Fda Warehouse Audit Checklist Medical Device

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Facility Requirements

- [ ] Facility design appropriate
- [ ] Adequate space for operations
- [ ] Temperature/humidity controlled
- [ ] Environmental monitoring active
- [ ] Pest control program effective
- [ ] Cleaning/sanitization procedures
- [ ] Maintenance program documented
- [ ] Security measures adequate
- [ ] Access control enforced
- [ ] Visitor procedures followed
- [ ] Emergency procedures posted
- [ ] Safety equipment available

Quality System

- [ ] Quality manual current
- [ ] SOPs comprehensive
- [ ] Document control effective
- [ ] Change control procedures
- [ ] Training program documented
- [ ] CAPA system functioning
- [ ] Management review conducted
- [ ] Internal audits performed
- [ ] Supplier qualification done
- [ ] Validation/verification complete
- [ ] Risk management implemented
- [ ] Regulatory compliance maintained

Receiving & Inspection

- [ ] Receiving procedures documented
- [ ] Incoming inspection performed
- [ ] Acceptance criteria defined
- [ ] Sampling plans appropriate
- [ ] Non-conforming product controlled
- [ ] Supplier documentation verified
- [ ] Chain of custody maintained
- [ ] Temperature excursions checked

- [ ] Damage assessment done
- [ ] Lot/serial numbers recorded
- [ ] Quarantine procedures followed
- [ ] Release procedures proper

Storage Conditions

- [ ] Storage requirements defined
- [ ] Temperature mapping completed
- [ ] Monitoring systems calibrated
- [ ] Alarm systems functional
- [ ] Backup systems available
- [ ] Cold chain maintained
- [ ] Segregation requirements met
- [ ] FIFO/FEFO practiced
- [ ] Shelf life management active
- [ ] Expired product controlled
- [ ] Product identification clear
- [ ] Location system accurate

Inventory Control

- [ ] Inventory system validated
- [ ] Cycle counting performed
- [ ] Discrepancy investigation done
- [ ] Lot traceability maintained
- [ ] Serial number tracking active
- [ ] Expiration dating controlled
- [ ] Recall procedures ready
- [ ] Product holds managed
- [ ] Consignment inventory tracked
- [ ] Returns processing controlled
- [ ] Destruction procedures documented
- [ ] Annual physical inventory done

Distribution & Shipping

- [ ] Order processing controlled
- [ ] Pick/pack procedures accurate
- [ ] Shipping validation done
- [ ] Temperature monitoring included
- [ ] Package integrity verified
- [ ] Documentation complete
- [ ] Chain of custody maintained
- [ ] Export requirements met
- [ ] Transportation qualified
- [ ] Delivery confirmation obtained
- [ ] Customer complaints tracked

- [ ] Return procedures defined

Computer Systems

- [ ] System validation completed
- [ ] Access control enforced
- [ ] Audit trail functional
- [ ] Data backup performed
- [ ] Disaster recovery tested
- [ ] Change control followed
- [ ] Electronic signatures compliant
- [ ] Data integrity maintained
- [ ] System security adequate
- [ ] User training documented
- [ ] Periodic review conducted
- [ ] Vendor management active

Documentation & Records

- [ ] Device History Records complete
- [ ] Distribution records maintained
- [ ] Complaint files organized
- [ ] MDR procedures followed
- [ ] Recall records available
- [ ] Training records current
- [ ] Validation documentation complete
- [ ] Calibration records maintained
- [ ] Audit records filed
- [ ] Regulatory correspondence kept
- [ ] Retention periods followed
- [ ] Electronic records compliant

Complaint Handling

- [ ] Complaint procedures documented
- [ ] Complaint intake systematic
- [ ] Investigation thorough
- [ ] Root cause analysis performed
- [ ] Corrective actions taken
- [ ] MDR reportability assessed
- [ ] Trending analysis conducted
- [ ] Customer feedback provided
- [ ] Records maintained properly
- [ ] Regulatory reporting timely
- [ ] Management review included
- [ ] Effectiveness verified

Recall Management

- [ ] Recall procedures established
- [ ] Recall team identified
- [ ] Communication plan ready
- [ ] Product identification possible
- [ ] Distribution records accessible
- [ ] Mock recall conducted
- [ ] Effectiveness checks defined
- [ ] Regulatory notification procedures
- [ ] Customer notification templates
- [ ] Product retrieval procedures
- [ ] Destruction/correction procedures
- [ ] Termination criteria defined

Regulatory Compliance

- [ ] FDA registration current
- [ ] Device listing updated
- [ ] QSR compliance demonstrated
- [ ] UDI requirements met
- [ ] Labeling compliant
- [ ] Import/export compliant
- [ ] State requirements met
- [ ] International requirements addressed
- [ ] Inspection readiness maintained
- [ ] Regulatory changes tracked
- [ ] Training on regulations current
- [ ] Compliance metrics tracked

Audit & Improvement

- [ ] Audit program established
- [ ] Audit schedule maintained
- [ ] Qualified auditors used
- [ ] Findings tracked to closure
- [ ] Effectiveness verified
- [ ] Management review conducted
- [ ] Metrics/KPIs tracked
- [ ] Trending performed
- [ ] Continuous improvement demonstrated
- [ ] Best practices implemented
- [ ] Benchmarking conducted
- [ ] Customer satisfaction measured