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QMSR is Coming: How to Prepare for FDA's Alignment with ISO 13485

RQM+ and Jama Software

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Steve Keverline provides regulatory and quality consulting to a wide range of companies – from large global conglomerates to small startups. With over 28 years of experience in the medical device industry, he has supported more than 100 medical device, diagnostic, and combination product companies during his 13 years at RQM+. This experience has given him a diverse background in a wide array of products and the ability to tailor his approach based on the context of the organization.

- Steve's expertise spans regulatory affairs, quality management systems, regulatory compliance, design and manufacturing quality engineering.
- He is a certified ISO 13485 Lead Auditor, ASQ-Certified Auditor and Six Sigma Black Belt.
- Known for his results-driven approach, Steve leads cross-functional teams throughout the full product lifecycle, delivering effective, business-balanced solutions.

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Tom Rish is a biomedical engineer with over 15 years of experience developing medical devices. His work has spanned the entire MedTech product lifecycle, from initial concept through market launch. He is passionate about helping others navigate the complex journey of bringing a device to market so that patients around the world can benefit from life-changing technologies. Tom is currently a member of the Product Marketing team at Jama Software.

QMSR is Coming: How to Prepare for FDA's Alignment with ISO 13485

- QMSR Refresher
  - Background information
  - Why is FDA aligning with ISO 13485
  - Key elements to watch for
  - Transition timeline
- QMSR Impact and Adoption
  - Companies early in adoption of ISO 13485
  - Companies mature in ISO 13485 needing to adjust to QMSR nuances
- Implementation Guidance
  - Best practices to align design control and risk management activities
  - Common pitfalls and how to avoid them
  - Preparation and planning

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QMSR Refresher

Key motivations for FDA aligning with ISO 13485 and what to watch for

QMSR Refresher

QSR Background

- FDA defines current good manufacturing practice (CGMP) requirements for medical device manufacturers within ***21 CFR Part 820***, known as the ***Quality System Regulation (QSR)***.
- ***Compliance with the QSR is mandatory*** for commercializing medical devices in the U.S., ***unless*** your device's FDA product code is listed as ***GMP-exempt***.
- The QSR ***originally took effect in 1978*** and was ***significantly revised in 1996***.
- The 1996 revision aimed to align CGMP with the ***ISO committee draft of ISO 13485***.
- Notably, the QSR revision was published ***before*** the release of ***ISO 13485:1996***.
- Since then, ISO 13485 has undergone ***two major revisions (ISO 13485:2003 and ISO 13485:2016)*** since the QSR's last significance revision.

QMSR Refresher

ISO 13485:2016 Background

- The ***International Organization for Standardization (ISO)*** is an independent, non-governmental international body that develops global standards.
- ***ISO 13485:2016*** Third Edition (published March 1, 2016), defines ***Quality Management System (QMS)*** requirements for medical devices ***intended for regulatory purposes***.
- The standard applies to medical device manufacturers ***at any stage of the product lifecycle***, including design, production, installation and servicing.
- It provides a framework for establishing QMS processes that help organizations meet ***regulatory requirements***.
- ISO 13485:2016 serves as the ***foundation for most QMS frameworks outside the United States.***

Key motivations for FDA aligning with ISO 13485

1. Global Harmonization

- ISO 13485:2016 and FDA's QSR have become increasingly aligned.
- Adopting ISO 13485 reduces the compliance burden for manufacturers in multiple markets.

2. Outdated Regulation

- The last major update to 21 CFR Part 820 was in ***1996*** – the same year ISO 13485 was introduced.
- While ISO 13485 has evolved significantly, the QSR has remained largely unchanged.

3. Efficiency for Industry and FDA

- Harmonization streamlines compliance, eliminating redundant efforts.
- Enables FDA to focus on ***risk-based oversight*** rather than duplicative inspections.

4. Regulatory Clarity

- Incorporating ISO 13485:2016 by reference provides a clearer, international recognized framework.
- Where differences exist, ***QMSR requirements will take precedence***.

5. Patient Safety Remains Central

- The FDA emphasizes that this shift is not about relaxing standards.
- It aims to enhance ***regulatory effectiveness*** while maintaining high standards for ***patient and user safety***.

QMSR Final Rule - Key elements to watch for

- The QMSR Final Rule was published on Jan. 31, 2024, with an effective date of Feb 2, 2026.

