

CASE STUDY

Enhancing Quality Systems with MBCA's Expertise in the MedTech Industry

Client Profile:

Company: [Confidential]*

Industry: Combination Product (Medical Device & Pharma)

Client Challenge:

For years, our combination product company had been striving to maintain regulatory compliance while managing an ever-evolving landscape of laws and requirements. Ensuring that our products met quality standards and adhered to FDA regulations was critical to our business success, but it was an ongoing challenge.

Over the past few years, we faced several FDA Warning Letters and identified significant gaps in our Quality Management System (QMS). We knew that addressing these issues was imperative to maintain our operations, safeguard our reputation, and continue bringing essential products to market. We needed expert guidance and comprehensive training to bridge these

Introduction to MBCA:

In our quest to enhance our regulatory compliance efforts, we were introduced to MBCA. Melita Ball, Founder & Principal Consultant, and her team specialize in providing professional expertise and guidance to MedTech and Combination product companies in achieving regulatory compliance and operational excellence.

The MBCA Solution:

Instead of one singular consultant with limited services, MBCA offered a range of services tailored to our needs and a team of experts to support us:

1.Consulting Expertise: MBCA provided us with fully qualified consultants with in-depth knowledge of the regulatory and quality space for combination products. These experts worked closely with our team, helping us define and achieve our project goals while ensuring regulatory compliance and operational efficiencies.

2.FDA Warning Letter/QMS Remediation: With their extensive experience, MBCA guided us through the complex process of remediating FDA Warning Letters and improving our Quality Management System. Their insights and strategies were instrumental in resolving past compliance issues and preventing future ones.

3.Auditing and Compliance Qualification Training: MBCA offered comprehensive training programs for our staff, covering essential aspects of regulatory compliance, quality assurance, and auditing. These training sessions were customized to align with the specific laws and requirements relevant to our industry.

4.Regulatory Guidance: Melita and her team provided ongoing regulatory guidance, ensuring that we stayed up-to-date with the latest industry standards and regulatory changes. Their timely insights helped us make informed decisions and proactively address potential compliance issues.

Results and Benefits:

Working with MBCA yielded significant benefits for our company:

1.Improved Compliance: With the guidance of the MBCA team, we successfully addressed regulatory compliance gaps and significantly reduced the risk of FDA Warning Letters in the future.

2.Operational Efficiencies: The MBCA team not only showed and mentored us through transformational changes for compliance but also reduced the complexity of our QMS in the process. Having a simple, compliant QMS has exponentially added to our bottom line profits and had an ROI of 350% over what we paid them for their help.

3.Enhanced Quality: Our Quality Management System has undergone a transformation, resulting in improved product quality, patient safety, employee satisfaction, and our culture.

4.Well-Trained Team: Our staff is now well-versed in regulatory compliance, ensuring that our company operates with the highest level of integrity and adherence to industry standards.

5.Peace of Mind: With MBCA as our trusted partner, we have the peace of mind that we are well-prepared to navigate the ever-changing regulatory landscape and are ever ready for FDA inspections and Notified Body audits.

Recommendation:

We are privileged to recommend MBCA MedTech or Combination Product company seeking to achieve and maintain regulatory compliance excellence. Melita and her team's unwavering commitment to our success, their expertise, and their tailored solutions have made a significant impact on our business operations. Thanks to their guidance, we are better equipped to meet the challenges of our industry while delivering high-quality products to our customers and patients.