SOP FOR SUPPLY CHAIN MANAGEMENT

Example of a Pharmaceutical Company

Document Control Information

SOP Number:	SCM-001-2025
Version:	1.0
Effective Date:	[Insert Date]
Review Date:	[Annual Review]
Document Owner:	Supply Chain Manager
Approved By	Quality Assurance Head
Distribution:	All Supply Chain Personnel

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1. PURPOSE AND SCOPE

1.1 Purpose

This Standard Operating Procedure (SOP) establishes guidelines for effective supply chain management in pharmaceutical manufacturing and distribution operations in India. It ensures compliance with regulatory requirements while maintaining product quality, safety, and efficacy throughout the supply chain.

1.2 Scope

This SOP applies to:

- [ ] All pharmaceutical products (prescription drugs, OTC medications, biologics)
- [ ] Raw materials, Active Pharmaceutical Ingredients (APIs), excipients
- [ ] Packaging materials
- [ ] All personnel involved in supply chain activities
- [ ] Third-party logistics providers and distributors
- [ ] Import and export operations

1.3 Objectives

- [ ] Ensure compliance with Central Drugs Standard Control Organization (CDSCO) regulations
- [ ] Maintain product integrity throughout the supply chain
- [ ] Optimize inventory management and reduce wastage
- [ ] Establish robust vendor qualification and management processes
- [ ] Implement effective risk management strategies
- [ ] Ensure traceability and serialization compliance

2. DEFINITIONS AND ABBREVIATIONS

2.1 Key Definitions

- [ ] **API (Active Pharmaceutical Ingredient):** The biologically active component of a drug product
- [ ] **Cold Chain:** Temperature-controlled supply chain for temperature-sensitive products
- [ ] FIFO **(First In, First Out):** Inventory management method ensuring older stock is used first
- [ ] **GDP (Good Distribution Practice):** Guidelines for proper distribution of medicinal products
- [ ] **GMP (Good Manufacturing Practice):** Quality assurance system for pharmaceutical manufacturing
- [ ] **Serialization:** Process of assigning unique identifiers to pharmaceutical packages

2.2 Abbreviations

- [ ] **CDSCO:** Central Drugs Standard Control Organization
- [ ] **WHO:** World Health Organization
- [ ] **PIC/S:** Pharmaceutical Inspection Co-operation Scheme
- [ ] **ERP:** Enterprise Resource Planning
- [ ] **WMS:** Warehouse Management System
- [ ] **HVAC:** Heating, Ventilation, and Air Conditioning
- [ ] **SLA:** Service Level Agreement
- [ ] **KPI:** Key Performance Indicator

3. RESPONSIBILITIES

3.1 Supply Chain Manager

- [ ] Overall responsibility for supply chain operations
- [ ] Ensures compliance with regulatory requirements
- [ ] Approves vendor qualifications and agreements
- [ ] Reviews and approves supply chain strategies
- [ ] Monitors KPIs and performance metrics

3.2 Procurement Team

- [ ] Sourcing and qualification of suppliers
- [ ] Purchase order management
- [ ] Contract negotiations
- [ ] Supplier performance monitoring
- [ ] Cost optimization initiatives

3.3 Inventory Management Team

- [ ] Inventory planning and forecasting
- [ ] Stock level monitoring
- [ ] Inventory turnover optimization
- [ ] Expiry date management
- [ ] Physical stock verification

3.4 Warehouse Team

- [ ] Receipt and inspection of materials
- [ ] Storage and handling operations
- [ ] Order fulfillment and dispatch
- [ ] Maintenance of storage conditions
- [ ] Physical security of inventory

3.5 Quality Assurance Team

- [ ] Quality control of incoming materials
- [ ] Batch release procedures
- [ ] Deviation investigation
- [ ] Audit of supply chain processes
- [ ] Validation of storage and distribution conditions

3.6 Regulatory Affairs Team

- [ ] Regulatory compliance monitoring
- [ ] License and permit management
- [ ] Serialization compliance
- [ ] Import/export documentation
- [ ] Regulatory communication

4. Regulatory Framework

4.1 Indian Regulatory Requirements

- [ ] Drugs and Cosmetics Act, 1940 and Rules, 1945
- [ ] Narcotic Drugs and Psychotropic Substances Act, 1985
- [ ] Pharmaceutical Policy, 2012
- [ ] Medical Device Rules, 2017
- [ ] New Drugs and Clinical Trials Rules, 2019

