MBCA

CASE STUDY

MedTech Start-Up's Regulatory Strategy and Rapid eQMS Deployment

Introduction:

This MedTech company, founded in 2022, is a pioneering start-up in the Software as a Medical Device (SAMD) sector. This company specializes in developing innovative computer-aided detection software that performs algorithms on radiological images to help detect tumors and breast cancer. The company's focus is to improve patient outcomes and hospital efficiency. This case study explores how this start-up partnered with MBCA to craft a Regulatory Strategy for its inaugural product and to develop its first Quality Management System (eQMS) within an extraordinary timeframe of just eight weeks while achieving significant cost savings.

Challenges

Regulatory Compliance: This start-up faced the formidable challenge of navigating the complex and stringent regulatory landscape governing medical devices for the first time without extensive experience or staff. Complying with FDA regulations and obtaining the necessary clearance to market was a paramount concern.

Time Constraints: The company aimed to swiftly bring its flagship product to market to meet the pressing needs of healthcare providers and patients. A prolonged development and regulatory approval process could have resulted in missed opportunities.

Budgetary Constraints: As a start-up, the company was keen to manage its resources judiciously. They sought to develop an eQMS that met the highest quality standards while keeping costs significantly lower than other available solutions.

Approach

The company embraced MBCA's methodology to devise a systematic approach to address their challenges:

Regulatory Strategy
Phase 1: Research and Assessment (Week 1)
Conducted an extensive review of FDA requirements applicable to this SAMD product.
Found the appropriate FDA product code for this device and researched potential predicate devices that could be used in a submission to the FDA.

Phase 2: Strategy Formulation and Report (Week 2)
Outlined a step-by-step roadmap for the FDA clearance process. Identified the clinical data requirements for getting the product on the market.
Worked with the company to formulate their Intended Use Statement and identified key indications for use.
Identified technical Standards that must be met before they could submit to the FDA.
Identified the framework for the Quality Management System
Defined costs, milestones, responsibilities, and timelines.
Compiled everything into a comprehensive Strategy Report that the company could use as a roadmap to get the product on the market.

eQMS Development
Phase 1: Needs Assessment & QMS Mapping (Weeks 1-2)
Identified the essential requirements for the product and the company's operations.
Mapped each Regulation and Standard required per the Regulatory Strategy to pre-built base procedures and automated workflows closely aligned with their needs.
Set up and configured the electronic tool with the client's organizational structure, users, and training and approval matrices.
Load all procedures and workflows from the QMS mapping session into the sandbox/development environment of the tool.

Phase 2: Training & Tailoring (Weeks 3-6)
MBCA's dedicated team of regulatory compliance, quality, and software development experts trained the client teams on navigating and using the electronic tool.
MBCA's team then trained the client teams to their new, fully compliant quality system procedures and automated workflows, tailoring any processes and workflows for unique elements of the client's business along the way.

Phase 3: Testing and Implementation (Weeks 7-8)
MBCA rigorously validated the eQMS to ensure it met its intended use, 21 CFR Part 11 requirements for electronic signatures and electronic records. Provided hyper-vigilant support for seamless adoption after going live. Successfully integrated the eQMS into daily operations.

Results

The MedTech company achieved remarkable outcomes through the MBCA-driven approach:

Regulatory Success:
Obtained FDA clearance for their flagship product 6 months ahead of the initial target.
Positioned the new MedTech as a reliable and compliant player in the MedTech industry, instilling trust among stakeholders and potential customers.

Rapid eQMS Development:
Developed a customized eQMS in just eight weeks, a fraction of the time required for most commercial solutions.
Achieved a cost savings of approximately 50% compared to purchasing a generic eQMS that didn't fit its business or needs.
Enhanced operational efficiency by streamlining quality management processes.

Competitive Advantage:
Gained a competitive edge by swiftly entering the market with a compliant product and efficient quality management system.
Attracted investor interest and additional funding due to the impressive achievements.

Conclusion:

This company's innovative approach to regulatory strategy development and eQMS creation using MBCA and its powerful IntelaSolve solution accelerated its entry into the MedTech market and positioned it as a cost-efficient and regulatory-compliant industry leader. This case study demonstrates the potential for small start-ups to thrive in highly regulated industries by embracing creative solutions and leveraging cutting-edge methodologies.