

# DaCS Audit Trail Review

## A New Response to FDA and MHRA Guidelines



For years, DaCS users have been generating audit trails from our systems.  
You may be aware that recent data integrity guidance from both the FDA and the MHRA highlight that simply generating an audit trail but not routinely making use of it is no longer acceptable.

**Both recommend that audit trails should be periodically reviewed.**

### Data Integrity and Compliance with CGMP - Guidance for Industry - FDA. April 2016

*“FDA recommends that audit trails that capture changes to critical data be reviewed with each record and before final approval of the record.”*

*“FDA recommends routine scheduled audit trail review based on the complexity of the system and its intended use.”*



Medicines &  
Healthcare products  
Regulatory Agency

### MHRA GMP Data Integrity Definitions and Guidance for Industry - March 2015

*“Audit trail review should be part of the routine data review / approval process.*

*There should be evidence available to confirm that review of the relevant audit trails have taken place.”*

### Why is reviewing the audit trail problematic?

The audit trail **can** provide very valuable information, either to identify potential problems, or to look for activities where we can improve.

When something goes wrong, it is common to undertake a detailed review of the audit trail and analyse the event in question.

But, for most systems, audit trails are “event logs” of everything that has happened in the system. We have seen that reviewing a long and complex audit trail is time-consuming and usually adds little value; potential issues are easily overlooked due to the sheer weight of data.

**Despite the request from the regulators, the fact remains that a comprehensive review of the whole audit trail as a part of your regular routine just isn't practical.**



We believe that the reviewer needs help in quickly and efficiently finding what they consider to be the key items they are concerned with.

**So how do we filter out and present the audit trail activities that really matter from a compliance point of view?**



CSV Compliance is the global leader in spreadsheet validation services for the Life Sciences and regulated industries. The CSV Compliance team supply spreadsheet validation and compliance services worldwide.





# DaCS Audit Trail Review

The second example below highlights that we expected a routine audit trail review to occur periodically (at least every 90 days) and that the review is overdue. The audit review worksheet is highlighted as needing review.

We can also see that some data modification events have occurred (“Entry Errors”), indicating that users have changed data since it was initially added. This would of course be recorded in the audit trail and in this situation the rules allow it to occur five times without triggering a critical flag. It recognises that mistakes do happen and users do have flexibility to correct data.

Spreadsheet Name: QC Drug Factor  
 Template Ref: Drug\_1\_0.XLTX  
 Worksheet: Audit Review  
 Spreadsheet Ver: 1.0

Filename: \\Cvs\server\csv\DaCS\_Share\Files\Drug\_DaCS\_ATF\_Example.xls  
 Modified Date: 25 Jan 2017 13:02:22  
 Print/Save Date: 25 Jan 2017 12:04:22  
 Timezone: GMT Standard Time

Critical Activity	QA Flag?	Allowable No of Events	Audited No of Events
<b>Workbook / Workbook Protection</b>			
Workbook Protection Removed?	No	0	0
Worksheet Protection Removed?	No	0	0
<b>Integrity Errors</b>			
Integrity Errors Present	No	0	0
<b>Electronic Signatures</b>			
Electronic Signatures Removed?	No	0	0
<b>Data Modification</b>			
Entry Error	No	5	2
Change Control Request	No	2	1
Reapply Electronic Signature	N/A	Any	1
Unspecified Reason	No	0	0
Silent Entry	No	0	0
Delete Data	No	0	0
Delete Data Silent	No	0	0
<b>Rows and Columns</b>			
Rows Inserted?	No	0	0
Rows Deleted?	No	0	0
Columns Inserted?	No	0	0
Columns Deleted?	No	0	0
<b>Comments</b>			
Comments Removed?	No	0	0
<b>Notable Activities</b>	<b>Warning Flag?</b>	<b>Allowable No of Events</b>	<b>Audited No of Events</b>
<b>Workbook / Workbook Protection</b>			
Workbook Protection Added?	No	0	0
Worksheet Protection Added?	No	0	0
<b>Electronic Signatures</b>			
Electronic Signatures Added ?	N/A	Any	1
<b>Macro Execution</b>			
Macro:Import	No	1	1
Macro:Delete	No	1	1
	N/A	Any	0
	N/A	Any	0
	N/A	Any	0

Audit Trail Review Tracking					
Reviewed By:	Date:	Time:	Reset Flags?	Comments	
David Harrison	09 Nov 2016	12:52:22	No	None	
David Harrison	25 Oct 2016	13:02:22	Yes	QA Investigation CSV-123	

Comments  
 QA Investigation CSV-123 raised to investigate Worksheet protection unlocking. See audit trail line 456. Audit trail flags reset.

Audit Trail Review Due			
Audit Trail Review Next Due	23 January 2017	Audit Trail Review Period	90 days
Audit Trail Review Due?	YES	Workbook Finalised	

Once an audit trail review has occurred, the review is recorded in the tracking table, and any warning flags can be reset by the reviewer. The reviews are clearly recorded using electronic signatures.

The last example shows that when a workbook is finalised, no further audit trail reviews are required and the workbook will stop flagging the need for periodic review.

Audit Trail Review Due			
Audit Trail Review Next Due		Audit Trail Review Period	90 days
Audit Trail Review Due?	NO - Finalised	Workbook Finalised	25 Jan 2017 13:02:22

This new functionality is being implemented into future versions of DaCS, and we are working hard on making it possible to add the audit trail review feature into existing workbooks and templates. We envisage the ability to validate this functionality once, and then apply it as standard functionality to all your new workbooks or to append it to existing validations.

**Please contact us.....**

- if you have any feedback on this new functionality.
- would like to be involved in trialling the functionality.
- if you think it would be useful for your business.

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