4.2 International Guidelines

- [ ] WHO Good Distribution Practices for pharmaceutical products
- [ ] PIC/S Guide to Good Distribution Practice for Medicinal Products
- [ ] ICH Q10 Pharmaceutical Quality System
- [ ] ISO 13485 for Medical Devices

4.3 Serialization Requirements

- [ ] Compliance with global serialization standards
- [ ] Unique Device Identification (UDI) for medical devices
- [ ] Track and trace capabilities
- [ ] Aggregation and disaggregation processes

5. Procurement Management

5.1 Supplier Qualification Process

5.1.1 Initial Assessment

- [ ] Technical capability evaluation
- [ ] Quality system assessment
- [ ] Regulatory compliance verification
- [ ] Financial stability analysis
- [ ] Risk assessment

5.1.2 Documentation Requirements

- [ ] Valid manufacturing/trading licenses
- [ ] GMP certificates
- [ ] ISO certifications
- [ ] Quality agreements
- [ ] Supply capability statements

5.1.3 Audit Process

- [ ] On-site audit for critical suppliers
- [ ] Document review and verification
- [ ] Quality system evaluation
- [ ] Corrective action plan if required
- [ ] Re-audit schedule determination

5.2 Purchase Order Management

- [ ] Approved vendor list maintenance
- [ ] Purchase requisition approval workflow
- [ ] Purchase order generation and approval
- [ ] Order confirmation and acknowledgment
- [ ] Delivery schedule monitoring

5.3 Contract Management

- [ ] Master service agreements
- [ ] Quality agreements
- [ ] Service level agreements
- [ ] Price agreements
- [ ] Termination and renewal procedures

6. Inventory Management

6.1 Inventory Planning

6.1.1 Demand Forecasting

- [ ] Historical consumption analysis
- [ ] Market trend consideration
- [ ] Seasonal variation adjustment
- [ ] New product launch planning
- [ ] Safety stock determination

6.1.2 Inventory Classification

- [ ] ABC analysis for prioritization
- [ ] XYZ analysis for demand variability
- [ ] Critical vs. non-critical categorization
- [ ] Fast-moving vs. slow-moving classification

6.2 Stock Control Procedures

6.2.1 Minimum and Maximum Stock Levels

- [ ] Reorder point calculation
- [ ] Safety stock maintenance
- [ ] Maximum stock level determination
- [ ] Economic order quantity optimization

6.2.2 Stock Movement Procedures

- [ ] FIFO/FEFO implementation
- [ ] Batch tracking and traceability
- [ ] Stock transfer procedures
- [ ] Quarantine and release procedures

6.3 Expiry Date Management

- [ ] Expiry date monitoring system
- [ ] Near expiry alert mechanism
- [ ] Short expiry product handling
- [ ] Expired product disposal procedures

6. Inventory Management

7.1 Facility Requirements

7.1.1 Infrastructure Standards

- [ ] Adequate floor space and ceiling height
- [ ] Proper lighting and ventilation
- [ ] Temperature and humidity control systems
- [ ] Pest control measures
- [ ] Fire safety systems

7.1.2 Storage Area Segregation

- [ ] Quarantine area
- [ ] Approved materials area
- [ ] Rejected materials area
- [ ] Returned goods area
- [ ] Controlled substances area

7.2 Storage Conditions

7.2.1 Environmental Controls

- [ ] Temperature monitoring (15-25°C for general storage)
- [ ] Humidity control (45-65% RH)
- [ ] Light protection measures
- [ ] Air quality maintenance
- [ ] Continuous monitoring systems

7.2.2 Special Storage Requirements

- [ ] Refrigerated storage (2-8°C)
- [ ] Frozen storage (-15 to -25°C)
- [ ] Controlled room temperature storage
- [ ] Hazardous material storage
- [ ] Narcotic and psychotropic substances storage

7.3 Material Handling Procedures

- [ ] Receipt and inspection procedures
- [ ] Put-away processes
- [ ] Picking and packing procedures
- [ ] Loading and dispatch procedures
- [ ] Equipment maintenance

8. Distribution and Transportation

8.1 Distribution Planning

- [ ] Route optimization
- [ ] Vehicle scheduling
- [ ] Load planning
- [ ] Delivery prioritization
- [ ] Contingency planning

8.2 Transportation Requirements

8.2.1 Vehicle Specifications

- [ ] GDP-compliant vehicles
- [ ] Temperature monitoring systems
- [ ] Security features
- [ ] Cleanliness standards
- [ ] Maintenance requirements

8.2.2 Driver Qualifications

- [ ] Valid driving license
- [ ] GDP training certification
- [ ] Background verification
- [ ] Health fitness certificate
- [ ] Emergency response training

