



WHITEPAPER

# The Evolution of FDA Design Controls (21 CFR 820.30) and How Jama Software® Supports Compliance

# History of US Regulation

The US medical device industry is governed by a complex framework of regulations designed to ensure the safety and effectiveness of products. A thorough understanding of this history provides valuable insights into the development of 21 CFR 820.30 and its critical importance to the industry.



## General Background

Medical devices have long played a pivotal role in modern healthcare, but the need for regulatory oversight only became apparent as unsafe and ineffective products led to accidents that caused massive human casualties, including losses of life. These risks are what drive the creation and enforcement of industry regulations. Early regulatory efforts focused primarily on pharmaceuticals, with little attention paid to devices until significant public health incidents highlighted their potential risks.



## The Federal Food, Drug, and Cosmetic Act (FD&C Act)

Enacted in 1938, the FD&C Act marked a turning point in U.S. healthcare regulation. Initially focused on drugs and food safety, the Act introduced basic oversight for medical devices. However, it was not until the 1976 Medical Device Amendments that the FDA's authority to regulate devices was significantly expanded due to another massive healthcare tragedy. These amendments established a classification system based on risk and required premarket approval for high-risk devices.



## Quality System Regulation (QSR)

The QSR, introduced in 1996, revolutionized medical device regulation by emphasizing quality management throughout the product lifecycle. It expanded the FDA's focus from inspecting end products to evaluating manufacturers' processes, requiring the implementation of comprehensive quality systems. Central to the QSR are the design controls outlined in 21 CFR 820.30, which ensure that products are developed with quality and safety embedded in every stage.

# Introduction of Design Controls

Design controls were added to the QSR to address the growing complexity of medical devices and the risks associated with poor design practices. These controls mandate a systematic approach to device development, from initial planning to post-market monitoring. They are required for all Class II and III devices, as well as select Class I devices such as software or devices with measuring functions

## **Class I – General Controls (Gloves, bandages)**

Least regulated, and minimal harm to user/patient

Includes GMP, label regulations, enterprise registration

## **Class II – Special Controls (NextGen Sequencing, PCR tests)**

Includes General Controls plus additional special controls (performance verification, labeling, post-market surveillance)

Premarket Notification 510(k) required, but some exemptions

## **Class III – Premarket Approval (HIV assay, pacemaker)**

Highest risk and most stringent regulation.

Requires Premarket Approval (PMA)



# Design Controls

Design controls are a cornerstone of medical device quality management, providing a structured framework to ensure medical devices meet safety, efficacy, and regulatory standards.



## Purpose of Design Controls

The overarching goal of design controls is to integrate quality into the design and development process. They help manufacturers:

- Mitigate potential risks before products reach the market.
- Deliver devices that reliably meet user needs and perform as intended.
- Ensure alignment with regulatory requirements, reducing the likelihood of non-compliance.

Design controls are not merely a regulatory requirement but a best practice that enhances quality, reduces development costs, and minimizes post-market issues.

## 10 Sections of Design Controls

The 10 sections outlined in 21 CFR 820.30 provide a comprehensive framework for managing the design and development process:

### 1. Design and Development Planning

This section requires manufacturers to establish a detailed plan outlining development activities, responsibilities, and deliverables. Key considerations include:

- Identifying project milestones.
- Assigning roles and responsibilities.
- Allocating resources effectively.

### 2. Design Input

Inputs define the requirements the device must meet, including user needs, regulatory standards, and intended use. Effective design input processes involve:

- Collaborating with stakeholders to gather comprehensive requirements.
- Prioritizing critical features.
- Ensuring inputs are clear, measurable, and verifiable.

### 3. Design Output

Outputs represent the tangible results of the design process, such as specifications, drawings, and manufacturing instructions. To ensure quality, outputs must:

- Be traceable to design inputs.
- Include acceptance criteria.
- Meet requirements for functionality and safety.

### 4. Design Review

Formal reviews are conducted at defined stages to evaluate progress and identify potential issues. These reviews involve cross-functional teams and should:

- Assess compliance with inputs and outputs.
- Document findings and corrective actions.
- Provide a platform for collaborative problem-solving.

### 5. Design Verification

Verification confirms that design outputs meet the specified inputs. Activities may include testing, inspections, and analyses. Manufacturers must:

- Use objective evidence to support verification.
- Maintain thorough documentation of results.

