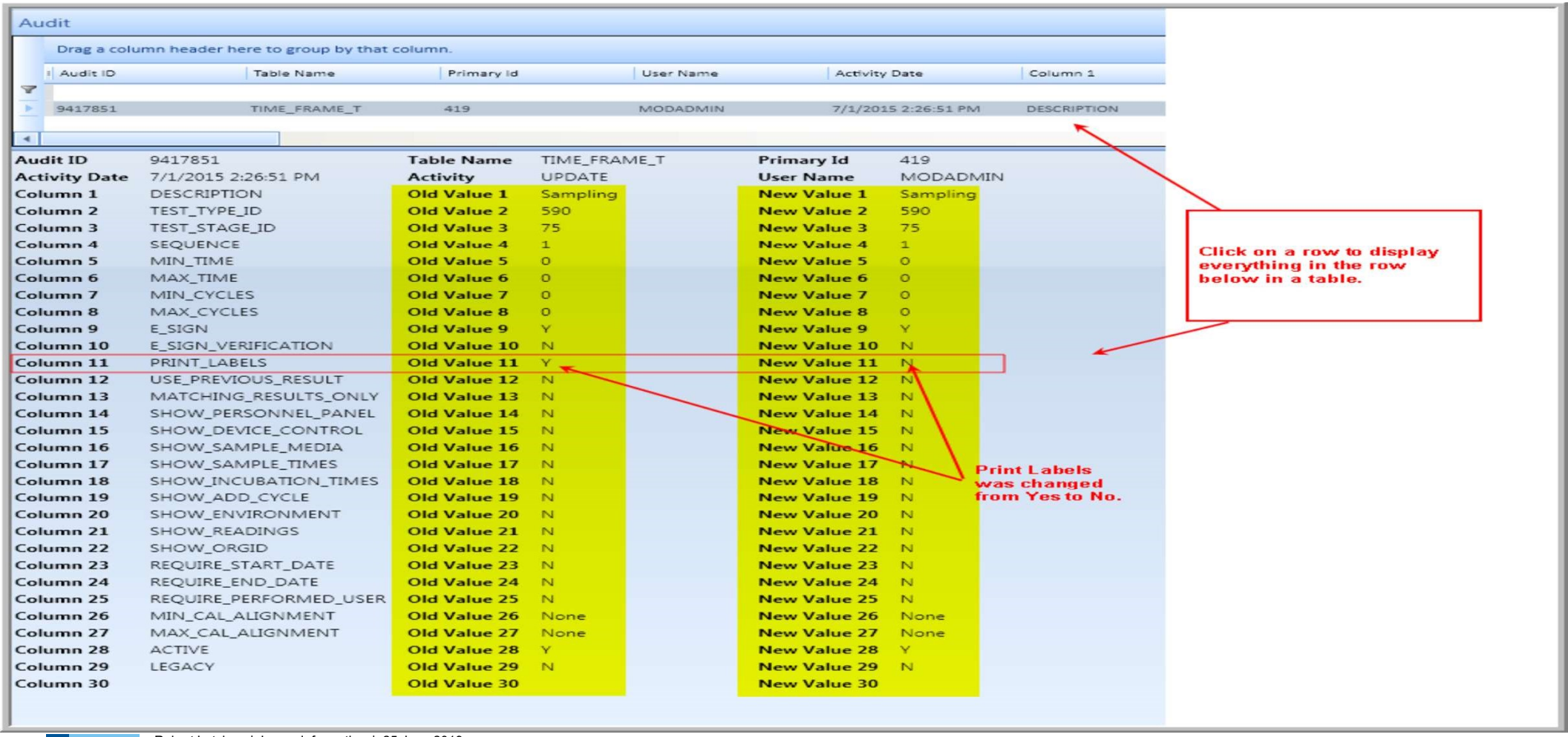
Audit Trail Examples

Ugly



Audit Trail Examples

Ugly



Audit Trail Examples

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Good

Standards Results

Standards	Conc./Dil.	Well	Reaction Time (sec)	Average Reaction Time (sec)	Back Prediction (Linear Regression)
Blank	Blank	A 5	****	****	****
		A 6	****		
Std. 1	0.05	B 5	3236	3258	0.0318
		B 6	3280		
Std. 2	0.5	C 5	1401	1405	1.23
		C 6	1409		
# Std. 3	5	F 5	1138	1130	3.18
		H 8	1122		