Part 820 – Quality System Regulation	
Subpart A - General Provisions	820.1 - Scope. 820.3 - Definitions. 820.5 - Quality system.
Subpart B - Quality System Requirements	820.20 - Management responsibility. 820.22 - Quality audit. 820.25 - Personnel.
Subpart C - Design Controls	820.30 - Design controls.
Subpart D - Document Controls	820.40 - Document controls.
Subpart E - Purchasing Controls	820.50 - Purchasing controls.
Subpart F - Identification and Traceability	820.60 - Identification. 820.65 - Traceability.
Subpart G - Production and Process Controls	820.70 - Production and process controls. 820.72 - Inspection, measuring, and test equipment. 820.75 - Process validation.
Subpart H - Acceptance Activities	820.80 - Receiving, in-process, and finished device acceptance. 820.86 - Acceptance status.
Subpart I - Nonconforming Product	820.90 - Nonconforming product.
Subpart J - Corrective and Preventive Action	820.100 - Corrective and preventive action.
Subpart K - Labeling and Packaging Control	820.120 - Device labeling. 820.130 - Device packaging.
Subpart L - Handling, Storage, Distribution, and Installation	820.140 - Handling. 820.150 - Storage. 820.160 - Distribution. 820.170 - Installation.

Part 820 – Quality Management System Regulation

Subpart A - General Provisions	820.1 - Scope. 820.3 - Definitions. 820.5 – [Reserved] 820.7 – Incorporated by reference 820.10 – Requirements for a quality management system
Subpart B – Supplemental Provisions	820.20 – 820.20 - [Reserved] 820.35 – Control of Records 820.40 - [Reserved] 820.45 – Device labeling and packaging controls
Subparts C-O	[Reserved]

QMSR Final Rule - Key elements to watch for

- Under QMSR, manufacturers must maintain a ***documented QMS*** that complies with applicable requirements of ***ISO 13485:2016*** *(QMSR 820.10(a)).*
- The FDA also imposes ***additional requirements*** beyond ISO 13485:2016 *(QMSR 820.10 (b))* which include:
  - ***Unique Device Identification (UDI)*** **-** 21 CFR Part 830,
  - ***Medical Device Tracking*** **-** 21 CFR Part 821,
  - **Adverse Event Reporting -** 21 CFR Part 803,
  - **Corrections and Removals -** 21 CFR Part 806.
- Certain existing QSR provisions will be ***retained,*** such as:
  - ***Design Control*** exemptions,
  - ***Complaint and Servicing*** records,
  - ***Device Labeling and Packaging*** requirements.

QMSR Final Rule - Key elements to watch for

Definitions – New or Different

New to QMSR	Different in QMSR (than in ISO 13485 or ISO 9000)
• Component • Federal Food, Drug, and Cosmetic Act • Finished Device • Human cell, tissue or cellular or tissue-based products (HCT/P) regulated as device • Remanufacturer	• Implantable medical device • Manufacturer • Organization • Rework • Safety and Performance

QMSR Final Rule – Key ISO 13485 Focus Areas

- ***ISO 13485:2016*** emphasizes a process-based approach, risk management throughout the product lifecycle, prescriptive supplier management, and proactive post-market surveillance.
- Areas to watch:
  - ***Documented procedures***

    Requires more formal and comprehensive documentation than many legacy QSR systems.
  - ***Risk-based decision making***

    Risk management is integrated across aa processes - not limited to product design.
  - ***Supplier management***

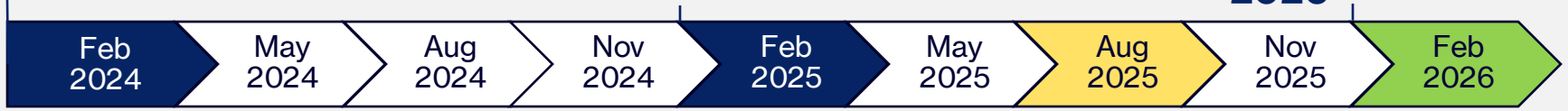
    Organizations must evaluate, select, and monitor suppliers based on risk and performance.
  - ***Post-market surveillance***

    ISO expects a proactive approach to monitoring device performance – not just reactive complaint handling.

QMSR Transition Timeline

Final Rule Published – **January 31, 2024**

QMSR Effective Date – **February 2, 2026**



2 Year Transition Period Begins

1 Year to Transition

QMSR Enforced

Milestone	Date	Description
First Rule Published	January 31, 2024	FDA officially published the QMSR final rule in the Federal Register
Transition Period Begins	January 31, 2024	Start of the 2-year period for industry to prepare for QMSR implementation
QMSR Effective Date	February 2, 2026	QMSR becomes enforceable; compliance with ISO 13485:2016 is requried.

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QMSR Impact and Adoption

Strategies for adopting QMSR-specific requirements to your business

Companies early in adoption of ISO 13485:2016

While ISO 13485:2016 is largely aligned with the current QSR, it includes several clauses that introduce requirements and processes not currently covered under legacy QSR only systems.