## 6. Design Validation

Design Validation ensures that the devices conforms to user needs/intended uses at production equivalent units. Activities may include testing, inspections, and analyses. Manufacturers must:

- Conducting usability testing with end-users.
- Comparing performance against real-world scenarios.
- Documenting validation results for regulatory review.
- Performing a risk analysis to ensure patient safety.

## 7. Design Transfer

Transitioning from design to production requires careful planning to ensure manufacturing processes align with design specifications. Key steps include:

Collaborating with stakeholders to gather comprehensive requirements.

- Developing detailed production procedures.
- Training staff on new processes.
- Conducting pilot runs to identify potential issues.

## 8. Design Changes

Any changes to the design must be systematically evaluated for their impact on the device's safety, performance, and regulatory compliance. Effective change control processes involve:

- Identifying the need for changes early.
- Conducting risk assessments for proposed modifications.
- Updating documentation accordingly.

## 9. Design History File (DHF)

The DHF is a compilation of records that demonstrate compliance with design controls. It should include:

- Evidence of adherence to each section of 21 CFR 820.30.
- Documentation of design reviews, verifications, and validations.
- A complete history of design changes.

## 10. Traceability in Design Controls

Traceability is a critical aspect of design controls, linking design inputs, outputs, verification, and validation activities. Comprehensive traceability matrices:

- Simplify compliance audits by providing clear documentation.
- Ensure that all requirements are addressed and verified.
- Support efficient change management processes.

# Upcoming Factors Impacting Design Controls

The regulatory landscape is evolving, and manufacturers must adapt to upcoming changes to remain compliant.

## Aligning FDA's New Quality Management System Regulation (QMSR) with ISO 13485

The FDA's recent initiative to align its Quality Management System Regulation (QMSR) with ISO 13485:2016 reflects this commitment to standardization and international collaboration. This chapter explores the rationale behind the FDA's decision, the implications for manufacturers, and the expected benefits of this alignment.

### The FDA's Commitment to Harmonization

For decades, the FDA's 21 CFR Part 820 Quality System Regulation (QSR) has served as the foundation for quality assurance in medical device manufacturing in the United States. However, with ISO 13485 emerging as the globally recognized standard for quality management systems in the medical device industry, discrepancies between the two frameworks have created challenges for manufacturers operating in multiple markets.

The FDA's initiative to transition from QSR to QMSR, aligning more closely with ISO 13485, is rooted in the following objectives:

- **Global Competitiveness:** By harmonizing with ISO 13485, the FDA aims to streamline compliance for manufacturers operating internationally, reducing duplicative regulatory efforts.
- **Enhanced Safety and Effectiveness:** Aligning with a widely adopted standard enables consistency in quality management practices, improving device reliability and patient safety across markets.
- **Regulatory Efficiency:** The FDA seeks to modernize its regulatory framework to reflect the realities of an increasingly interconnected global marketplace.

### Key Differences and Convergences

While QSR and ISO 13485 share common principles, there are differences in their structure, terminology, and emphasis. ISO 13485 places a stronger focus on risk management and supplier controls, while QSR emphasizes general good manufacturing practices (GMP). Through the alignment process, the FDA is working to bridge these differences while retaining the rigor needed to uphold its mandate of ensuring public health and safety.

The QMSR framework adopts ISO 13485's risk-based approach, aligning key elements such as:

- **Documentation Requirements:** Emphasizing detailed documentation for risk assessment and quality controls.
- **Design and Development Controls:** Aligning design processes to ensure uniformity and accountability throughout the product lifecycle.
- **Supplier Management:** Establishing stronger oversight and traceability in supply chain processes.

## Implications for Manufacturers

For medical device manufacturers, the shift to QMSR represents a significant change in compliance requirements. However, organizations already compliant with ISO 13485 will likely find the transition seamless, as many processes and practices under ISO 13485 align with the proposed QMSR.

Key impacts include:

- **Reduced Burden for Dual Compliance:** Harmonization eliminates the need for separate systems to address QSR and ISO 13485, saving time and resources.
- **Training and Adaptation:** Companies currently following QSR exclusively will need to invest in training and process updates to align with the risk-based methodologies of ISO 13485.
- **Global Market Access:** Meeting ISO 13485 requirements under the QMSR framework strengthens manufacturers' readiness to enter international markets.