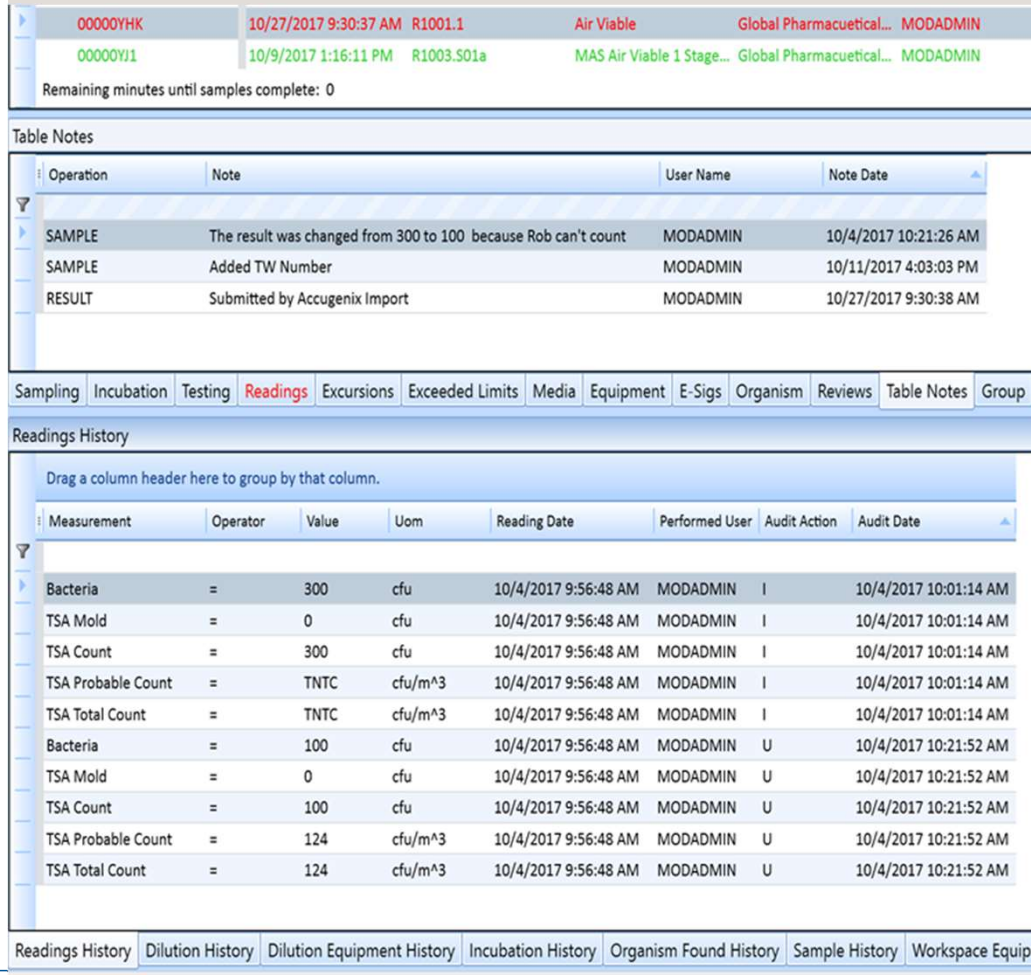
Reviewed By : _____ Date/Time : _____

(!! = Masked, **** = reaction time > 3300, ???? = atypical, # = Modified, >>>> = High OD)
(In Notes : ! = Masked Point(s), * = Point(s) Did Not React, ? = Atypical Point(s), # = Modified, > = High OD, <LS = Less than the lowest standard)

