QMSR transition checklist

Looking to adapt your medical device quality management system from the requirements of the FDA's legacy QSR to its new, ISO 13485-aligned QMSR?

Use this checklist to understand and work through the new requirements going into force when the QMSR goes live on February 2, 2026.

QS Regulation	ISO 13485:2016	QMSR Final Rule
Subpart A- General Provisions	Clause 1. Scope Clause 4. Quality Management System	Requirements substantively similar
Subpart B- QS Requirements	Clause 4. Quality Management System Clause 5. Management Responsibility Clause 6. Resource Management Clause 8. Measurement, Analysis, & Improvement	
Subpart C- Design Controls	Clause 7. Product Realization	
Subpart D- Document Controls	**Clause 4. Quality Management System**	**Differences addressed in 820.35**
Subpart E- Purchasing Controls	Clause 7. Product Realization	Requirements substantively similar
Subpart F- Identification and Traceability	Clause 7. Product Realization	
Subpart G- PP&C	Clause 4. Quality Management System Clause 6. Resource Management Clause 7. Product Realization	
Subpart H- Acceptance Activities	Clause 7. Product Realization Clause 8. Measurement, Analysis, & Improvement	
Subpart I- Nonconforming Product	Clause 8. Measurement, Analysis, & Improvement	
Subpart J- CAPA	Clause 8. Measurement, Analysis, & Improvement	
Subpart K- Labeling and Packaging Control	**Clause 7. Product Realization**	**Differences addressed in 820.45**
Subpart L- Handling, Storage, Distribution, and Installation	Clause 7. Product Realization	Requirements substantively similar
Subpart M- Records	**Clause 4. Quality Management System**	**Differences addressed in 820.35**
Subpart N- Servicing	**Clause 7. Product Realization**	
Subpart O- Statistical Techniques	Clause 7. Product Realization Clause 8. Measurement, Analysis, & Improvement	Requirements substantively similar

Background reading: familiarizing yourself with the QMSR's new sections

- [ ] Section 820.7: Incorporation by reference
- [ ] Section 820.10: QMS requirements
- [ ] Section 820.35: Control of records
- [ ] Section 820.45: Device labeling & packaging controls

Definitions & terminology

☐	Replace Device Master Record (DMR), Design History File (DHF) and Device History Record (DHR) with Medical Device File (MDF)
☐	Replace old DMR requirements with ISO 13485 Clause 4.2.3 adherence
☐	Replace old DHF requirements with ISO 13485 Clause 7.3 adherence
☐	Replace old DHR requirements with ISO 13485 Clause 7.5.1 adherence
☐	Rewrite risk statements and processes to incorporate broader definition of risk, incorporating regulatory compliance risk, borrowed from ISO 14971
☐	Keep using legacy FDA definitions of ‘device’, ‘labeling’ and ‘manufacturing’ (these override ISO definitions)

QMS requirements

☐	Reporting: combine requirements of 21 CFR 803 and ISO 13485 Clause 8.2.3
☐	Advisory notices: combine requirements of 21 CFR 806 and ISO 13485 Clauses 7.2.3 / 8.2.3 / 8.3.3
☐	Traceability & tracking: combine requirements of 21 CFR 821 and ISO 13485 Clause 7.5.9
☐	Identification & UDI: combine requirements of 21 CFR 830 and ISO 13485 Clause 7.5.8
☐	Design controls: replace 21 CFR 820.30 requirements with ISO 13485 Clause 7.3 design & development requirements
☐	Create a quality manual

Control of records

☐	Ensure ISO 13485 Clause 4.2.5 requirements are met alongside 820.35 requirements
☐	Add date/signature to approval processes
☐	Replace CAPA processes with ISO 13485 Clauses 8.5.2 and 8.5.3 requirements
☐	Ensure complaint records include associated CAPA records
☐	Ensure complaints involving device/packaging/labeling failures are investigated
☐	Build centralized complaint procedures and coordinating unit to ensure standardized complaint handling