- Quality Manual
- QMS Planning
- Management Review Inputs and Outputs
- Training Competency and Evaluation
- Product Realization (including Risk Mgmt.)
- Customer-Related Processes (including customer property and data)
- Verification of Purchased Product based upon Supplier Evaluation results
- Cleanliness of Product
- Explicit Sterilization Requirements
- Feedback (in addition to complaint handling)
- Analysis of Data

Companies early in adoption of ISO 13485:2016

Risk Management

- ISO 13485 establishes explicit risk management QMS integration requirements
  - Required to incorporate a risk-based approach to establishing the QMS
- This risk-based approach is explicitly required for the following processes:
  - QMS Software Validation
  - Training
  - Product Realization
  - Design and Development
  - Purchasing
  - Servicing
  - Calibration
- Updates to risk procedures and records will be needed to comply with the QMSR
  - Must establish a Risk Management File (RMF) for each device/device family – design controls
  - Additional information on product risk management can be found in ISO 14971:2019

Companies early in adoption of ISO 13485:2016

Design Control

- Additional details on various aspects of Design Control will need to be updated from QSR to meet ISO 13485:2016/QMSR requirements.
  - Risk management outputs must be incorporated within Design Inputs
  - Design Verification must be planned and documented, include statistical rationale, and address device interfaces (other devices, software, etc.)
  - Design Transfer must be verified as suitable for manufacturing.
  - Design and Development File is the new term for Device History File (DHF)

Medical Device File

- ISO requires a Medical Device File for each device. This is very similar to the QSR's Device Master Record (DMR), with the following additional requirements:
  - General description of the device, intended use/purpose, and labelling (including IFU)
  - Specifications or procedures for packaging, storage, handling, and distribution.

Companies early in adoption of ISO 13485:2016

Non-conformance

- Additional requirements for nonconforming product identified pre and post delivery
- Methods of disposition are now explicitly defined (eliminated NC, preclude its use, use under concession)
  - Required to take action if nonconforming product is detected after delivery
- Rework requirements are better defined in ISO 13485 and these updates will be in QMSR

Quality Objectives

- Required to be established at relevant functions and levels, and to be measurable and consistent with the quality policy
- These should be reviewed at each management review. Failure to meet quality objectives should result in a CAPA to address the issue.
- Quality objectives are an excellent way to trend your QMS and ensure you are improving.

Companies mature in ISO 13485 needing to adjust to QMSR nuances

- If your current QMS is only compliant to the ISO 13485 standard and does not include FDA QSR, you will need to address the following requirements:
  - UDI requirements – 21 CFR Part 830
  - Device Tracking requirements – 21 CFR Part 821 (if applicable)
  - Adverse Event Reporting requirements – 21 CFR Part 803
  - Corrections and Removals Reporting requirements – 21 CFR Part 806
  - Complaint Records requirements – 21 CFR Part 820.198 (will transition to 21 CFR Part 820.35(a) under QMSR).
  - Servicing Records requirements – 21 CFR Part 820.200 (will transition to 21 CFR Part 820.35(b) under QMSR).
  - Device Labeling and Packaging Controls – 21 CFR Part 820.120, 820.130 (will transition to 21 CFR Part 820.45 under QMSR)

Companies mature in ISO 13485 needing to adjust to QMSR nuances

Control of Records (QMSR 21 CFR §820.35)

- In addition to the requirements of ***ISO 13485 Clause 4.2.5***, the manufacturer must include the following information in certain records:
  - ***820.35(a) Records of Complaints*** - ***In addition*** to ISO 13485 clause 8.2.2, manufacturers must record:

    (1) Name of device; (2) Date the complaint was received; (3) Any UDI or UPC and any other device identification; (4) The name, address, and phone number of the complainant; (5) The nature of details of the complaint; (6) Any correction or corrective action taken; and (7) Any reply to the complainant.
  - ***820.35(b) Records of Servicing – In addition*** to ISO 13485 clause 7.5.4, manufacturers must record:

    (1) Name of device; (2) Any UDI or UPC, and any other device identification(s); (3) Date of service; (4) Individual(s) who serviced the device: (5) Service performed; and (6) Any test and inspection data.
  - ***820.35(c) Unique Device Identification – In addition*** *to ISO 13485 clauses 7.5.1, 7.5.8, and 7.5.9, the UDI must be recorded for each medical device or batch of medical devices.*
  - ***820.35(d) Confidentiality –*** *Records deemed confidential by the manufacturer* ***(formerly §820.180 (c))*** *may be marked to aid FDA in determining whether information may be disclosed under the public information regulation in part 20 of this chapter.*

Companies mature in ISO 13485 needing to adjust to QMSR nuances

Device Labeling & Packaging Controls (QMSR 21 CFR §820.45)

- In addition to the requirements of ***ISO 13485 Clause 7.5.1***, the manufacturer must document procedures that provide a detailed description of the activities to ***ensure the integrity, inspection, storage, and operations for labeling and packaging***, during the customary conditions of processing, storage, handling, distribution, and, as appropriate, use of the device:
  - ***820.45(a)*** - The manufacturer must ensure labeling and packaging has been ***examined for accuracy prior to release or storage*** where applicable, to include:

    (1) Correct UDI or UPC and any other device identification; (2) Expiration date; (3) Storage instructions; (4) Handling instructions; and (5) Any additional processing instructions.