Audit Trail Examples

Good

- Data Audit Trail
  - Audit Trail review as part of sample review
- The system will automatically flag any sample that has had a value changed from an initial save/signature.
- Reviewer doesn't need to go to the historical "Audit Trail" that is difficult to find information for end users.
- System displays a history of the sample information in a user-friendly, tab based design
- Reviewer can see
  - Initial Entry
  - Who Performed the action
  - When the performed the action
  - Updated Entry
  - Who performed edit/update
  - When the performed the action/update
  - The note associated with the change



00000YHK	10/27/2017 9:30:37 AM	R1001.1	Air Viable	Global Pharmaceutical...	MODADMIN
00000YJ1	10/9/2017 1:16:11 PM	R1003.S01a	MAS Air Viable 1 Stage...	Global Pharmaceutical...	MODADMIN

Remaining minutes until samples complete: 0

Table Notes

Operation	Note	User Name	Note Date
SAMPLE	The result was changed from 300 to 100 because Rob can't count	MODADMIN	10/4/2017 10:21:26 AM
SAMPLE	Added TW Number	MODADMIN	10/11/2017 4:03:03 PM
RESULT	Submitted by Accugenix Import	MODADMIN	10/27/2017 9:30:38 AM

Sampling | Incubation | Testing | Readings | Excursions | Exceeded Limits | Media | Equipment | E-Sigs | Organism | Reviews | Table Notes | Group

Readings History

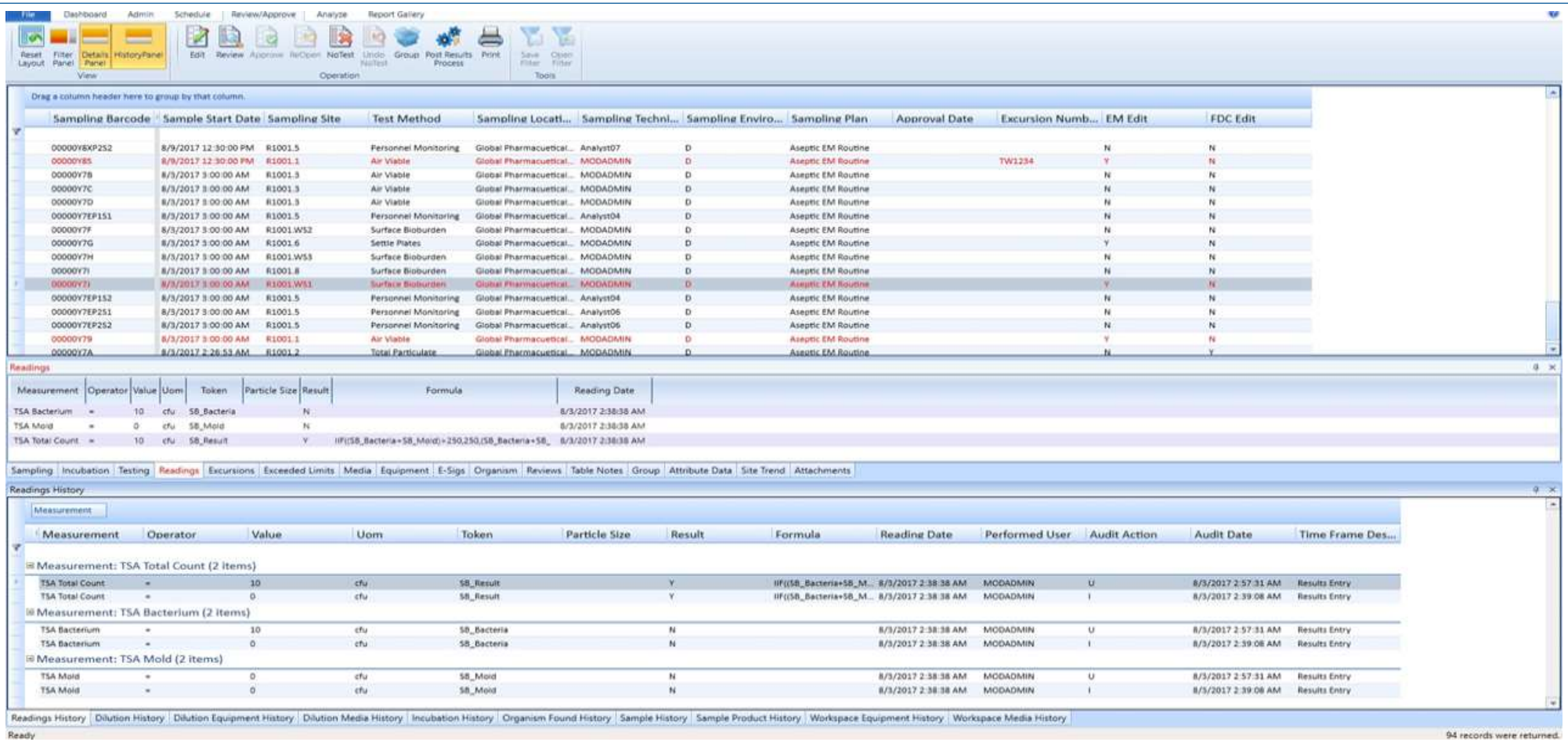
Drag a column header here to group by that column.

