

# User Requirement Document

1. The system must allow users to modify tables within documents, including:

- Adding or removing rows
- Adding columns
- Updating specific cell values based on user instructions (e.g., “Remove the last row in Table 2”).

2. The Chatbot must generate content aligned with global perspectives and regulatory frameworks,

ensuring compliance with international medical device standards.

3. The chatbot may utilize an invisible reasoning/thinking layer to improve output quality while

keeping internal reasoning hidden from users.

4. The system must support uploading of all reference document types, including CADV, DDP, VVP, SOPs, PDFs, JIRA exports, and similar internal files.

5. All uploaded reference documents must be stored in a secure, access-controlled repository.

6. The platform must maintain a file deck, allowing users to retrieve and reuse files simply by referring to the filename.

7. The system must save and maintain user-specific information, including:

- Previously edited documents
- Past interactions and chatbot responses
- Document history with timestamps
- Ability for users to reopen and continue previous work

8. The system must automatically generate a Change Summary Table containing all modifications

made

9. The system must parse, extract, and process content department-wise (HD, PD, ACUTE, etc.).

10. Only department-relevant content should be used to autofill documents; the system must avoid mixing information across departments.

11. The platform must be usable even by new or non-expert users with no background in medical device design documentation.

## Chatbot Features

### Scaling:

0 - This feature is unwanted or harmful to the project

1 - This feature is somewhat desired, and will be added with sufficient time

2 - This feature is desired

3 - This feature is highly desired, but does not kill the project if not fulfilled

4 - This feature is necessary, as without this feature there is no point in doing the project

### Requirement 1: User Identification (4)

The chatbot shall prompt the user to sign in or confirm their identity before any actions.

### Requirement 2: Document History Access (4)

The chatbot shall display the user's previously created or edited design documents and allow selection.

### Requirement 3: Department Confirmation (4)

The chatbot shall ask the user to specify their department (e.g., HD, PD, ACUTE) before processing any documents.

### Requirement 4: Department-Specific Document Filtering (4)

The chatbot shall retrieve and use only the department-specific reference documents from Azure Blob for autofill operations.

### Requirement 5: File Upload Support (3)

The chatbot shall allow users to upload one or more reference documents (in PDF/Docx format) directly within the chat interface.

### Requirement 6: Relevant Information Extraction (3)

The chatbot shall extract only relevant information from each uploaded document based on the user's prompt .

**Requirement 7: Change Detection (1)**

The chatbot shall identify and summarize differences between uploaded reference documents, previous design documents, and JIRA data.

**Requirement 8: Autofill Functionality (4)**

The chatbot shall autofill the selected design document using extracted information from:

- Department-specific reference documents
- Uploaded user reference documents
- JIRA change summaries

**Requirement 9: Follow-Up Questions (3)**

The chatbot shall ask targeted follow-up questions when required information is missing, or conflicting.

**Requirement 10: Support for Clarification Inputs (3)**

The chatbot shall allow the user to respond to follow-up questions using either text input or by uploading additional reference files.

**Requirement 11: Section-Level Review (2)**

The chatbot shall present auto filled sections back to the user for review, confirmation, or modification.

**Requirement 12: Regeneration and Editing (2)**

The chatbot shall allow the user to regenerate or manually edit individual sections of the auto filled document.

**Requirement 13: Undo / Revert Capability (3)**

The chatbot shall allow the user to revert the last change or restore a previous version of the document.

Fallbacks:

**Requirement 14: Department-Safe Content Enforcement (2)**

The chatbot shall prevent cross-department content contamination by ensuring that extracted information relates only to the user's specified department.

**Requirement 15: Error Handling (2)**

The chatbot shall detect and notify users of invalid, corrupted, or unsupported file types, and provide guidance to correct the issue.

Requirement 16: Formatting Regulations (2)

The chatbot must generate text in accordance with international medical regulatory standards. A sample document has been provided for reference and training purposes.

SCALE	REQUIREMENTS
0	
1	Req 11,12,14,15
2	Req 11,12,14,15,16
3	Req 5,6,9,10,13
4	Req 1,2,3,4,8

Workflow