  - **820.45(b) – *Release of labeling for use*** must be documented according to ***ISO 13485 clause 4.2.5.***
  - **820.45(c) –** The manufacturer must ensure labeling and packaging operations have been established and maintained to ***prevent mix-up's***, including, but not limited to, ***inspection of the labeling and packaging before use to assure that all devices have correct labeling and packaging***, as specified in the medical device file. Results of such labeling inspection must be documented in accordance with ***ISO 13485 clauses 4.2.5.***

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Implementation Guidance

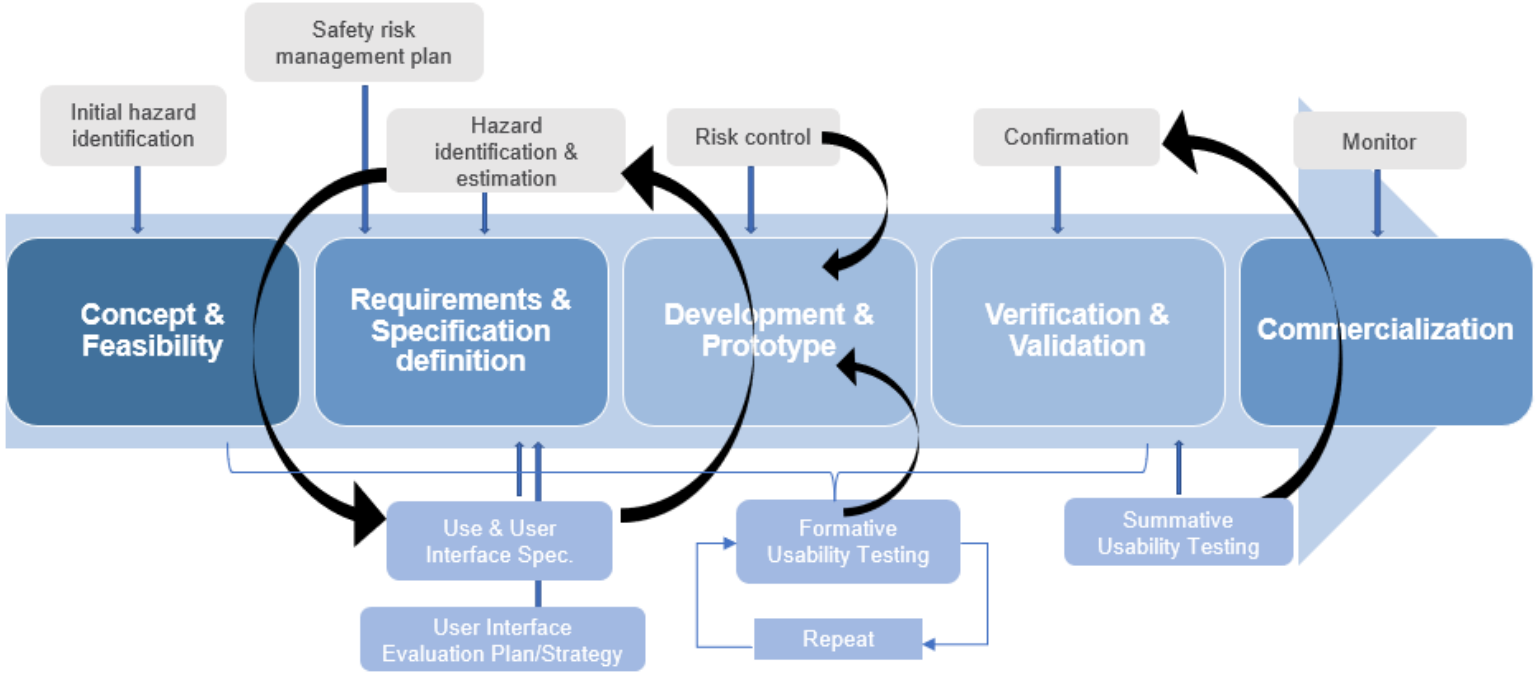
Preparation, planning and best practices

Bridging gap between design control & risk mgmt.

- **FDA QSR Design Controls – 820.30(g)**
  - "Design validation shall include software validation and ***risk analysis*** where appropriate."
  - While not explicitly stated, FDA expects risk management activities to be integrated throughout the product lifecycle.
- **ISO 13485:2016 Design and development inputs – 7.3.3**
  - "Design and development inputs shall include applicable outputs of ***risk management***"
  - Risk Management Outputs
    - Identified hazards and hazardous situations
    - Risk estimate (severity and probability)
    - Risk control measures
  - Design and Development Inputs
    - Functional, performance, and safety requirements
    - Regulatory and standards compliance
    - User needs and intended use

Ensures that risk controls are not just theoretical but are built into the product design from the beginning, making the device safer and more compliant.