Measurement	Operator	Value	Uom	Reading Date	Performed User	Audit Action	Audit Date
Bacteria	=	300	cfu	10/4/2017 9:56:48 AM	MODADMIN	I	10/4/2017 10:01:14 AM
TSA Mold	=	0	cfu	10/4/2017 9:56:48 AM	MODADMIN	I	10/4/2017 10:01:14 AM
TSA Count	=	300	cfu	10/4/2017 9:56:48 AM	MODADMIN	I	10/4/2017 10:01:14 AM
TSA Probable Count	=	TNTC	cfu/m^3	10/4/2017 9:56:48 AM	MODADMIN	I	10/4/2017 10:01:14 AM
TSA Total Count	=	TNTC	cfu/m^3	10/4/2017 9:56:48 AM	MODADMIN	I	10/4/2017 10:01:14 AM
Bacteria	=	100	cfu	10/4/2017 9:56:48 AM	MODADMIN	U	10/4/2017 10:21:52 AM
TSA Mold	=	0	cfu	10/4/2017 9:56:48 AM	MODADMIN	U	10/4/2017 10:21:52 AM
TSA Count	=	100	cfu	10/4/2017 9:56:48 AM	MODADMIN	U	10/4/2017 10:21:52 AM
TSA Probable Count	=	124	cfu/m^3	10/4/2017 9:56:48 AM	MODADMIN	U	10/4/2017 10:21:52 AM
TSA Total Count	=	124	cfu/m^3	10/4/2017 9:56:48 AM	MODADMIN	U	10/4/2017 10:21:52 AM

Readings History | Dilution History | Dilution Equipment History | Incubation History | Organism Found History | Sample History | Workspace Equip