8.3 Documentation and Tracking

- [ ] Delivery challan preparation
- [ ] Transportation documentation
- [ ] Real-time tracking systems
- [ ] Proof of delivery collection

9. Cold Chain Management

9.1 Temperature-Sensitive Products

- [ ] Vaccines and biologics
- [ ] Insulin and diabetic medications
- [ ] Certain antibiotics
- [ ] Oncology products
- [ ] Blood products

9.2 Cold Chain Infrastructure

9.2.1 Storage Equipment

- [ ] Walk-in cold rooms
- [ ] Pharmaceutical refrigerators
- [ ] Freezers and ultra-low temperature freezers
- [ ] Cold storage chambers
- [ ] Backup power systems

9.2.2 Transportation Equipment

- [ ] Refrigerated vehicles
- [ ] Insulated containers
- [ ] Temperature data loggers
- [ ] Gel packs and dry ice
- [ ] Emergency power backup

9.3 Temperature Monitoring

- [ ] Continuous temperature monitoring
- [ ] Alarm systems for temperature excursions
- [ ] Data logging and record keeping
- [ ] Calibration of monitoring equipment

9.4 Cold Chain Qualification

- [ ] Installation qualification (IQ)
- [ ] Operational qualification (OQ)
- [ ] Performance qualification (PQ)
- [ ] Requalification schedule
- [ ] Change control procedures

10. Quality Control in Supply Chain

10.1 Incoming Material Inspection

- [ ] Identity verification
- [ ] Quality parameter testing
- [ ] Certificate of analysis review
- [ ] Batch record verification
- [ ] Quarantine procedures

10.2 In-Process Quality Checks

- [ ] Storage condition verification
- [ ] Handling procedure compliance
- [ ] Equipment calibration status
- [ ] Environmental monitoring
- [ ] Personnel hygiene checks

10.3 Product Release Procedures

- [ ] Batch testing completion
- [ ] Quality review and approval
- [ ] Release documentation
- [ ] Batch disposition
- [ ] Market complaint monitoring

10.4 Quality Deviation Management

- [ ] Deviation identification and reporting
- [ ] Root cause analysis
- [ ] Corrective and preventive actions (CAPA)
- [ ] Impact assessment
- [ ] Regulatory notification if required

11. Vendor Management

11.1 Vendor Qualification

- [ ] Initial assessment and approval
- [ ] Performance monitoring
- [ ] Annual review and requalification
- [ ] Risk assessment updates
- [ ] Supplier development programs

11.2 Performance Monitoring

11.2.1 Key Performance Indicators

- [ ] On-time delivery performance
- [ ] Quality performance metrics
- [ ] Cost competitiveness
- [ ] Service level achievements
- [ ] Regulatory compliance status

11.2.2 Vendor Scorecards

- [ ] Monthly performance reviews
- [ ] Quarterly business reviews
- [ ] Annual supplier conferences
- [ ] Performance improvement plans

11.3 Supplier Audits

- [ ] Risk-based audit frequency
- [ ] Audit planning and scheduling
- [ ] Audit execution and reporting
- [ ] Follow-up on findings
- [ ] Supplier certification programs

12. Documentation and Record Keeping

12.1 Required Documentation

- [ ] Standard Operating Procedures
- [ ] Work instructions and protocols
- [ ] Quality manuals and policies
- [ ] Training records
- [ ] Validation and qualification documents

12.2 Record Management

- [ ] Purchase orders and invoices
- [ ] Goods receipt and inspection records
- [ ] Storage and distribution records
- [ ] Temperature monitoring records
- [ ] Batch records and certificates

12.3 Data Integrity

- [ ] Accurate and complete records
- [ ] Contemporaneous documentation
- [ ] Original record preservation
- [ ] Controlled access to records
- [ ] Audit trail maintenance

12.4 Document Control

- [ ] Version control systems
- [ ] Approval workflows
- [ ] Distribution control
- [ ] Obsolete document management
- [ ] Periodic review and updates

13. Risk Management

13.1 Risk Assessment Process

- [ ] Risk identification and categorization
- [ ] Risk analysis and evaluation
- [ ] Risk control measures
- [ ] Risk monitoring and review
- [ ] Risk communication

13.2 Supply Chain Risk Categories

13.2.1 Supplier Risks

- [ ] Single source dependencies
- [ ] Supplier financial instability
- [ ] Quality and regulatory issues
- [ ] Capacity constraints
- [ ] Geopolitical risks

