

Factory Audit Checklist

A concise framework for assessing manufacturing capability, quality controls and production readiness.

1. Facility & Organization

- Production areas suitable for the process
- Material and finished-goods areas controlled
- Production flow is understandable
- Housekeeping and basic safety conditions acceptable

2. Equipment & Process

- Required equipment available and suitable
- Equipment condition reviewed
- Process parameters defined where relevant
- Tooling / fixtures controlled and maintained

3. Incoming Quality Control

- Materials checked against requirements
- Material identification / traceability where needed
- Nonconforming material segregated
- Supplier material issues recorded

4. In-Process Quality Control

- Inspection points defined
- Operators understand key requirements
- Critical parameters monitored where appropriate
- Defects recorded and escalated

5. Final Inspection & Testing

- Final inspection criteria defined
- Functional testing performed where required
- Measurement equipment suitable
- Inspection records retained

6. Production Management

- Production orders identifiable
- Work instructions available where needed
- Production planning organized
- Packaging and labeling controlled

7. Corrective Action

- Root cause investigated
- Corrective action assigned
- Responsible owner identified
- Effectiveness checked where appropriate

— Audit Conclusion

- Meets project requirements
- Requires clarification / corrective action
- Further sample or process validation recommended
- Decision considers both capability and risk

Important Note

An audit is a point-in-time assessment. It does not guarantee future product conformity without ongoing production and quality controls.