

Business Requirements (BR)

- **BR-01 — User Registration & Account Creation**

The system shall require users to register with a unique email address and shall enforce password policies including minimum length, complexity rules, account lockout thresholds, and secure cryptographic hashing.

- **BR-02 — Login Authentication**

The system shall authenticate users using verified credentials and shall enforce multi-factor authentication for all administrative accounts.

- **BR-03 — Blockchain Infrastructure Management**

The system shall operate a permissioned blockchain network and shall monitor ledger integrity to detect unauthorised modification events.

- **BR-04 — Smart Contract Deployment**

Administrators shall create, deploy, and assign immutable smart contracts using the Stratis blockchain platform.

- **BR-05 — Supplier Order Management**

Suppliers shall manage raw-material orders and shall update order status with blockchain verification.

- **BR-06 — Manufacturer Medicine Production**

Manufacturers shall manage medicine production in compliance with verified Good Manufacturing Practice (GMP) certification.

- **BR-07 — Wholesaler Distribution**

Wholesalers shall process and verify orders in compliance with Good Distribution Practice (GDP) requirements, with audit logs recorded for regulatory review.

- **BR-08 — Distributor Order Fulfilment**

Distributors shall verify product authenticity using blockchain custody records prior to order fulfilment.

- **BR-09 — Customer Medicine Ordering**

Customers shall place medicine orders only after successful prescription validation, where applicable.

- **BR-10 — Medication Source Verification**

The system shall enable users to verify medicine provenance by retrieving complete custody history from the blockchain.

- **BR-11 — Transporter Logistics Management**

Transporters shall provide periodic GPS location updates during shipment transit and shall digitally confirm custody transfers.

- **BR-12 — Role-Based Access Control (RBAC)**

The system shall enforce role-based access control following the principle of least privilege for all user roles.

- **BR-13 — Custody Transfer Recording**

Each custody transfer shall be recorded as a blockchain transaction with UTC timestamp and digital signatures from both parties.

- **BR-14 — Order Status Tracking**
Order status shall be updated within five seconds of blockchain transaction confirmation and shall notify relevant users of status changes.
- **BR-15 — Product Master Data Management**
Product master data shall validate National Drug Code (NDC) entries against the HSA registry prior to approval.
- **BR-16 — Regulatory Compliance Reporting**
The system shall generate regulatory compliance reports aligned with MOH, HSA, and PDPC requirements, with a minimum retention period of seven years.
- **BR-17 — Epic EHR Integration**
The system shall integrate with Epic EHR using HL7/FHIR APIs solely for prescription validation.
- **BR-18 — SAP ERP Integration**
The system shall synchronise inventory and financial data with SAP ERP on a daily basis.
- **BR-19 — Tamper Detection & Alerts**
The system shall issue tamper-detection alerts within 30 seconds of detection and automatically flag affected accounts.
- **BR-20 — Batch & Lot Number Tracking**
The system shall support batch and lot number tracking to enable recalls, audits, and regulatory traceability.

Technical Requirements (TR)

- **TR-01 — Cloud Infrastructure**

The system shall be hosted on secure cloud infrastructure with $\geq 99.9\%$ uptime and geographic redundancy.

- **TR-02 — Production Environment**

The production environment shall be hosted in a primary region with secondary-region replication for business continuity.

- **TR-03 — Environment Separation**

The system shall maintain separate development, staging, UAT, and production environments.

- **TR-04 — Three-Tier Architecture**

The system shall implement a three-tier architecture separating presentation, application, and data layers.

- **TR-05 — Load Balancing & Scaling**

The system shall support load-balanced application servers with auto-scaling capabilities.

- **TR-06 — Blockchain Node Servers**

Dedicated blockchain validator nodes shall meet minimum hardware specifications defined in the infrastructure standard.

- **TR-07 — Application Framework**

The web application shall be implemented using ASP.NET Core MVC.