13.2.2 Operational Risks

- [ ] Equipment failures
- [ ] Power outages
- [ ] Natural disasters
- [ ] Transportation disruptions
- [ ] Cybersecurity threats

13.3 Business Continuity Planning

- [ ] Emergency response procedures
- [ ] Alternative supplier identification
- [ ] Backup facility arrangements
- [ ] Communication protocols
- [ ] Recovery time objectives

14. Emergency Procedures

14.1 Product Recall Procedures

- [ ] Recall team activation
- [ ] Recall classification determination
- [ ] Regulatory notification
- [ ] Customer communication
- [ ] Product retrieval and disposition

14.2 Supply Disruption Management

- [ ] Alternative sourcing activation
- [ ] Inventory reallocation
- [ ] Emergency procurement procedures
- [ ] Customer prioritization
- [ ] Communication strategies

14.3 Facility Emergency Procedures

- [ ] Fire emergency procedures
- [ ] Natural disaster response
- [ ] Security incident management
- [ ] Medical emergency protocols
- [ ] Business continuity activation

15. Training Requirements

15.1 Training Program Structure

- [ ] Induction training for new employees
- [ ] Role-specific training programs
- [ ] GDP and GMP training
- [ ] Regulatory update training
- [ ] Emergency response training

15.2 Training Content Areas

- [ ] Supply chain fundamentals
- [ ] Pharmaceutical regulations
- [ ] Quality management systems
- [ ] Cold chain management
- [ ] Documentation requirements

15.3 Training Records and Certification

- [ ] Training attendance records
- [ ] Assessment and certification
- [ ] Refresher training schedules
- [ ] Competency evaluations
- [ ] External training programs

16. Performance Monitoring

16.1 Key Performance Indicators (KPIs)

16.1.1 Operational KPIs

- [ ] Order fulfillment accuracy (Target: >99%)
- [ ] On-time delivery performance (Target: >95%)
- [ ] Inventory turnover ratio (Target: 6-8 times/year)
- [ ] Stock-out incidents (Target: <1% of SKUs)
- [ ] Storage condition compliance (Target: 100%)

16.1.2 Quality KPIs

- [ ] Supplier quality performance (Target: >98%)
- [ ] Product recall incidents (Target: <0.1%)
- [ ] Customer complaints (Target: <0.5%)
- [ ] Audit findings (Target: <5 critical findings/year)
- [ ] Regulatory compliance score (Target: 100%)

16.1.3 Financial KPIs

- [ ] Supply chain cost as % of revenue (Target: <15%)
- [ ] Inventory carrying cost (Target: <5% of inventory value)
- [ ] Transportation cost optimization (Target: 5% annual reduction)
- [ ] Procurement savings (Target: 3% annual improvement)

16.2 Performance Review Process

- [ ] Daily operational dashboards
- [ ] Weekly performance reviews
- [ ] Monthly management reports
- [ ] Quarterly business reviews
- [ ] Annual strategic planning

17. Review and Revision

17.1 Document Review Schedule

- [ ] Annual review of SOP
- [ ] Regulatory update assessments
- [ ] Performance-based reviews
- [ ] Post-incident reviews
- [ ] Continuous improvement initiatives

17.2 Change Control Process

- [ ] Change request initiation
- [ ] Impact assessment
- [ ] Approval workflow
- [ ] Implementation planning
- [ ] Training and communication

17.3 Version Control

- [ ] Version numbering system
- [ ] Change history documentation
- [ ] Distribution of revised versions
- [ ] Obsolete version withdrawal
- [ ] Archive management

Appendices

Appendix A: Regulatory References

- [ ] Central Drugs Standard Control Organization (CDSCO) guidelines
- [ ] Schedule M (Good Manufacturing Practices)
- [ ] WHO Good Distribution Practice guidelines
- [ ] PIC/S GDP guide
- [ ] Relevant pharmacopeial standards

Appendix B: Forms and Templates

- [ ] Supplier qualification checklist
- [ ] Audit report template
- [ ] Deviation report form
- [ ] Temperature excursion report
- [ ] Training record template

Appendix C: Emergency Contact Information

- [ ] Regulatory authorities contact details
- [ ] Key supplier emergency contacts
- [ ] Internal emergency contact list
- [ ] Third-party service provider contacts
- [ ] Customer service contact details

DOCUMENT CONTROL

Prepared by:	[Supply Chain Manager Name]
Reviewed by:	[Quality Assurance Head Name]
Approved by:	[Operations Head Name]
Distribution:	All Supply Chain Personnel, Quality Team, Regulatory Affairs
Next Review Date:	[Date + 1 Year]