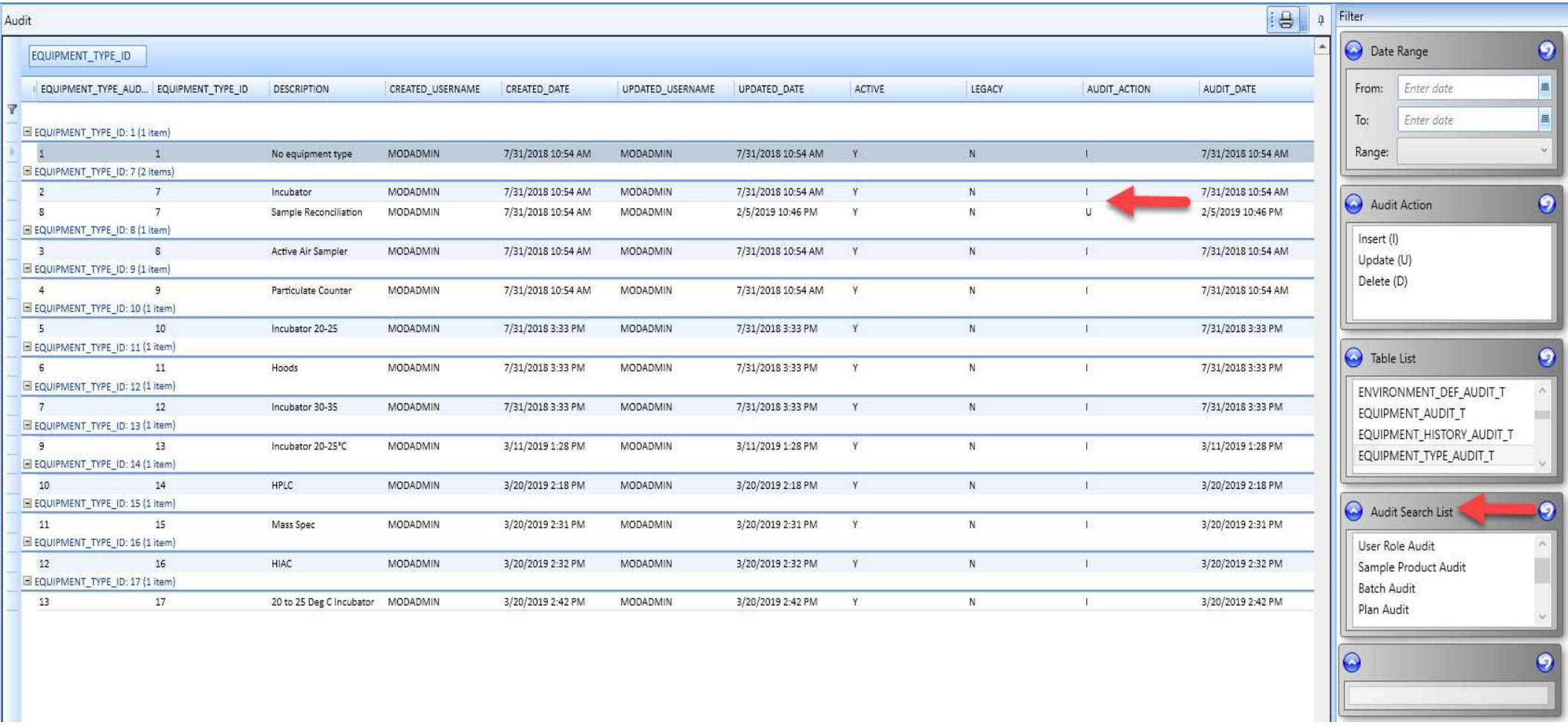
Audit Trail Examples

Good



Audit Trail Examples

Good



Review and Auto Approval

Concentrate on the most important samples

- Review and Approve by Exception
  - Allows reviewer to concentrate on samples with issues instead of the 95-98% that followed the defined, validated process
  - System only approvers samples that meet criteria
    - No edits to information
    - No out of specification results
    - No notes from users
    - And many more…
- System Checks
  - Controls sample workflow
  - Enforces incubation/hold times
  - Ensures scheduled samples are taken
  - Ensures media is within expiration and passed qualifying testing
  - Ensures equipment is within calibration
  - Ensures all fields are filled out
  - Ability to have secondary electronic verifier signatures
  - Flags any sample with a change, note or out of specification limit
    - Displays audit trail if any changes occurred

