

ISO 13485

Management Responsibility and Review Readiness Checklist

Use this checklist to assess whether your management controls meet ISO 13485 Clause 5 requirements.



01 Management Commitment



- ☐ Quality responsibilities are defined
- ☐ Leadership involvement is documented
- ☐ Resources are reviewed and assigned

02 Quality Policy and Objectives



- ☐ Quality policy is established
- ☐ Objectives are measurable
- ☐ Progress is monitored

03 Roles and Communication



- ☐ Responsibilities are documented
- ☐ QMS ownership is assigned
- ☐ Internal communication processes exist

04 Management Review



- ☐ Required inputs are reviewed
- ☐ Decisions and actions are documented
- ☐ Follow-up effectiveness is monitored

05 Evidence Readiness



- ☐ Management records are maintained
- ☐ Actions have owners and timelines
- ☐ Improvement opportunities are tracked



Strengthen your ISO 13485 management controls and be audit ready.

Download Checklist 