

Business & Operational Requirements

Assumptions (A)

ID	Assumption	Notes / Implication
A-01	MediCare Plus will operate a permissioned blockchain network	Limits participants to vetted stakeholders
A-02	All participants are known, registered, and vetted entities	Supports trust model/onboarding controls
A-03	Blockchain is used for verification and audit, not physical enforcement	Still needs physical anti-counterfeit controls
A-04	Transporters are third-party logistics providers	Requires transporter onboarding + tracking
A-05	Users have basic computer literacy and can complete training	Training plan needed
A-06	Compatible with any browser	Implies cross-browser testing scope

Company Constraints (C) & Rules (R)

ID	Statement	How to verify
C-01	Must operate within cybersecurity policies, including AES-256 encryption	Security audit / encryption-at-rest + in-transit evidence
C-02	Integration must not disrupt current operations during deployment	Cutover plan + rollback + staging/UAT signoff
C-03	Max downtime: 4 hours/month during off-peak (2–6 AM EST)	Monitoring + SLA report (also align timezone)
R-01	All medication orders must be verified by authorized personnel before shipment	Workflow enforcement + role-based approvals
R-02	Dual authorization for high-value shipments exceeding \$50,000	Threshold rule + 2-person approval logs (also clarify currency)

External Business Systems

System Name	Purpose	Integration Method
Epic EHR System	Patient prescription validation	HL7/FHIR API
SAP ERP	Inventory management, financials	REST API with OAuth 2.0
Omnicell Automated Dispensing	Medication dispensing verification	Vendor API connector
FDA Sentinel System	Adverse event reporting	HTTPS data submission

BR ID	Cogent Requirement Summary	SRS Category
BR-01	Password policy enforcement	Non-Functional (Security)
BR-02	MFA authentication	Non-Functional (Security)
BR-03	Permissioned blockchain operation	Functional Requirement
BR-04	Smart contract lifecycle management	Functional Requirement
BR-05	Supplier order management	Business Requirement
BR-06	Manufacturer production compliance	Business Requirement
BR-07	Wholesaler GDP processing	Business Requirement
BR-08	Distributor authenticity verification	Functional Requirement
BR-09	Prescription validation	Functional Requirement
BR-10	Provenance verification	Functional Requirement
BR-11	Transporter GPS updates	Non-Functional (Operational)
BR-12	Role-based access control	Non-Functional (Security)
BR-13	Custody transfer recording	Functional Requirement
BR-14	Order status update timing	Non-Functional (Performance)
BR-15	Product master data validation	Data Requirement
BR-16	Regulatory compliance reporting	Functional Requirement
BR-17	Epic EHR integration	External Interface Requirement
BR-18	SAP ERP synchronisation	External Interface Requirement
BR-19	Tamper alert notification	Non-Functional (Reliability)
BR-20	Batch and lot tracking	Data Requirement