Needs Review by Qualified Reviewer

Sampling Barcode	Sample Start Date	Sampling Site	Test Method	Most Severe Excursion	Approval Date
MG452397	7/14/2009 10:51:12 AM	R1003.S01a	Air Viable	Action	
000006T7	7/9/2009 6:41:38 AM	R1001.8	Surface Bioburden	Action	
0000097Q	6/24/2009 5:35:05 PM	WFI-D1	TOC Analysis	Alert	
000009H5	6/24/2009 5:35:05 PM	WFI-D1	LAL/Endotoxin Analysis	Action	
000006SF	6/11/2009 7:56:13 AM	R1001.8	Surface Bioburden	Action	
000005Z3P1S2	6/10/2009 5:13:24 PM	R1001.5	Personnel Monitoring	Action	
000006GO	6/10/2009 5:13:24 PM	R1001.WS1	Surface Bioburden	Action	
000008F0	6/10/2009 5:13:24 PM	R1003.S01a	Air Viable	Alert	
MG452149	5/1/2009 10:36:28 PM	R1003.D01	Surface Bioburden	Action	

Reviewed by System

Sampling Barcode	Sample Start Date	Sampling Site	Test Method	Most Severe Excursion	Approval Date
P-10027379452	5/5/2017 10:43:44 PM	R1001.WS2	Surface Bioburden		7/11/2018 11:54:42 AM
00000Y5R	7/26/2017 11:00:00 PM	R1001.WS1	Surface Bioburden		7/11/2018 11:54:42 AM
00000Y5P	7/26/2017 11:00:00 PM	R1001.WS3	Surface Bioburden		7/11/2018 11:54:42 AM
00000Y5Q	7/26/2017 11:00:00 PM	R1001.8	Surface Bioburden		7/11/2018 11:54:42 AM
00000Y5N	7/26/2017 11:00:00 PM	R1001.WS2	Surface Bioburden		7/11/2018 11:54:42 AM
00000YAF	8/15/2017 11:00:00 PM	R1001.WS2	Surface Bioburden		7/11/2018 11:54:42 AM
00000YAH	8/15/2017 11:00:00 PM	R1001.WS3	Surface Bioburden		7/11/2018 11:54:42 AM
00000YAJ	8/15/2017 11:00:00 PM	R1001.WS1	Surface Bioburden		7/11/2018 11:54:42 AM
00000YBO	9/6/2017 12:00:00 PM	R1001.WS1	Surface Bioburden		7/11/2018 11:54:42 AM
00000YBN	9/6/2017 12:00:00 PM	R1001.8	Surface Bioburden		7/11/2018 11:54:42 AM
00000YBM	9/6/2017 12:00:00 PM	R1001.WS3	Surface Bioburden		7/11/2018 11:54:42 AM
00000YBK	9/6/2017 12:00:00 PM	R1001.WS2	Surface Bioburden		7/11/2018 11:54:42 AM

System Selection

Current state vs Future State

- Understand how your current system is capturing data.
- Remediate?
- Replace?

- When selecting new systems:
- RFP/URS Considerations
- System Implementation

- Show and Prove!

How to Review

Audit Trail Review

General

- The system must be validated first
- Define which data is critical to patient safety and regulatory compliance
- Analyze the path of data in the system and the business process, specifically looking at the defined data
- Identify areas of high risk to patient safety and compliance
- Develop risk-based approach based on criticality of data

Audit Trail Review

The type of review shall be based on the type of audit trail…

Data Audit Trail

- Reviewed as part of regular review
- Must be reviewed before e.g. a batch is dispositioned.
- Review needs to be done as an integrated part during approval process clearly outlined in a procedure
- MODA enables an easy review within the approval screen as shown before... No additional reports, windows and pain

System Audit Trail

- Applied to system settings or actions
- Reviewed periodically based on risk = focus on anything with direct impact to product or release via FMEA
- Can be very specific for a company because it ensures changes of master data, configuration, interfaced devices/systems, infrastructure or settings.
- Change management is where the pain comes in.
  - If the system lacks certain controls, making changes require significantly more verification steps to ensure the change was made appropriately.

