Manufacturing Process Audit Checklist

(Sample)

1. REGULATORY COMPLIANCE

Licensing and Registration

- [ ] Valid Factory License under Factories Act, 1948
- [ ] MSME/SSI Registration (if applicable)
- [ ] GST Registration
- [ ] Pollution Control Board Consent to Operate (CTO)
- [ ] BIS Certification for relevant products
- [ ] Export licenses (if applicable)
- [ ] Import-Export Code (if applicable)

Labor Compliance

- [ ] ESI (Employees' State Insurance) Registration
- [ ] PF (Provident Fund) Registration
- [ ] Valid Standing Orders
- [ ] Wage Register maintained as per Payment of Wages Act
- [ ] Working hours compliance as per Factories Act
- [ ] Child Labor prohibition compliance
- [ ] Contract Labor management as per regulations
- [ ] Grievance handling mechanism in place
- [ ] Sexual Harassment Committee formed as per POSH Act, 2013

Environmental Compliance

- [ ] Valid Consent to Establish (CTE) and Consent to Operate (CTO)
- [ ] Environmental clearance for specified industries
- [ ] Hazardous waste authorization
- [ ] E-waste management compliance
- [ ] Effluent Treatment Plant (ETP) operational and records maintained
- [ ] Air pollution control measures in place
- [ ] Environmental monitoring records maintained
- [ ] Extended Producer Responsibility (EPR) plan for packaging waste

2. QUALITY MANAGEMENT SYSTEM

Documentation

- [ ] Quality Policy established and communicated
- [ ] Quality Manual available and up-to-date
- [ ] Standard Operating Procedures (SOPs) documented
- [ ] Work Instructions available at workstations
- [ ] Record retention policy established
- [ ] Document control system implemented
- [ ] Quality objectives defined and measured

Quality Certifications

- [ ] ISO 9001 certification
- [ ] Industry-specific certifications (ISO 13485, IATF 16949, etc.)
- [ ] BIS/ISI marks for applicable products
- [ ] FSSAI certification (for food products)
- [ ] GMP/GLP compliance (for pharmaceuticals/chemicals)
- [ ] Other relevant certifications

3. MANUFACTURING PROCESS CONTROLS

Production Planning

- [ ] Production planning process documented
- [ ] Capacity planning conducted regularly
- [ ] Man-machine balance charts utilized
- [ ] Production scheduling system in place
- [ ] Material requirements planning documented
- [ ] Production targets communicated to shop floor

Equipment and Machinery

- [ ] Preventative maintenance schedule established
- [ ] Equipment calibration program in place
- [ ] Machine logbooks maintained
- [ ] Breakdown maintenance records kept
- [ ] Equipment validation/qualification (IQ/OQ/PQ) conducted
- [ ] Equipment cleaning procedures documented
- [ ] Machine guarding and safety interlocks operational

4. MATERIALS MANAGEMENT

Raw Material Control

- [ ] Approved vendor list maintained
- [ ] Incoming material inspection procedure documented
- [ ] Material sampling plan defined
- [ ] Identification and traceability system in place
- [ ] Non-conforming material handling procedure established

- [ ] Material storage conditions defined and monitored
- [ ] FIFO/FEFO (First In First Out/First Expired First Out) practiced

Inventory Management

- [ ] Inventory levels monitored and controlled
- [ ] Inventory accuracy verified periodically
- [ ] Stock reconciliation conducted regularly
- [ ] Physical verification schedule established
- [ ] Economic order quantity analysis conducted
- [ ] Minimum/maximum inventory levels defined
- [ ] Obsolete/expired material handling procedure in place

5. SAFETY AND OCCUPATIONAL HEALTH

Safety Management

- [ ] Occupational Health and Safety Policy established
- [ ] Safety committee formed as per regulations
- [ ] Risk assessments conducted for all operations
- [ ] HAZOP/HIRA studies conducted for high-risk areas
- [ ] Emergency response procedures documented
- [ ] Mock drills conducted periodically
- [ ] Accident/incident reporting system implemented
- [ ] Safety inspections scheduled and documented
- [ ] Personal Protective Equipment (PPE) provided and usage monitored

Fire Safety

- [ ] Valid Fire NOC (No Objection Certificate) from Fire Department
- [ ] Fire detection systems installed and operational
- [ ] Fire fighting equipment installed and inspected regularly
- [ ] Evacuation plan displayed prominently
- [ ] Emergency exits marked and unobstructed
- [ ] Fire drills conducted as per schedule
- [ ] Fire wardens appointed and trained

6. TRAINING AND COMPETENCE

Personnel Training

- [ ] Training needs assessment conducted
- [ ] Training calendar established
- [ ] Job-specific training provided and documented
- [ ] GMP/GHP training conducted (if applicable)
- [ ] Safety training conducted regularly
- [ ] Training effectiveness evaluation conducted
- [ ] Refresher training schedule established
- [ ] Training records maintained
- [ ] Skill matrix developed and maintained

