MBCA

CASE STUDY

Ensuring Regulatory Compliance and Quality Excellence with MBCA

Client Profile:

Medical Device manufacturer of robotic-assisted surgical devices.

Introduction:

This case study highlights a long-standing partnership between the client and MBCA. MBCA has played a pivotal role in assisting the client in maintaining substantial compliance with regulatory authorities worldwide.

Challenges:

The client faced an array of challenges in maintaining compliance with regulatory agencies, particularly the FDA, Notified Bodies in the EU, and various regulatory agencies in Asia. These challenges included:

1.Warning Letter from the FDA: When the company engaged MBCA, they were facing a significant Warning Letter from the FDA.

2.Ever-changing Regulations: Regulatory requirements and standards for medical devices are constantly evolving, making it imperative for the company to stay up-to-date and compliant.

3.Global Presence: The company operates worldwide, which requires adherence to various international regulatory frameworks, each with its unique demands.
4.**Stringent Audits:** The company is subject to rigorous audits from government agencies. Ensuring readiness for these audits is essential to maintain a positive regulatory standing.

5.Data Integrity and Cybersecurity: With the increasing reliance on technology and data in the medical device industry, compliance with Computer System Assurance and 21 CFR Part 11 regulations is a crucial step in their overall compliance and business success.

Solutions:

MBCA has been instrumental in addressing these challenges. Their engagement spanned over eight years and has encompassed a wide range of services and solutions, including:

1. Warning Letter mitigation, response, and remediation: MBCA assessed the issues cited by the FDA, helped the company respond comprehensively and proactively, and devised a hands-on approach that rectified the problems with the agency.

2. Mock FDA Inspections: Conducting simulated FDA inspections to identify potential compliance gaps and areas for improvement.

3. MDSAP Readiness Assessments: Preparing for participation in the Medical Device Single Audit Program (MDSAP), streamlining compliance with multiple international regulatory authorities.

4. EU MDR Readiness: Ensuring readiness for compliance with the European Medical Device Regulation (EU MDR) to facilitate continuing market access in the European Union.

5. Internal Audits: Conducting comprehensive internal audits to proactively identify and rectify compliance issues, ensuring preparedness for government audits.

6. Computer System Assurance & Part 11 Training and Support: Providing training and guidance on Computer System Assurance and Part 11 compliance to safeguard data integrity and cybersecurity.

7. Internal Auditor Training: Equipping internal teams with the necessary skills and knowledge to conduct effective audits and maintain a robust quality management system.

8.Compliance Projects: Offering expert advice and support on specific compliance projects, tailoring solutions to meet their unique needs.

Results and Impact:

The partnership with MBCA has yielded significant results and had a profound impact on the company's operations:

1. **Sustained Regulatory Compliance:** When the company first engaged MBCA, it faced a significant Warning Letter from the FDA. MBCA helped them successfully rectify the issues. Since partnering with MBCA, the company has consistently maintained compliance with the FDA, EU MDR, and Asian regulatory agencies, avoiding costly penalties and market access delays.

2. **Audit Preparedness:** The company has been well-prepared for government audits through mock FDA inspections and internal audits, resulting in smoother interactions with regulatory authorities.

3. **Enhanced Data Security:** Compliance with Computer Assurance and Part 11 regulations has fortified the company's data integrity and cybersecurity measures, safeguarding sensitive information.

4. **Quality Excellence:** The commitment to quality assurance and compliance has bolstered the company's reputation as a trusted provider of surgical technology.

5. **Global Reach:** With MBCA's assistance, the company has successfully navigated the intricacies of international regulatory frameworks, expanding its global presence.

6. **Employee Empowerment:** Internal auditor training and annual refresher training have empowered the company's staff to actively contribute to maintaining a culture of compliance and quality excellence.

Conclusion:

Maintaining compliance and ensuring quality excellence are non-negotiable in the highly regulated field of medical device manufacturing. The enduring partnership with MBCA has proven to be invaluable. In particular, MBCA's Founder and Principal Consultant, Melita Ball's expertise, ethics, and communication skills have played a pivotal role in helping the company overcome regulatory challenges and maintain a position of prominence in the industry.
As a result of this longstanding relationship, MBCA received the highest endorsement from the executive team. They highly recommend MBCA services to organizations seeking to enhance regulatory compliance and quality management systems. Engaging MBCA is a strategic choice that ensures excellence in quality, compliance, and regulatory standing.