Audit Trail Review

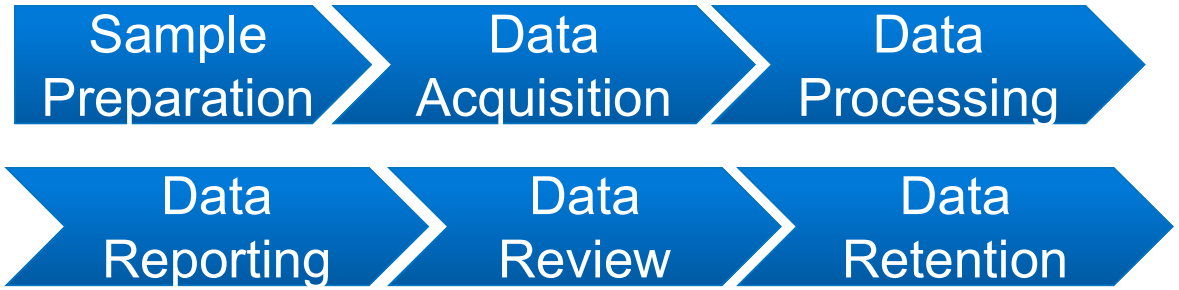
Risk Assessment

- The goal is to create a risk assessment that is:
  - Quantifiable
  - Objective
  - Actionable
- Take into account the possible measures that can be implemented to reduce the risk to data integrity
- FMEA is commonly used as a risk assessment for data integrity
- Standard way of assessing all QC systems
- This provides a framework to consistently assess the risk to data integrity and perform standardized reassessments as the systems and processes change and evolve.

Audit Trail Review

Risk Assessment

- Define data integrity failure modes for the different stages



- Where can manual steps compromise the integrity of the data?
  - Define accepted level and not acceptable level
  - Calculate score
  - Define actions for score above acceptable level
  - Recalculate score taking into account actions
  - Repeat until score below acceptable level or risk accepted

Audit Trail Review

What to look at for all types of Audit Trails

- Periodic Review – Scheduled Review of System Audit Trail
  - Deletions
  - Modifications of GxP critical data items
  - Undocumented configuration changes
  - Corrupt entries
  - Anomalies in date and time stamps
  - Changes inconsistent with adjacent data
  - Generic account access recordings (outside of system-required accounts, such as accounts required to run background jobs).
  - Addition of critical authorizations
  - Sequence of samples

- Frequency of Periodic Review
  - Based on GAMP category
  - Criticality of Data

Audit Trail Review

Documentation

- System Tools vs External Tools
- If possible, evidence of audit trial review is made in the computerized system software itself, rather than using a (hybrid) paper record.
- Allows for clearer link between the audit trail and the review.
- Tools to efficiently identify the required Critical Audit Trail Entries should be developed and validated. These can include: validated Excel spreadsheets, validated access data bases (Scripts), customized reports or other validated software (using a validated interface)

Summary

Summary

- Good Audit Trails:
  - Captures the information required by regulations
  - Separate data audit trails from system audit trails
  - Saves the audit trails compliantly within the system
  - Allow you to easily review the relevant audit entries
- “Ugly” Audit Trails:
  - Captures the information required by regulations
  - Mix data audit trails with system audit trails
  - Require you to have a process for searching the audit trail during review
- Bad Audit Trails:
  - Mix data audit trails with system audit trails
  - Saves the audit trails as files outside of the application/database, or
  - Does not fully capture the information required by regulations

Summary

- Define a process to evaluate existing systems for audit trail review
- Define a process to review existing system audit trails
- Review relevant data audit trail when approving the data
- Review relevant system audit trail periodically
- Implement the search criteria in your procedures to make the review process easier
- Evaluate the quality of the audit trail when implementing new systems

Q&A Session

Any questions?

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Thank you