MBCA

CASE STUDY

MBCA's Quality Training and FDA Audit Prep

Introduction:

A leading medical device manufacturer of the vascular and orthopedic products sector engaged MBCA for two critical occasions. MBCA positively impacted her team's performance and preparedness for FDA inspections and significantly contributed to the quality team's education and performance. In this case study, we will explore this company's experiences and the positive outcomes of its collaboration with MBCA.

Background:

An executive member of this Medical Device company was responsible for overseeing operations and quality, leading change initiatives, and ensuring regulatory compliance. With a pivotal FDA inspection on the horizon, she sought external expertise to help her team prepare effectively.

Engagement 1: Pre-FDA Inspection Prep Activities/Mock Inspection

MBCA's Principal Consultant, Melita Ball, was brought in to assist the team in preparing for an impending FDA inspection. The objective was to provide first-time Subject Matter Experts (SMEs) with hands-on experience through a "hats on/hats off" auditing experience and workshop.

Melita's support and coaching played a pivotal role in this endeavor. She worked with the client team in an engaging and supportive manner. Melita carefully listened to the specific requirements and challenges faced by the group, delivering a tailored approach that helped boost the team's confidence and understanding of the inspection process.

Outcome 1: Successful Inspection Experience

Thanks to Melita's guidance and the mock inspection preparation, the team had a successful FDA inspection. The FDA inspection concluded one day early, a testament to the team's preparedness and Melita's effective coaching.

Engagement 2: In-House Medical Device Quality Auditor Training

Recognizing the need to enhance the team's expertise further, Melita was engaged once again. This time, Melita conducted in-house training focused on Medical Device Quality Auditor training. The comprehensive training covered various aspects, including Quality System auditing, audit phases, and key auditing elements based on regulatory requirements, such as 21 CFR Parts 7, 11, 803, 806, and 820; ISO 13485, ISO 14971, the Medical Device Directive (MDD), Canadian Medical Device Regulations, and more.

The training, spanning five full days, maintained an optimal pace and provided valuable course materials, case studies, and a final assessment. Importantly, all team members provided overwhelmingly positive feedback on the training.

Outcome 2: Empowered Quality Team

The impact of Melita's training was evident as the quality team became more effective in their roles. Melita's approach, which involved listening to and addressing customer requirements, proved instrumental in ensuring the team gained the knowledge and skills needed to excel in their roles.

Conclusion:

This collaboration with Melita profoundly and positively impacted the preparedness of the client's quality team for FDA inspections and their overall effectiveness in the company as Subject Matter Experts (SME). Melita's engaging and supportive coaching style, tailored approach, and comprehensive training modules contributed significantly to the team's success. The client highly appreciated Melita's positive and customer-centric approach, making her an invaluable asset to the client's Medical Device sector's quality and regulatory compliance efforts.