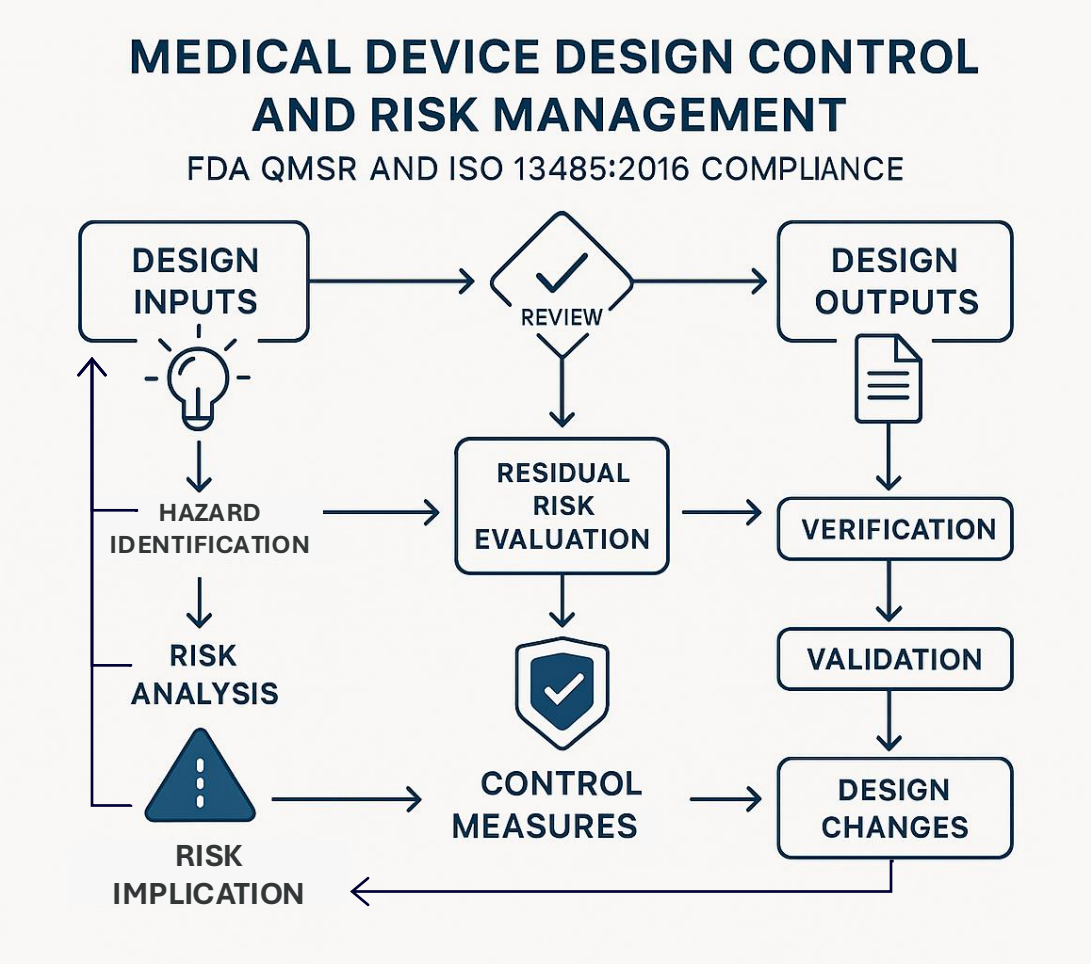
Best practices to align design control and risk management activities



Key Integration Points

Design Control Element	Risk Management Link
Design Inputs	Identify hazards and risk control measures early; ensure inputs reflect risk
Design Outputs	Verify that outputs implement risk controls (e.g., alarms, software limits, labeling)
Design Verification	Confirm that risk control measures are correctly implemented
Design Validation	Ensure the device meets user needs and mitigates risks in real-world use
Design Changes	Re-assess risks when changes are made; update risk files accordingly

Best practices to align design control and risk management activities



Best Practices for Integration

1. Use a Unified Risk Management

- Maintain a single, living document that evolves with the design process and links to all design control elements.

2. Cross-functional Teams

- Involve engineering, quality, regulatory, and clinical experts in both design and risk activities.

3. Traceability Matrix

- Map design inputs/outputs to risk control measures and verification/validation activities.

4. Risk-Based Decision Making

- Use risk severity and probability to prioritize design features and testing.

5. Software Tools

- Consider using software that supports integrated risk and design control workflows.

