

# File Review Template Fields

Use the following table when creating a File Review Template.

**Field**

**Description**

**Action**

|                                    |  |                                      |
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| <b>Name</b>                        | The name of your File Review Template. <b>Note:</b> This will display each time you create a file review from this template. | Enter a name in the field.           |
| <b>Review Type</b>                 | The type of file review provided from the File Review Types Data Dictionary.   | Select one of the File Review Types. |
| <b>Description</b>                 | (Optional) A description of the template purpose.  | Enter a description.                 |
| <b>Minimum Sampling Percentage</b> | The minimum percentage of study items to include as review items in file reviews created from this template.                 | Enter the minimum percentage.        |

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| <p><b>Apply Sampling Percentage Before or After All Filtering</b></p> | <p>Filtering mechanism to determine the number of review items for reach file review.</p>   | <p>Select one of the following: <b>Before:</b> Mandatory items are counted towards the sample size.<br/><b>After:</b> Mandatory items are not counted towards the sample size.</p>              |
| <p><b>Sample Size Parameters</b></p>                                  | <p>Parameters for calculating the sample size percentage for your file review template.</p> | <p>Select the button and enter your calculation. For more information on sample size calculation, see <a href="#">here</a>.</p>   |
| <p><b>Review Manager Groups</b></p>                                   | <p>The group of users who can create and manage File Reviews of this template.</p>          | <p>Click <b>Select Groups</b>. In the Groups &amp; Roles screen, select the check box for each group to specify. Use the search and filter fields on the left to reduce the list as needed.</p> |
| <p><b>Review Participant Groups</b></p>                               | <p>The group of users who can evaluate review items for this template.</p>                  | <p>See Above.</p>   |
| <p><b>Review Reader Groups</b></p>                                    | <p>The group of users who can view File Reviews created from this template.</p>             | <p>See Above.</p>   |

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| <p><b>Risk Level</b></p>               | <p>The specified document type risk level.</p>  | <p>Set the risk level between 1 (low) to 10 (high).</p>   |
| <p><b>Mandatory Document Types</b></p> | <p>The required document types that are added to the file review. Note: These documents can not be deleted during a review.</p> | <p>Click <b>Select Document Types</b>, then choose the documents from the TMF Master List. Use the search and filter fields on the left to reduce the list as needed.</p> |
| <p><b>Excluded Document Types</b></p>  | <p>The document types to exclude when performing the file review.</p>   | <p>See Above.</p>   |

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| <p style="text-align: center;"><b>Document Selection</b></p> | <p><b>All Documents</b> – Includes all finalized documents that satisfy other conditions for the template.</p> <p><b>All Unreviewed Documents</b> – Includes all documents that satisfy other conditions for the template AND that have not been included in another File Review of the same type.</p> <p><b>All Unreviewed Documents Within Specified Period</b> – Includes all finalized documents that satisfy other conditions for the template, have not been included in another File Review of the same type, AND have a Finalization Date that falls within the dates of the File Review.</p> <p><b>Note:</b> The dates of the File Review are specified during File Review creation.</p> | <p style="text-align: center;">Select All Documents, All Unreviewed Documents, or All Unreviewed Documents Within Specified Period.</p> |
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| <p><b>Include all Study Items satisfied without content</b></p> | <p><b>No Empty Study Items</b> – Excludes all empty Study Items from File Reviews</p> <p><b>All Empty Study Items</b> – Includes all empty Study Items that satisfy other conditions for the template.</p> <p><b>All Unreviewed Empty Study Items</b> – Includes all empty Study Items that satisfy other conditions for the template AND that have not been included in another File Review of the same type.</p> <p><b>All Unreviewed Empty Study Items Within Specified Period</b> – Includes all empty Study Items that satisfy other conditions for the template, have not been included in another File Review of the same type, AND have a Creation Date that falls within the dates of the File Review.</p> <p><b>Note:</b> Available if <b>All Unreviewed Documents Within Specified Period</b> was selected in the Document Selection field.</p> | <p>Select No Empty Study Items, All Empty Study Items, All Unreviewed Empty Study Items, or All Unreviewed Empty Study Items within a Specified Date.</p> |
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| <p><b>Country</b></p>            | <p>Used to control selection of country and site level study items.</p> <p><b>Note:</b> Using a country filter does not prevent selection of enterprise, program, or study level study items</p>          | <p>Select one or multiple countries.</p>                             |
| <p><b>Site Status</b></p>        | <p>Used to control the selection of site level study items by status.</p>   | <p>Select a site status from the dropdown.</p>                       |
| <p><b>Site</b></p>               | <p>Used to control the selection of site level study items by site.</p>   | <p>Select your site from the dropdown.</p>                           |
| <p><b>Document Owner</b></p>     | <p>Filter study items by document owner.</p>  | <p>Select one or multiple document owners from the dropdown.</p>     |
| <p><b>Document Submitter</b></p> | <p>Filter study items by document submitter.</p>  | <p>Select one or multiple document submitters from the dropdown.</p> |
| <p><b>Exclude Unblinded</b></p>  | <p>The option to exclude unblinded documents from the file review.</p>  | <p>Select <b>Yes</b> or <b>No</b>.</p>                               |
| <p><b>Non Document Items</b></p> | <p>Review Items that are not related to specific documents (e.g., Check Correspondence). The list of non-document review items is provided from the File Review Non Document Review Items dictionary.</p> | <p>Select one or more non-document items.</p>                        |