

Sample Healthcare Requirements Document

Document Control

- **Version:** 1.0
 - **Date:** 2025-09-01
 - **Status:** Draft
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1. User Authentication

Requirement ID: REQ-001

- **Description:** The system shall require users to authenticate via username and password before accessing patient data.
 - **Priority:** High
 - **Acceptance Criteria:**
 1. A user entering a valid username and password shall be granted access.
 2. A user entering an invalid username or password shall be denied access.
 3. The password field must be masked.
 4. The system must comply with HIPAA password complexity rules.
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2. Patient Data Viewing

Requirement ID: REQ-002

- **Description:** An authenticated clinician shall be able to view a patient's medical history.
 - **Priority:** High
 - **Acceptance Criteria:**
 1. The view shall display patient demographics, past diagnoses, and prescribed medications.
 2. Data must be loaded within 2 seconds.
 3. The interface must be read-only to prevent accidental modification.
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3. Audit Logging

Requirement ID: REQ-003

- **Description:** All access to patient records must be logged for auditing purposes.
- **Priority:** Medium
- **Acceptance Criteria:**
 1. The log entry must include the user ID, patient ID, timestamp, and type of action (e.g., VIEW, EDIT).
 2. Logs must be stored securely and be tamper-proof.
 3. The system must meet IEC 62304 documentation requirements for traceability.