Common pitfalls in QMSR implementation and how to avoid them

- **Incomplete Gap Analysis**
  - Many firms underestimate the differences between legacy QSR (21 CFR Part 820) and ISO 13485:2016.
  - ***Avoidance Strategy:*** *Conduct a thorough gap analysis to identify discrepencies in documentation, procedures, and risk management practices.*
- **Insufficient Risk Management Integration**
  - ISO 13485 emphasizes risk-based thinking across all QMS processes, which may be underdeveloped in legacy systems.
  - ***Avoidance Strategy:*** *Embed risk management into design, production, and post-market activities. Use ISO 14971 as a guide for medical device risk management.*
- **Poor Document Control**
  - Legacy systems often lack robust document control aligned with ISO 13485.
  - ***Avoidance Strategy:*** *Update document control procedure to ensure traceability, version control, and accessibility.*

Common pitfalls in QMSR implementation and how to avoid them

- **Neglecting Supplier Oversight**
  - ISO 13485:2016 requires rigorous supplier qualification and monitoring which may be overlooked.
  - ***Avoidance Strategy:*** *Audit suppliers for ISO 13485 compliance and maintain documented evaluations and corrective actions.*
- **Overreliance on ISO 13485 Certification**
  - ISO certification does not guarantee FDA compliance.
  - ***Avoidance Strategy:*** *Ensure your QMS meets FDA-specific requirements, especially where definitions or expectations differ.*
- **Ignoring Labeling and Packaging Controls**
  - Section 820.45 introduces stricter controls, a common source of recalls.
  - ***Avoidance Strategy:*** *Review and update procedures for UDI, expiration dates, and handling instructions.*

1. Access Impact

- Attain a copy of ISO 13485:2016.
- For those newer to the standard, consider purchasing:
  - AAMI/ISO 13485:2016 Medical Devices – a Practical Guide
  - AAMI TIR102:2019 US FDA 21 CFR mapping to the applicable regulatory requirement references in ISO 13485:2016.
- Determine approach
  - QMSR vs QSR
  - QMSR vs ISO 13485:2016 (early adoption)
  - QMSR vs ISO 13485:2016 (well established)
- Context of the organization
  - Internal/ external stakeholders
  - Complexity of the QMS
  - Strictly gaps or include improvements
  - How to handle terms being removed
- Will the effort be more administrative in nature or requires significant update (not currently ISO 13485 compliant)
- Assess resources to support the change.

2. Quality Planning

"Plan your work for today and every day, then work your plan."

- Margaret Thatcher

- Initiate a Quality Plan for QMSR implementation to scope the work that is required and approach to be taken.

Table of Contents

3. Execute Plan

1. **Gap Analysis**
   - Perform a gap analysis to identify gaps between your current practices and the requirements of the new regulation.
2. **Create an Action Plan**
   - Develop and implement the action plan, including staff training, to address any identified discrepencies.
3. **Implementation**
   - Make sure you get input from all effected units
   - Incorporate feedback into consolidated document
   - Allow time for thoughtful review by all affected parties
4. **Audit Changes**
   - Conduct mock audit or use a third party to assess the effectiveness of the changes

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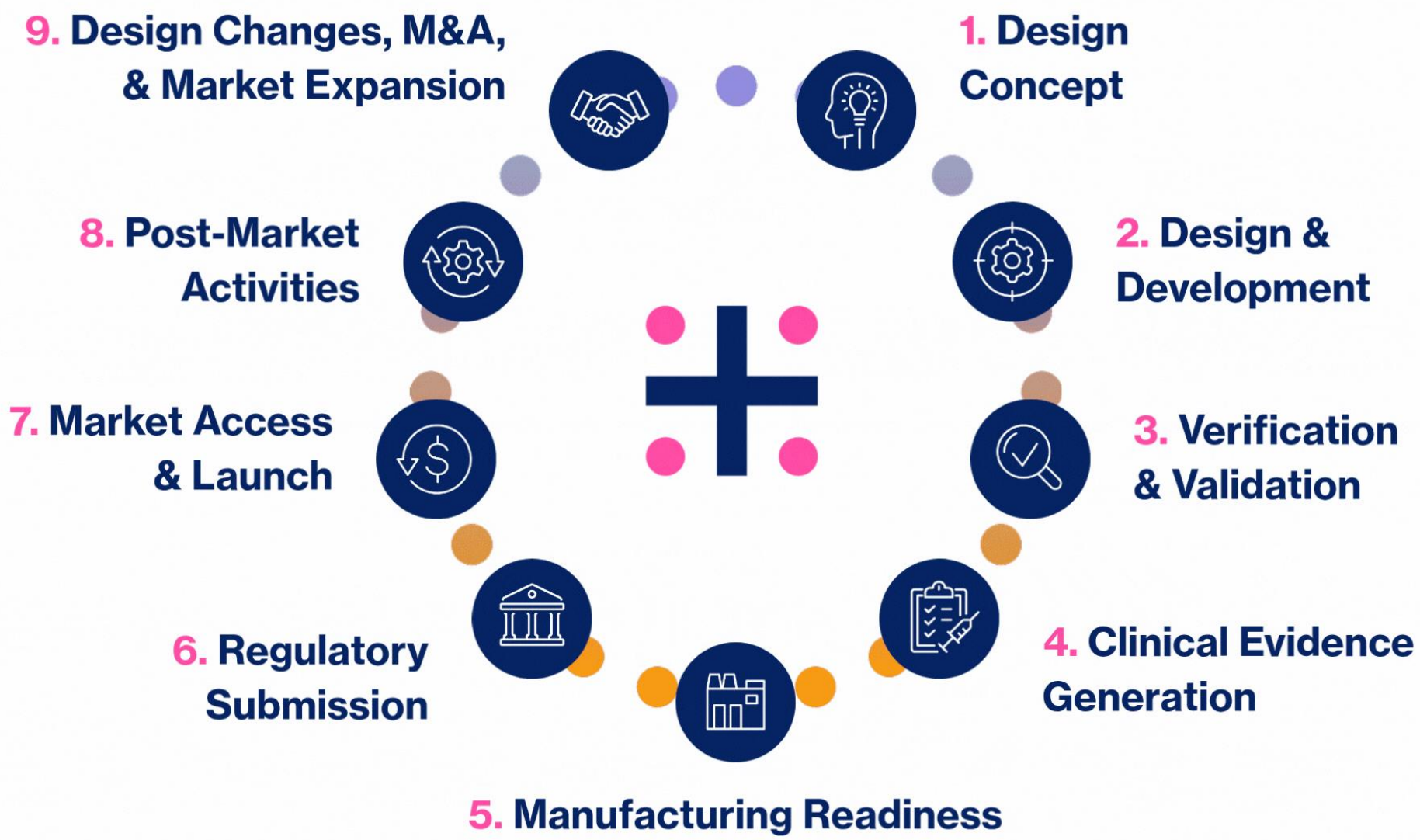

