FDA QSR to QMSR

Regulatory, Legal, and Risk Implications for Industry

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Disclaimer

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About the Speaker

20+ Years in Medical Devices

- Engineer, Manager, Director
- Consultant
- ISO Auditor
- Professor
- Expert Witness

Education/Certifications

- Doctorate Regulatory Science – *coming soon!*
- M.S. Regulatory Science
- B.S. Chemical Engineering, Biomedical Engineering
- ASQ – CQE, CQA
- RAPS RAC – DEVICES
- ISO 13485 Lead Auditor

Agenda

- Background
- Significant Changes
- FDA Inspection Changes
- Citation Data
- Key Takeaways
- Resources

BACKGROUND

What is the QMSR?

- 21 CFR Part 820
- Effective February 2, 2026
- Incorporates ISO 13485:2016 by reference
- Establishes current good manufacturing practice (cGMP) requirements for medical devices
- Applies throughout the medical device lifecycle

Who Must Comply?

- Manufacturers
- Specification Developers
- Contract Manufacturers
- Repackagers
- Relabelers
- Remanufacturers
- Sterilizers
- Installers
- Servicers
- Initial U.S. Distributors performing regulated activities

Why the Change?

- Harmonize with ISO 13485:2016
- Reduce duplicate regulatory systems
- Support the Medical Device Single Audit Program (MDSAP)
- Improve consistency across global markets
- Modernize FDA's quality system framework

Why Should You Care?

Regulatory	Legal	Financial
• FDA inspections • Warning letters • Enforcement	• Product liability • Discovery • Expert testimony	• Insurance underwriting • Recalls • Cost of poor quality • Brand reputation

SIGNIFICANT CHANGES

Incorporation by Reference (IBR)

- FDA incorporated **ISO 13485:2016** by reference
- ISO 13485 now forms the foundation of the QMSR
- IBR allows FDA to reference existing standards rather than reproducing them in the CFR
- Harmonizes U.S. requirements with international quality system expectations
- Reduces duplication while maintaining FDA enforcement authority

What Does This Mean for Manufacturers?

ISO 13485 Certification is not required

ISO certification does not replace FDA inspections

Become familiar with ISO terminology and definitions

Update your procedures

Risk, Risk, and More Risk

- Risk management is no longer limited to design controls.
- Risk-based thinking is expected throughout the Quality Management System.
- Risk management extends across the entire product lifecycle.
- Decisions should be proportionate to the level of risk.
- Risk is now woven throughout ISO 13485—not confined to a single clause.

What Does “Risk-Based” Really Mean?

- Supplier controls
- Purchasing decisions
- Process validation
- Production controls
- Complaint investigations
- CAPA activities
- Internal audits
- Management review
- Post-market surveillance
- Change management

You do not have to comply with ISO 14971

What Does This Mean for Stakeholders?

FDA

- Inspection focus
- Evidence-based decisions
- Lifecycle oversight

Insurance

- Better risk profile
- Stronger underwriting position
- Reduced likelihood of major losses

Product Liability

- Demonstrates due diligence
- Supports defensible decision-making
- Strengthens litigation posture

FDA Access

Now Available for FDA Inspection:

- Internal audit records
- Supplier audit records
- Management review records

What this means:

- Greater regulatory transparency
- Increased importance of documenting issues and resolutions
- Stronger emphasis on effective quality system implementation

Practical Implications

- Remove outdated statements such as “Do Not Show to FDA”
- Document findings objectively
- Demonstrate follow-up and effectiveness
- Assume quality records may receive regulatory scrutiny
- Redaction may be appropriate for privileged or unrelated information when justified

Supplemental Provisions

- § 820.35 Control of records.
  a) Records of complaints
  b) Records of servicing activities
  c) Unique Device Identification
  d) Confidentiality
- § 820.45 Device labeling and packaging controls.

Practical Implications

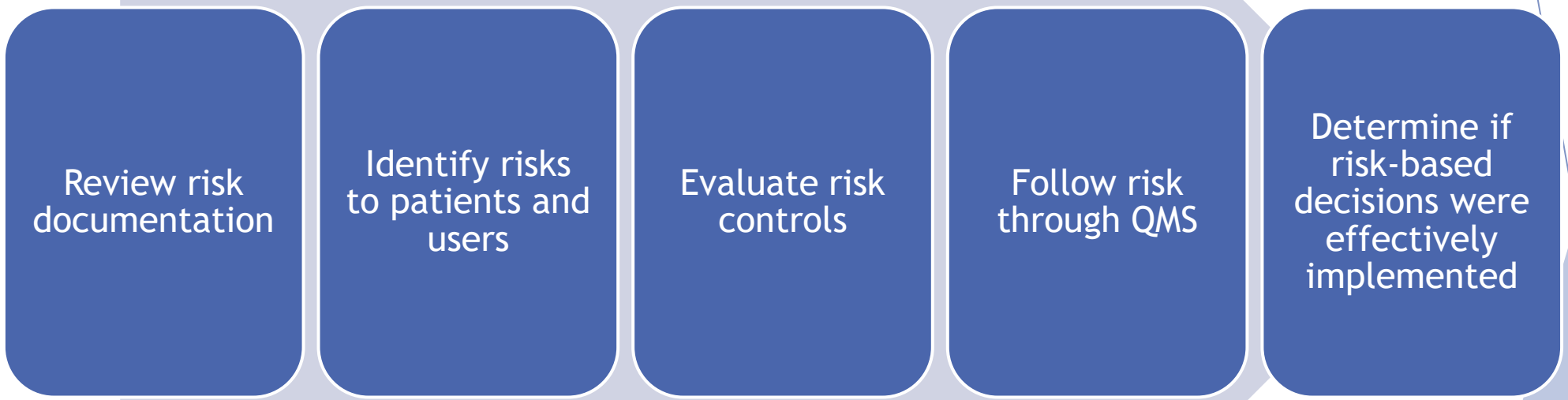
- All complaint and service records must include all elements required per the regulation – anything that cannot be obtained must be documented and justified
- Confidential records should be marked as such
- You must designate an individual to examine a sample of all labels that have been checked by automatic readers

