

Harmonised ISO 13485 Transition Checklist

1. Conduct a gap analysis

Identify differences between your current QMS and the harmonised ISO 13485 requirements.

2. Map regulatory requirements

Align ISO 13485 clauses with applicable regulatory frameworks such as EU MDR or EU IVDR and other target markets.

3. Update documentation

Revise quality manuals, procedures, work instructions, and records to ensure alignment with harmonised ISO 13485 requirements.

4. Apply risk-based approach

Ensure risk-based approach is implemented in the Quality Management System. This implies implementation of quality controls proportionate to the risks involved in each and every process.

5. Train your team

Train personnel on updated QMS procedures and plans. Ensure training is comprehensive and effective. Record the evidence.

6. Perform internal audits

Check implementation effectiveness, close gaps, and verify corrective actions before external audit.

7. Management review & launch

Have leadership assess readiness and commit to continual improvement.

8. Certification readiness

Engage a certification body or registrar and schedule the certification assessment.