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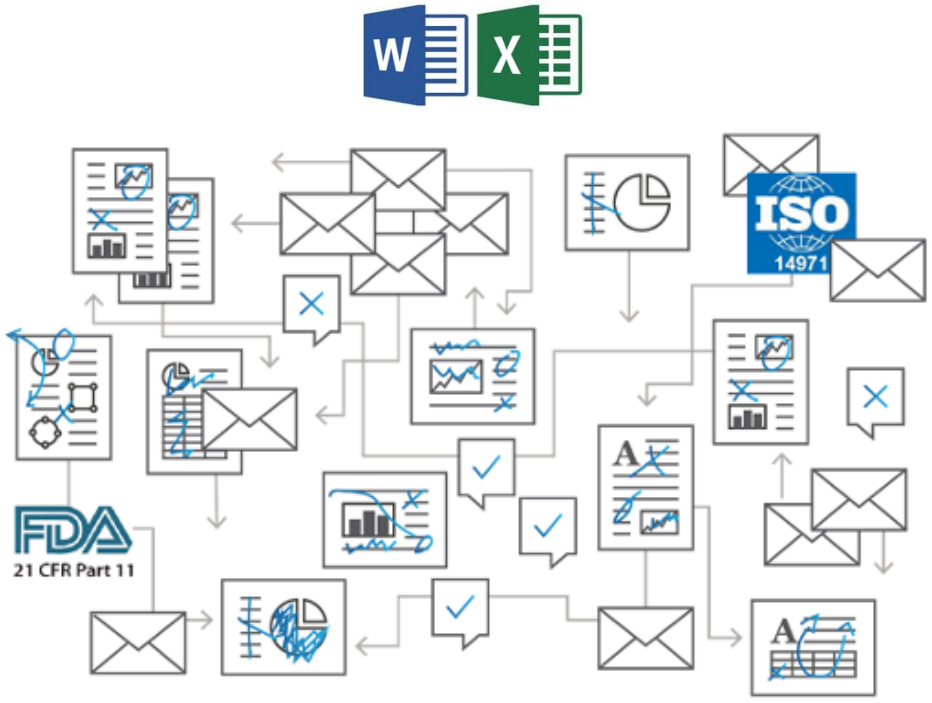
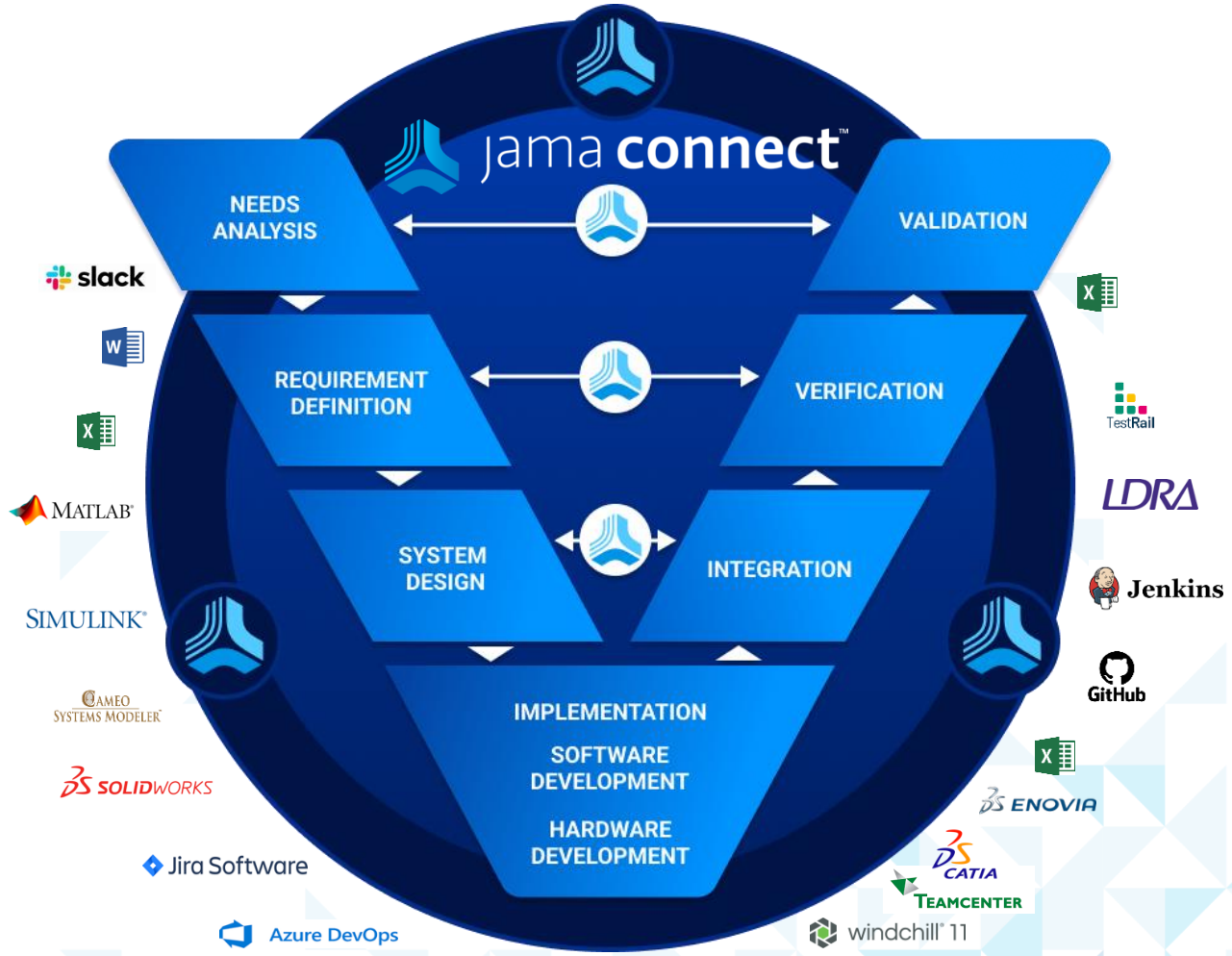
Common Challenge: Siloed Teams and Tools