- **TR-08 — CMS Exclusion**

The system shall be custom-built without reliance on a traditional CMS.

- **TR-09 — Development IDE**

Development shall be conducted using Microsoft Visual Studio or equivalent supported IDEs.

- **TR-10 — Admin Portal**

The system shall provide a web-based administrative portal for user, contract, and system management.

- **TR-11 — CLI Tools**

The system shall provide CLI tools limited to deployment, configuration, and monitoring functions.

- **TR-12 — Monitoring & Logging**

The system shall provide centralised logging and real-time monitoring dashboards.

- **TR-13 — Payment Processing**

Payment processing shall be handled through existing ERP integrations in Phase 1.

- **TR-14 — Future Payment Integration**

The system shall support extensibility for future payment gateway integration.

- **TR-15 — HL7/FHIR Compliance**

The system shall support HL7/FHIR R4 standards for Epic EHR integration.

- **TR-16 — API Performance**
The system shall respond to 95% of API requests within 2 seconds.
- **TR-17 — Integration Testing**
All external integrations shall be validated in sandbox environments prior to production deployment.
- **TR-18 — API Compatibility**
The system shall maintain backward compatibility for the two most recent API versions and publish a deprecation policy.
- **TR-19 — Backend Language**
Backend logic shall be implemented using C# with .NET 6.0.
- **TR-20 — Frontend Languages**
Frontend components shall be implemented using HTML5, CSS3, and JavaScript ES6+.
- **TR-21 — Smart Contract Language**
Smart contracts shall be written in C# for the Stratis platform.
- **TR-22 — Database Language**
Microsoft SQL Server with T-SQL shall be used for off-chain data storage.
- **TR-23 — Encryption at Rest**
All data at rest shall be encrypted using AES-256.
- **TR-24 — Encryption in Transit**
All data in transit shall be protected using TLS 1.3.
- **TR-25 — Access Controls**
The system shall enforce RBAC and MFA for administrative accounts.
- **TR-26 — Audit Logging**
Audit logs shall be retained for a minimum of seven years.
- **TR-27 — Backup & Recovery**
The system shall perform daily automated backups with RPO ≤ 24 hours and RTO ≤ 4 hours.
- **TR-28 — Maintenance Window**
Scheduled maintenance shall not exceed four hours per month during off-peak periods.
- **TR-29 — CI/CD Pipeline**
The system shall use automated CI/CD pipelines for build, test, and deployment.
- **TR-30 — Blue-Green Deployment**
The system shall support blue-green deployment with rollback capability.
- **TR-31 — Patch Management**
Security patches shall be applied within 48 hours of release.
- **TR-32 — Data Migration**
The system shall provide migration tools with post-migration validation reports.

- **TR-33 — Legacy Synchronisation**
The system shall support limited legacy-system synchronisation during transition periods.
- **TR-34 — Migration Validation**
All migrated data shall be validated for completeness and integrity.
- **TR-35 — Rollback Plan**
A documented rollback plan shall exist for migration failures.
- **TR-36 — Browser Support**
The system shall support modern desktop and mobile browsers.
- **TR-37 — OS Compatibility**
The system shall support Windows, macOS, and modern Linux distributions.
- **TR-38 — Mobile Responsiveness**
The web UI shall support responsive design for mobile devices.
- **TR-39 — Cross-Browser Testing**
Automated and manual cross-browser testing shall be conducted prior to release.
- **TR-40 — Page Load Performance**
Initial page loads shall complete within defined performance thresholds.
- **TR-41 — Interaction Response**
Standard user interactions shall respond within one second.
- **TR-42 — Concurrent Users**
The system shall support at least 500 concurrent users.
- **TR-43 — Transaction Volume**
The system shall support defined daily and peak transaction volumes.
- **TR-44 — Blockchain Confirmation**
Blockchain transactions shall confirm within agreed operational thresholds.
- **TR-45 — Database Performance**
Database queries shall meet defined latency thresholds.