Device labeling & packaging controls

☐	Ensure ISO 13485 7.5.1(e) requirements are met alongside 820.45 requirements
☐	Build processes to meet QMSR’s extra requirements for packaging, labeling and labeling inspection
☐	Ensure manual checks of label samples before release (pure automation not accepted)

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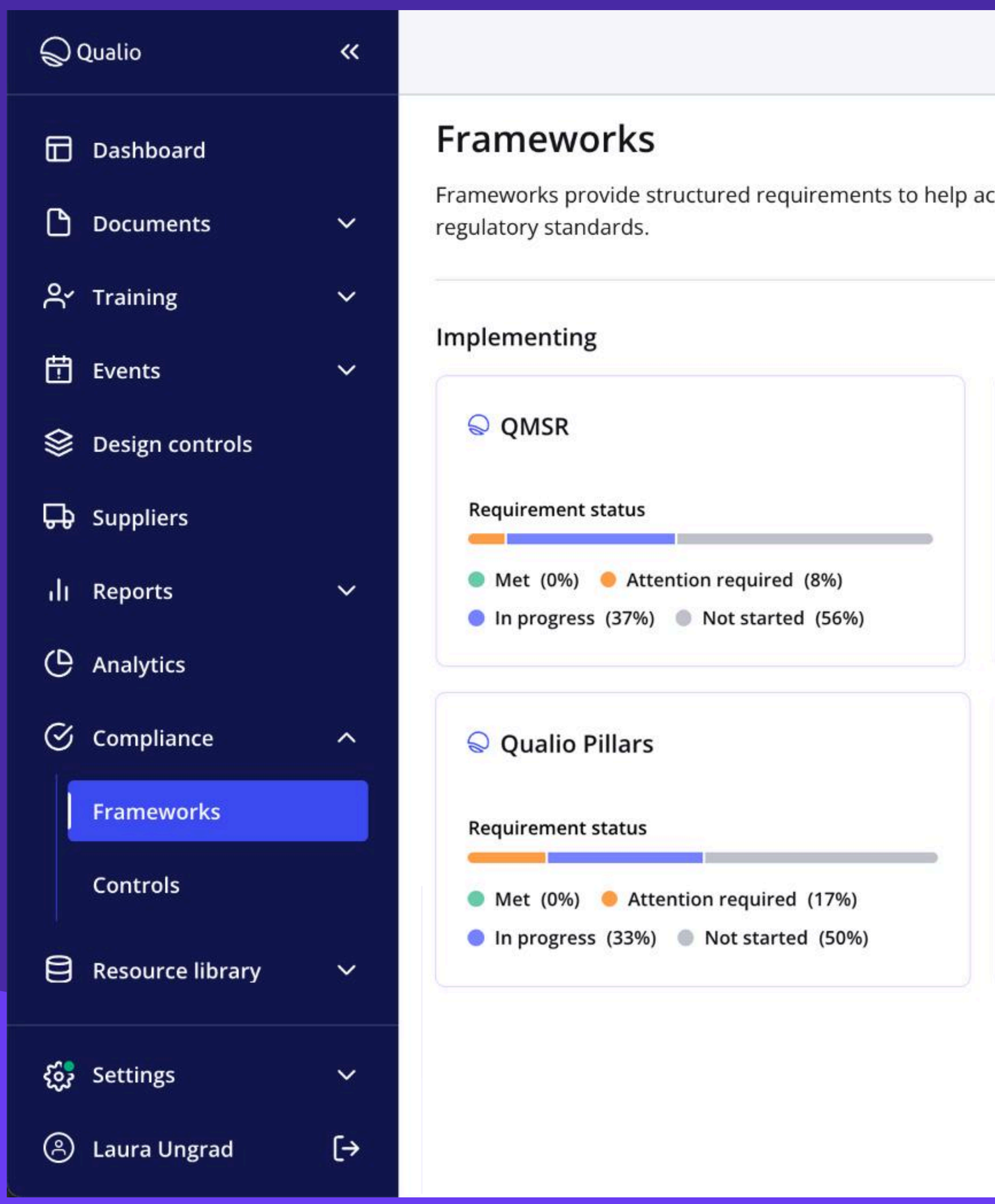

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