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ISO 13485 Resource Controls

Readiness Checklist

Clause 6 | People, infrastructure, work environment and contamination control

Organization: _____ Reviewer: _____

Date: _____ Tick verified items. Record gaps and evidence separately.

1. Resource Provision — Clause 6.1

- ☐ Resources needed for QMS effectiveness and applicable customer and regulatory requirements are identified.
- ☐ Identified resource needs are provided, with evidence of implementation.

2. Competence, Training and Awareness — Clause 6.2

- ☐ Competence requirements are defined for personnel whose work affects product quality.
- ☐ Training or other actions address identified competence gaps.
- ☐ Effectiveness is evaluated using methods proportionate to the risk of the work.
- ☐ Personnel understand how their activities contribute to quality objectives.
- ☐ Education, training, skills and experience records are maintained.

3. Infrastructure and Maintenance — Clause 6.3

- ☐ Applicable workspace, utilities, equipment and supporting-service requirements are documented.
- ☐ Infrastructure supports product conformity, orderly handling and prevention of mix-ups.
- ☐ Maintenance requirements, intervals and records are established where maintenance affects product quality.

4. Work Environment — Clause 6.4.1

- ☐ Environmental requirements needed for product conformity are documented.
- ☐ Conditions that could adversely affect product quality are monitored and controlled.
- ☐ Health, cleanliness, clothing and competence or supervision controls are established where applicable.

5. Contamination Control — Clause 6.4.2

- ☐ Applicable contaminated-product handling controls protect personnel, the environment and other products.
- ☐ For sterile devices, microorganism, particulate and assembly or packaging cleanliness controls are documented.

Mark product- or process-specific items N/A with a documented rationale. Cleanrooms are not universal requirements. This is an initial readiness aid, not a complete audit checklist.

Need help closing resource control gaps?

Discuss your ISO 13485 resource controls with Elexes.

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