

# Medical Devices

21 CFR Part 820 Regulations

Contact us today to ensure compliance



The U.S. Food and Drug Administration (FDA) has established 21 CFR Part 820 regulations for medical device manufacturers to ensure the safety and efficacy of finished devices. To prevent dangerous medical products from harming consumers, the FDA protects the health of the public by enforcing laws and regulations within the United States of America. The quality system (QS) regulation 21 CFR Part 820 provides the good manufacturing practice (GMP) requirements that medical device manufacturers must comply with. The QS regulation applies to finished device manufacturers who intend to commercially distribute medical devices.

## BENEFITS OF 21 CFR PART 820 COMPLIANCE

- ✓ Comply with medical device laws and regulations
- ✓ Ensure the safety and efficacy of medical devices
- ✓ Prevent dangerous or defective products from causing harm
- ✓ Reduce consumer risks
- ✓ Ensure consumer safety

## HOW WE CAN HELP

We understand 21 CFR Part 820 regulations and how to comply with them.

We can assist with:

- ✓ FDA registration
- ✓ Consulting
- ✓ Designing a 21 CFR Part 820 quality system
- ✓ Implementation
- ✓ Audits and inspections
- ✓ Responding to FDA warnings letters

## HIGHLIGHTS OF 21 CFR PART 820

- ✓ Subpart A – General Provisions
- ✓ Subpart B – Quality System Requirements
- ✓ Subpart C – Design Controls
- ✓ Subpart D – Document Controls
- ✓ Subpart E – Purchasing Controls
- ✓ Subpart F – Identification and Traceability
- ✓ Subpart G – Production and Process Controls
- ✓ Subpart H – Acceptance Activities
- ✓ Subpart I – O Ect.

## CLIENT TESTIMONIAL

“Our consultant was awesome, very friendly and extremely helpful. The ISO 9001 Group has an extensive background on the standard. They were able to relate directly to our industry. Our consultant gave us extremely in-depth feedback and suggestions on how to conform with requirements.”

*Joseph Labdik  
JSL Innovations*

## CONNECT WITH US



Consulting | Auditing | Training

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