DISCONNECTED DEVELOPMENT





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- Real-time collaboration & Review Center
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- Consulting & Training Services

Live Traceability

TRACEABILITY ENABLING **ISO 13485:2016, 21 CFR 820.30, ISO 14971:2019, IEC 62304**

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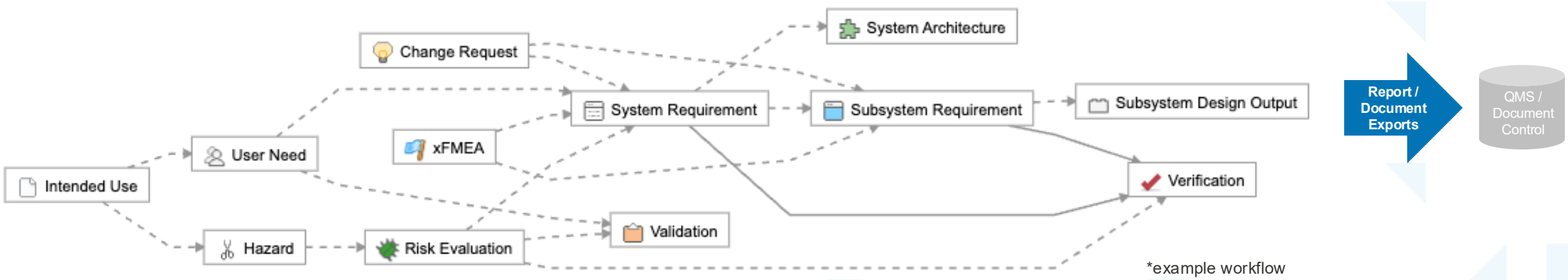

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Q&A

Thank You!