ISO 13485 Design and Development Readiness Checklist

Elexes

An initial self-assessment against clause 7.3 of ISO 13485:2016, which FDA's QMSR also applies in the US from February 2, 2026. Numbers refer to ISO 13485 sub-clauses. Tick an item only if you can show a controlled record for it.

Procedures and planning — 7.3.1–7.3.2

- [ ] A documented design and development procedure is approved and followed.
- [ ] Each project has a plan covering stages, reviews, verification, validation and transfer.
- [ ] Responsibilities, authorities and resources, including staff competence, are defined.
- [ ] The plan is updated and re-approved as the project changes.

Design inputs — 7.3.3

- [ ] Inputs cover functional, performance, usability and safety requirements for the intended use.
- [ ] Regulatory requirements and applicable standards are identified for each target market.
- [ ] Relevant risk management outputs are captured as inputs.
- [ ] Inputs are reviewed, approved, unambiguous, verifiable and free of conflicts.

Outputs and design reviews — 7.3.4–7.3.5

- [ ] Outputs can be verified against inputs and are approved before release.
- [ ] Outputs include or reference acceptance criteria and information for purchasing and production.
- [ ] Design reviews are held at planned stages with the functions concerned.
- [ ] Review records show the design reviewed, participants, date, decisions and actions.

Verification and validation — 7.3.6–7.3.7

- [ ] Plans define methods, acceptance criteria and sample-size rationale.
- [ ] Validation uses representative product, with the choice of product justified.
- [ ] Clinical or performance evaluation is completed where regulations require it.
- [ ] Connected or interfacing devices are covered when the intended use requires it.

Design transfer — 7.3.8

- [ ] A documented procedure governs transfer of outputs to manufacturing.
- [ ] Outputs are verified as suitable for manufacturing before becoming production specifications.
- [ ] Production capability is shown to meet product requirements.
- [ ] Transfer results are recorded, and contract manufacturer duties are set in quality agreements.

Design changes — 7.3.9

- [ ] Each change is identified and its significance assessed for function, performance, usability, safety and regulatory requirements.
- [ ] Effects on components, product in process or delivered, and risk management are evaluated.
- [ ] Changes are reviewed, verified or validated as appropriate, and approved before implementation.
- [ ] The need for a new or amended regulatory submission is assessed and recorded.

Design and development file — 7.3.10

- [ ] A design and development file exists for each device type or family.
- [ ] The file contains or references all design and development records, including changes.
- [ ] Traceability links inputs to outputs, verification, validation and risk controls.
- [ ] Records are controlled, retrievable and retained for the required period.

Found gaps?

Elexes can remediate, create or audit your design and development file for FDA, EU MDR, UK, Health Canada and TGA expectations.

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Disclaimer: This checklist is an initial readiness tool and does not replace regulatory assessment, certification, legal advice, or authority review.

References: ISO 13485:2016, clause 7.3; 21 CFR Part 820 (QMSR), effective February 2, 2026.