

Traceability Matrix

(Reference SOP: _____)

Project:	Project No:
Location:	Protocol:

1. Purpose

The Traceability Matrix

- Records the relationship between two or more products of the design and development process.
- Ensures that all requirements are met and can be traced to the appropriate design elements.
- Ensures all requirements are verified and can be traced to a test or verification activity that shows that requirements have been met.

2. Traceability Matrix

URS (User Requirement Specification) Reference Number	Description	Scope	GxP or regulatory impact	Other Impact (Business or Safety)	Functional Specification Reference	Design Specification Reference	Testing Required (Y or N)	Test or Verification Reference	How requirement met	Comments
All User Requirements need to be listed	Include the Full URS section or brief reference and key words, i.e Audit Trail, security	The scope that this URS section effects. This will also identify who has responsibility for maintaining	If there is a GxP or ER/ES, or other Regulatory impact, then there should be a test reference number in	The system may require formal verification or testing for other reasons other than GxP, e.g. financial, Safety for	Enter the FS that defines the URS section. If the URS will not be satisfied by the system this should be made clear by an appropriate notation, such as 'Not Met' or an SOP reference	Enter the Design Spec or Configuration that satisfies the FS	(Y or N) If Y then a test reference should be made in the test reference column. If No then	A reference to a specific test should be included where there is a GxP impact or any other impact. Completion of the column is required in order to trace all Requirements to	Some requirements may be met by means other than software and verified by means other than testing. Were the	Include and comments that add information particularly where reference needs to be made to additional testing or requirements

Prepared By:

Date Prepared:

Revision No:
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