## Expected Benefits of the Alignment

The FDA's QMSR alignment with ISO 13485 offers benefits that extend beyond regulatory compliance:

- **Improved Collaboration:** Manufacturers and regulators can engage in more streamlined dialogue, leveraging a common framework to address quality concerns.
- **Innovation Acceleration:** A unified regulatory environment reduces barriers to bringing innovative medical devices to market globally.
- **Patient-Centered Outcomes:** By fostering a risk-based approach, the QMSR ensures that safety and effectiveness remain central to quality management practices.

## Challenges and Industry Feedback

While the industry has broadly welcomed the alignment, concerns remain about the transition timeline, costs, and potential uncertainties during implementation. The FDA has actively sought feedback from stakeholders through public workshops, comments, and advisory panels to address these concerns and refine its approach.

## Laboratory Developed Test (LDT) Ruling

The FDA's proposed oversight of LDTs introduces new challenges for manufacturers. These tests often involve medical devices, making design controls crucial for ensuring compliance and maintaining market access.

Compliance with design control requirements is essential for developing product quality, maintaining regulatory approval, and safeguarding device safety and effectiveness.



## Preparing for Audits

FDA audits sometimes focus heavily on design controls (in addition to CAPAS, complaints, and risk management) to assess compliance with 21 CFR Part 820. Well-maintained records in the DHF are critical for demonstrating adherence to regulatory requirements and can:

- Reduce the risk of observations and warning letters.
- Streamline the audit process.
- Build confidence with regulatory authorities.



## Managing Change

Changes to a device design can have far-reaching implications. Effective design control processes ensure:

- Comprehensive risk assessments are conducted for all changes.
- Changes are documented and evaluated for regulatory impact.
- Modifications do not compromise safety or efficacy.



## Managing Risks and Complaints

Design controls enable proactive risk management and systematic complaint handling. Key benefits include:

- Early identification and mitigation of design flaws.
- Streamlined implementation of corrective and preventive actions (CAPAs).
- Improved post-market surveillance and product quality.

# How Jama Software Can Help

## **Accelerate compliance with Jama Software's Medical Device Framework, an out-of-the-box solution that complies with regulatory and industry standards, including FDA design controls, ISO 13485 and others.**

Jama Connect for Medical Device Development helps medical device teams reduce the effort required to achieve regulatory compliance throughout the development process. With this solution, medical device teams can manage design controls for device requirements and related risks, simplifying regulatory submissions and audit preparations while accelerating time to market.

You'll be able to:



### **Easily demonstrate traceability.**

Live Traceability™ ensures that design inputs have been met and verified, providing necessary evidence from the design control process. Jama Connect allows you to easily produce traceability documentation required by regulators.



### **Design verification and validation.**

Seamlessly manage traceability to verifications and validations, providing evidence to comply with government regulations and standards.



### **Maintain audit trails and export data.**

Real-time reporting and baselining allow you to track all changes to information within the system, including time stamps and associated users. Data is easily exported from Jama Connect if your current process dictates storage of documentation in a quality management system.



### **Manage risk analysis.**

Jama Connect helps teams identify and mitigate risks earlier in development, saving teams from frustrating late-stage design changes and supporting the path to regulatory compliance.

## Conclusion

Leveraging design controls effectively is crucial for medical device companies looking to reduce risk, increase efficiency, and meet strict regulatory requirements. Jama Connect enables organizations to seamlessly manage design controls throughout the product lifecycle, ensuring compliance while accelerating innovation. With features like Live Traceability™ and industry-specific solutions, Jama Connect empowers teams to stay ahead in a competitive and highly regulated market.

Now is the time to take the next step toward improving your design control processes.

Request a free trial of Jama Connect today and experience the difference it can make in your medical device development.

GET STARTED



Jama Software® is focused on maximizing innovation success in multidisciplinary engineering organizations. Numerous firsts for humanity in fields such as fuel cells, electrification, space, software-defined vehicles, surgical robotics, and more all rely on Jama Connect® requirements management software to minimize the risk of defects, rework, cost overruns, and recalls. Using Jama Connect, engineering organizations can now intelligently manage the development process by leveraging Live Traceability™ across best-of-breed tools to measurably improve outcomes. Our rapidly growing customer base spans the automotive, medical device, life sciences, semiconductor, aerospace & defense, industrial manufacturing, consumer electronics, financial services, and insurance industries. To learn more, please visit us at [jamasoftware.com](https://jamasoftware.com).