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Medical Device GMP Compliance Checklist

Mark Ready / Gap / N/A. Record evidence and justify N/A decisions.

Site / device: _____ Reviewer: _____

01 Scope & accountability

- ☐ Applicable market and QMS requirements identified.
- ☐ Process owners, responsibilities and training defined.
- ☐ Risk-based controls linked to device activities.

02 Documents & records

- ☐ Approved instructions available at point of use.
- ☐ Changes, versions and obsolete copies controlled.
- ☐ Records legible, retrievable and retained as required.

03 Suppliers & incoming controls

- ☐ Suppliers evaluated and monitored based on risk.
- ☐ Purchasing specifications and acceptance criteria defined.
- ☐ Incoming checks and supplier issues documented.

04 Production & environment

- ☐ Manufacturing instructions and process limits defined.
- ☐ Equipment maintenance and calibration current.
- ☐ Cleanliness and contamination controls appropriate.

05 Validation & change control

- ☐ Processes needing validation identified and justified.
- ☐ Approved protocols, acceptance criteria and results retained.
- ☐ Changes assessed; revalidation performed as needed.

06 Identification & release

- ☐ Identification and traceability maintained as applicable.
- ☐ Labeling, packaging and acceptance activities controlled.
- ☐ Release authorized against documented criteria.

07 Nonconformance & CAPA

- ☐ Nonconforming product identified and controlled.
- ☐ Causes investigated; corrective actions proportionate.
- ☐ Action effectiveness verified and documented.

08 Oversight & post-market feedback

- ☐ Complaints assessed, investigated and trended.
- ☐ Reporting obligations assessed under applicable rules.
- ☐ Internal audits and management reviews drive follow-up.

Screening aid only. Apply requirements relevant to the device, activities and market.

US reference: FDA QMSR / 21 CFR Part 820, incorporating ISO 13485:2016.