Case Study

U.S. Pharma Consulting
A direct link to the Pharmaceutical and MedTech industry

Medical Device Quality System Alignment and Regulatory Readiness

Strengthening quality governance, regulatory alignment, and operational execution through a practical, hands-on approach to 21 CFR Part 820 and ISO 13485 requirements.

Situation

A medical device company required support aligning its quality system and regulatory framework with evolving U.S. and international expectations. The organization needed a practical partner that could bridge regulatory requirements with day-to-day operational execution and help build a quality system that was not only compliant on paper, but functional in practice.

Challenge

The company needed to translate quality and regulatory expectations into a scalable operating model. Priority areas included quality governance, design controls, CAPA effectiveness, supplier oversight, risk management, and inspection readiness. The need was not simply documentation, but structured execution aligned to real-world business operations.

USPC Solution | Structured, hands-on alignment

Step 1	Step 2	Step 3	Step 4
Regulatory and Quality System Alignment USPC supported alignment to key medical device quality system requirements, including 21 CFR Part 820 and ISO 13485, with a focus on building a practical and sustainable quality framework.	**Design Controls and Risk Management** USPC helped integrate regulatory expectations into product development and quality-governance processes, including design controls, risk management, and documentation practices that support compliance and operational clarity.	**CAPA, Supplier Oversight, and Governance** USPC worked with the client to strengthen quality governance through improved CAPA structure, supplier oversight, escalation pathways, and accountability across the quality system.	**Inspection Readiness and Operational Execution** USPC applied a hands-on approach to improve inspection readiness by connecting regulatory strategy with practical execution, internal discipline, and cross-functional preparedness.

Results and Ongoing Engagement

Regulatory Alignment	**21 CFR Part 820 and ISO 13485**
Quality Governance	**Design controls, CAPA, supplier oversight, and risk management**
Inspection Readiness	**Structured, hands-on operational preparation**

USPC helped advance the company's quality system alignment through a more structured and execution-focused approach to regulatory and operational readiness.

The engagement strengthened the foundation across key quality-system elements, including design controls, CAPA effectiveness, supplier management, risk-based decision making, and broader quality governance.

By integrating regulatory strategy with practical implementation, USPC helped create a more inspection-ready and operationally aligned framework that could support both current requirements and future growth.

What USPC Brings

Practical Regulatory Alignment Support for alignment to 21 CFR Part 820 and ISO 13485 with a focus on real-world execution, not theoretical compliance.	**Quality Governance** Structured support across design controls, CAPA systems, supplier oversight, and risk management.
Inspection Readiness Hands-on preparation designed to improve internal readiness, documentation discipline, and cross-functional coordination.	**Operational Execution** A working approach that connects regulatory expectations to practical business processes and sustainable quality outcomes.

If your company is navigating medical device regulatory and quality system alignment, USPC is well positioned to assist and help move the opportunity forward efficiently.

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U.S. Pharma Consulting (USPC) - From Molecule to Market and, most importantly, Market back to Molecule development.

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