FDA INSPECTION CHANGES

Goodbye QSIT... Hello Risk-Based Inspections

- Compliance Program (CP) 7382.850
- Risk-driven
- Patient & User Focused
- Evidence-based decision making

Investigator Approach



Investigator Approach

- Use critical thinking and consider risk
- Learn your products, processes, and organizational role
- Identify risks to patients and users
- Review risk management documentation
- Evaluate selected QMS Areas and FDA requirements
- Expand the inspection where additional risk is identified
- Flexible inspection process

The FDA is no longer inspecting whether you have a quality system. They're inspecting whether your quality system actually manages risk.

CITATION DATA

Top Ten Citations[1]

ISO 13485	Count
Clause 7.1 – Planning of product realization	71
Clause 8.5.2 – Corrective action	45
Clause 8.2.2 – Complaint handling	43
Clause 7.5.6 – Validation of processes for production and service	39
Clause 7.4.1 – Purchasing process	37
Clause 8.3.1 – Control of nonconforming product	31
Clause 4.1.2 – QMS general requirements	25
Clause 8.2.4 – Internal audit	23
Clause 7.5.1 – Control of production and service provision	21
Clause 4.1.5 – QMS general requirements	19
Clause 7.3.9 – Control of design and development changes	19

[1]Inspection data publicly available as of 7/28/2026, inspection end date after 2/2/2026, ISO 13485 citations only

Top Citation Descriptions

- Product realization risk management processes not documented
- Records of risk management activities in product realization not maintained
- Processes needed for product realization not planned and developed
- Required elements not determined in planning product realization
- Planning of product realization not consistent with other QMS processes
- Risk-based approach not applied to QMS processes

Top Citation Descriptions

- Inadequate monitoring and control over outsourced processes
- External party controls do not include written quality agreements
- Control over outsourced processes not proportionate to risk
- Criteria for the evaluation and selection of suppliers not established
- Procedures for purchasing process not documented
- Records of supplier (re)evaluation, selection, and monitoring not maintained
- Supplier evaluation and selection criteria do not include required elements
- Supplier monitoring and re-evaluation not planned
- Supplier performance not monitored

Top Citation Descriptions

- Computer software used in production and service provision not validated
- Planned results not consistently met during validation of processes
- Procedures for production/service provision software validation not documented
- Procedures for validation of processes not documented
- Procedures for validation of processes lack required elements
- Process for production and service provision not validated
- Records of validation of processes and necessary actions not maintained

Top Citation Descriptions

- Complaint handling procedures lack required elements
- Complaint handling procedures not documented
- Complaint handling records not maintained
- Lack of documented justification for not investigating complaint(s)

KEY TAKEAWAYS

Key Takeaways

- Replace QSR references with QMSR references throughout your Quality Management System.
- Align your terminology with ISO 13485 and ISO 9000.
- Expand your risk management program to address both product and process risks.
- Review every clause that references "risk" and ensure a documented, risk-based approach supports that process.
- Study FDA Compliance Program Manual 7382.850 to understand the Agency's new inspection philosophy.

Key Takeaways

- Review SOPs and document access controls for management reviews, internal audits, and supplier records in light of FDA's expanded inspection authority.
- When appropriate, redact privileged or unrelated information rather than restricting FDA access.
- Verify that complaint and servicing records contain all required regulatory elements.
- Maintain appropriate human oversight for critical activities, including labeling review and approval.
- Start with your highest-risk product or process and work backward to verify that appropriate controls, documentation, and objective evidence are in place.

Key Takeaways

- Clearly identify "top management" by name, title, and responsibility within your Quality Management System.
- Strengthen oversight of outsourced processes and suppliers. Remember, you remain responsible for ensuring outsourced processes are appropriately controlled and validated, where applicable—not just for approving the supplier.

Looking Ahead

- ISO 14971 is not *currently* IBR into the QMSR
- Standards change

"While ISO 13485 allows flexibility, the FDA expects clarity."

RESOURCES

- “Free” ISO 13485: https://ibr.ansi.org/Standards/iso.aspx
- Title 21 Part 820: https://www.ecfr.gov/current/title-21/chapter-I/subchapter-H/part-820?toc=1
- Compliance Program Manual: https://www.fda.gov/media/71690/download
- FDA QMSR Summary: https://www.fda.gov/medical-devices/postmarket-requirements-devices/quality-management-system-regulation-qmsr
- FDA Compliance Dashboard: https://datadashboard.fda.gov/oii/cd/index.htm

Thank you!

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Q&A