7. MAINTENANCE AND CALIBRATION

Maintenance Management

- [ ] Preventive maintenance program documented
- [ ] Maintenance schedules adhered to
- [ ] Breakdown maintenance records maintained

- [ ] Spare parts inventory controlled
- [ ] Lubrication schedules established
- [ ] Equipment history cards maintained
- [ ] Predictive maintenance techniques employed
- [ ] Maintenance effectiveness measured

Calibration

- [ ] Calibration master list maintained
- [ ] Calibration procedures documented
- [ ] Calibration schedule adhered to
- [ ] Traceability to national/international standards established
- [ ] Calibration status identified on equipment
- [ ] Out-of-calibration equipment handling procedure in place
- [ ] Calibration records maintained

8. PRODUCT QUALITY CONTROL

In-process Quality Control

- [ ] In-process inspection points identified
- [ ] Sampling plans documented
- [ ] Quality checks conducted at defined frequencies
- [ ] Test methods validated
- [ ] Quality data recorded and analyzed
- [ ] Hold points established where necessary
- [ ] Non-conforming product handling procedure implemented

Final Product Testing

- [ ] Final product specifications documented
- [ ] Finished product testing procedure established
- [ ] Representative sampling performed
- [ ] Product release procedure documented
- [ ] Certificate of Analysis (COA) generated
- [ ] Retained samples maintained
- [ ] Stability testing conducted (if applicable)

9. NONCONFORMITY AND CORRECTIVE ACTION

Nonconformity Management

- [ ] Nonconformity identification and recording procedure established
- [ ] Nonconforming product segregation system in place
- [ ] Disposition decision-making process documented
- [ ] Rework/reprocessing procedures defined
- [ ] Customer notification process for shipped nonconforming products

Corrective and Preventive Action

- [ ] Root cause analysis conducted for nonconformities
- [ ] Corrective action procedure documented
- [ ] Preventive action system established
- [ ] CAPA effectiveness verification process in place
- [ ] CAPA tracking system implemented
- [ ] Recurrence prevention measures documented

10. CONTINUOUS IMPROVEMENT

Performance Measurement

- [ ] Key Performance Indicators (KPIs) established
- [ ] Data collection and analysis conducted
- [ ] Process capability studies performed
- [ ] Cost of quality measured
- [ ] Productivity metrics tracked
- [ ] Energy consumption monitored
- [ ] Waste generation measured

Improvement Initiatives

- [ ] 5S implemented on shop floor
- [ ] Kaizen/continuous improvement system in place
- [ ] Lean manufacturing techniques employed
- [ ] Six Sigma projects conducted
- [ ] Total Productive Maintenance (TPM) implemented
- [ ] Quality Circles/Small Group Activities operational
- [ ] Employee suggestion scheme in place

11. SUPPLIER MANAGEMENT

Supplier Control

- [ ] Supplier qualification procedure documented
- [ ] Supplier audits conducted periodically
- [ ] Supplier performance evaluation system in place
- [ ] Supplier quality agreements established
- [ ] Supplier development program implemented

- [ ] Critical suppliers identified and closely monitored
- [ ] Second-tier supplier control strategy established

12. DOCUMENTATION AND RECORDS

Records Management

- [ ] Records control procedure established
- [ ] Record retention periods defined
- [ ] Records securely stored and accessible
- [ ] Electronic records backed up regularly
- [ ] Records disposal procedure documented
- [ ] Records review during internal audits

13. INDUSTRY-SPECIFIC REQUIREMENTS

Food & Beverage Industry

- [ ] FSSAI license valid and displayed
- [ ] Food safety management system implemented (FSMS)
- [ ] HACCP/ISO 22000 principles followed
- [ ] Food grade materials used
- [ ] Pest control program implemented
- [ ] Medical examination of food handlers conducted
- [ ] Allergen control program established
- [ ] Water quality testing conducted regularly

Pharmaceutical Industry

- [ ] Schedule M compliance (GMP for pharmaceuticals)
- [ ] Drug Manufacturing License valid
- [ ] Batch Production Records maintained
- [ ] Analytical Method Validation conducted
- [ ] Stability studies performed
- [ ] Change control system implemented
- [ ] Annual Product Review conducted
- [ ] Validation Master Plan established

Automotive Industry

- [ ] IATF 16949 requirements implemented
- [ ] Production Part Approval Process (PPAP) followed
- [ ] Advanced Product Quality Planning (APQP) conducted
- [ ] Failure Mode and Effects Analysis (FMEA) performed
- [ ] Statistical Process Control (SPC) implemented
- [ ] Measurement System Analysis (MSA) conducted
- [ ] Production batch traceability maintained