

ISO 9001:2015 Manufacturing Checklist

Company Name: _____

Department: _____

Audit Date: _____

Auditor: _____

1. Context of the Organization

- ☐ Have the internal and external issues affecting quality been identified?
- ☐ Have the relevant interested parties and their requirements been determined?
- ☐ Is the scope of the Quality Management System (QMS) defined and documented?
- ☐ Are processes needed for the QMS identified, implemented, and maintained?

2. Leadership

- ☐ Has top management demonstrated leadership and commitment to QMS?
- ☐ Are quality policies established, communicated, and maintained?
- ☐ Are roles, responsibilities, and authorities clearly defined?

3. Planning

- ☐ Are risks and opportunities affecting product quality identified and addressed?
- ☐ Are quality objectives set and measurable?
- ☐ Are plans in place to achieve quality objectives?
- ☐ Are changes to the QMS properly planned and implemented?

4. Support

- ☐ Are resources adequate for QMS and manufacturing processes?
- ☐ Are personnel competent, trained, and aware of their responsibilities?
- ☐ Are infrastructure and work environment appropriate for product conformity?
- ☐ Are documented information and records controlled effectively?

5. Operation

- ☐ Are customer requirements reviewed and understood before production?
- ☐ Are production processes planned and controlled?
- ☐ Are criteria for process acceptance defined and monitored?
- ☐ Are nonconforming products identified, controlled, and disposed of properly?
- ☐ Are purchasing and supplier management processes in place?
- ☐ Are traceability and product identification maintained?

6. Performance Evaluation

- ☐ Is monitoring and measurement of processes and products conducted?
- ☐ Are customer satisfaction and feedback assessed?
- ☐ Are internal audits conducted on schedule?
- ☐ Are management reviews performed and documented?

7. Improvement

- ☐ Are corrective actions taken when nonconformities occur?
- ☐ Is there a process for continual improvement of the QMS?
- ☐ Are opportunities for improvement identified and implemented?

Notes / Observations:

Auditor Signature: _____

Date: _____