Production and Process Quality Checklist

Connect everyday manufacturing controls with the evidence behind release.

Product / process: _____ Reviewer / date: _____

Tick when verified. Reference the evidence and assign the highest-priority action.

01 Instructions and people

- ☐ Use approved instructions and current process settings.
- ☐ Define acceptance criteria and release responsibilities.
- ☐ Retain training and competence evidence for assigned tasks.

02 Validation and changes

- ☐ Document which processes need validation and why.
- ☐ Link protocols, acceptance criteria and executed results.
- ☐ Assess changes and define revalidation needs as applicable.

03 Equipment and measurement

- ☐ Confirm equipment suitability and maintenance status.
- ☐ Use measuring equipment with current calibration status.
- ☐ Assess product impact when equipment is out of tolerance.

04 Environment and cleanliness

- ☐ Define applicable cleanroom and contamination controls.
- ☐ Link sterilization, bioburden and packaging records as needed.
- ☐ Review monitoring excursions and document follow-up.

05 Identification and preservation

- ☐ Link materials, lots, work in progress and finished devices.
- ☐ Control labels, packaging issue and reconciliation records.
- ☐ Confirm storage, handling and distribution conditions.

06 Records, release and feedback

- ☐ Complete production and acceptance records before release.
- ☐ Document deviations, disposition and authorized decisions.
- ☐ Link servicing, recurring defects and trends to follow-up.

Priority gap / evidence reference:

Action / owner / due date: