

- 1. Login to the eTMF and navigate to the **Documents** Module.
- 2. Change the view to Audit Findings, then click Select.

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Index]* []	Submissions	14	Event	je
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Site	1	Audit Findings	3	Working Documents	ŀ
Country	14	eSignature		Redactions	J
Tag	14				
Query By Sender	3.4				
Query By Recipient	3				

3. Choose a **folder** to display <u>documents with findings</u> related to a specific audit. **Select** a document unclaimed for review (open padlock icon).

View by Audit Findings	1 - 3 of 3 (0 selected)		
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Full Audit - All Documents 3		🗆 🖪 \star 🛛 🖉 🗳	FDA 1572
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T R I A L INTERACTIVE How to Respond to an Audit Finding TI v 10.5

4. Claim the selected document. This makes you	🖌 Expand
the assigned responder.	Metadata
	KOMAtte
	Suggested
5. In the document Metadata pane, review	31 Jul 202
Audit History to ascertain the reason for the	Audit

Audit History to ascertain the reas Audit Finding.



Tip: Turning off the **Show Last History Record** option will display the full audit trail for the document

Audit History

Show Last History Record





6. Once the **reason** for the finding is determined, the Audit Responder makes any required changes or updates to the document.

(ex. **updating metadata**, or replacing document with new version)

Comments		
Date Type		
Meeting Date	w	×
Document Date *		
25-Jul-20	m	×
Document Description		
Generated Name		
KOMAttendSheet_24Jul2020		
Document Type *		
Meetings\01.04.01 Kick-off Meeting Material\KOMAttendSheet		×

Document URI



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7. Once the origin of the Finding has been corrected, the user will switch to the **Audit** tab inside the Metadata pane; insert comments detailing corrective actions taken, then finally click on **Mark Document as Corrected**. This concludes the finding response process.

Metadata	Queries	Versions	Audit
Comments*			
Document l	has been co	rrected.	
Delete th	is document	:	
Marl	k document	as corrected	

If the appropriate response to the finding is to delete the document, the user should tick the **Delete this document** checkbox located below the Comments field prior to proceeding.

