Manufacturer's Pre-Panel Checklist

CAPA Investigation & Root Cause Checks

1. Are recurring issues linked to previous CAPAs?
Repeated deviations or complaints may indicate ineffective corrective actions.

2. Is the root cause verified with objective evidence?
A probable cause is not enough. Investigations should confirm the true source of failure.

3. Are investigations focused on systemic causes instead of symptoms?
Temporary fixes often lead to repeat CAPAs.

4. Are complaint, audit, deviation, and NCR trends connected to CAPA triggers?
Disconnected systems create missed escalation risks.

CAPA Effectiveness Monitoring Checks

5. Are effectiveness checks measurable and documented?
"Reviewed and acceptable" is not sufficient evidence.

6. Is CAPA effectiveness evaluated after implementation over a defined period?
Immediate closure rarely proves long-term effectiveness.

7. Are repeat CAPAs tracked and trended?
Recurring CAPAs often indicate weak investigations or incomplete actions.

8. Are high-risk CAPAs escalated appropriately?
Critical issues should trigger stronger review and management visibility.

CAPA Closure & Governance Checks

9. Are CAPAs closed only after objective evidence is reviewed?
Closure should require verification, not assumptions.

10. Are overdue CAPAs reviewed for quality and resource risks?
Aging CAPAs often signal process bottlenecks.

11. Are closure criteria consistent across departments?
Different standards create inconsistent CAPA quality.

12. Can your team clearly explain CAPA decisions during an audit?
If closure rationale is difficult to defend, auditors will likely challenge it.