

**Business Requirements**

<b>BR ID</b>	<b>Requirement Name</b>	<b>Business Requirement Statement (Final)</b>	<b>Stakeholder</b>	<b>Priority</b>
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.	All Users	Essential
BR-02	Login Authentication	The system shall authenticate users using verified credentials and shall enforce multi-factor authentication for all administrative accounts.	All Users / Admin	Essential
BR-03	Blockchain Infrastructure Management	The system shall operate a permissioned blockchain network and shall monitor ledger integrity to detect unauthorised modification events.	Administrators	Essential
BR-04	Smart Contract Deployment	Administrators shall create, deploy, and assign immutable smart contracts using the Stratis blockchain platform.	Administrators	Essential
BR-05	Supplier Order Management	Suppliers shall manage raw-material orders and shall update order status with blockchain verification.	Suppliers	Acceptable
BR-06	Manufacturer Medicine Production	Manufacturers shall manage medicine production in compliance with verified Good Manufacturing Practice (GMP) certification.	Manufacturers	Desirable
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.	Wholesalers	Acceptable
BR-08	Distributor Order Fulfilment	Distributors shall verify product authenticity using blockchain custody records prior to order fulfilment.	Distributors	Acceptable
BR-09	Customer Medicine Ordering	Customers shall place medicine orders only after successful prescription validation, where applicable.	Customers / Healthcare Providers	Acceptable
BR-10	Medication Source Verification	The system shall enable users to verify medicine provenance by retrieving complete custody history from the blockchain.	Customers / Healthcare Providers	Essential

BR-11	Transporter Logistics Management	Transporters shall provide periodic GPS location updates during shipment transit and shall digitally confirm custody transfers.	Transporters	Desirable
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.	All Roles	Essential
BR-13	Custody Transfer Recording	Each custody transfer shall be recorded as a blockchain transaction with UTC timestamp and digital signatures from both parties.	All Supply-Chain Participants	Essential
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.	All Roles	Desirable
BR-15	Product Master Data Management	Product master data shall validate National Drug Code (NDC) entries against the HSA registry prior to approval.	Administrators / Manufacturers	Desirable
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.	Compliance Officers / Admin	Essential
BR-17	Epic EHR Integration	The system shall integrate with Epic EHR using HL7/FHIR APIs solely for prescription validation.	Healthcare Providers	Desirable
BR-18	SAP ERP Integration	The system shall synchronise inventory and financial data with SAP ERP on a daily basis.	Finance / Admin	Desirable
BR-19	Tamper Detection & Alerts	The system shall issue tamper-detection alerts within 30 seconds of detection and automatically flag affected accounts.	Administrators	Essential
BR-20	Batch & Lot Number Tracking	The system shall support batch and lot number tracking to enable recalls, audits, and regulatory traceability.	Manufacturers / Regulators	Essential

