



CASE STUDY

Transforming Quality Management Systems with MBCA

Client Profile:

Industry: Combination Product Medical Devices/Pharmaceuticals
Consulting Partner: MBC & Affiliates, Inc. (MBCA)

Background:

A leading combination product manufacturer faced several challenges related to its quality management system (QMS), software validations, and compliance processes. To overcome these obstacles, they enlisted the expertise of MBCA.

The Challenges:

1. Software Validation Gaps:

MBCA identified significant gaps in its software validation processes. Ensuring compliance with regulatory requirements was essential, and addressing these gaps was a top priority.

2. Transition to Paperless QMS:

The company aspired to move towards a paperless Quality Management System, but its existing software didn't support this transition effectively.

3. Multiple CAPAs:

Following an internal audit, the company was burdened with multiple Corrective and Preventive Actions (CAPAs) that had to be addressed promptly to maintain compliance.

The Solution:

1. Software Validation Enhancements:

The MBCA team conducted a thorough analysis of the software validation processes. They closed all identified gaps and established a comprehensive system that not only addressed existing issues but also ensured continued compliance. This enhanced system underwent rigorous reviews during notified body evaluations and internal audits, demonstrating its effectiveness.

2. Paperless QMS Implementation:

Recognizing the company's goal of a paperless QMS, the MBCA team assisted in the selection and configuration of a new, validated eQMS. Additionally, they revamped procedures, work instructions, and forms to align with this transition. This not only facilitated the move to a paperless system but also streamlined the overall QMS for efficiency.

3. CAPA Resolution:

The MBCA team concurrently addressed the multiple CAPAs stemming from the problematic external and internal audits. By implementing the new eQMS and associated processes, they systematically resolved these issues, ensuring regulatory compliance and operational efficiency.

Value Delivered:

1. Cost Savings through Risk Analysis:

MBCA's unique contribution in providing software guidance and the re-engineering of the client's software validation process saved the company over \$100,000 in validation costs alone. By conducting a formal risk analysis, the MBCA team identified areas where expensive validations were unnecessary, contrasting with other companies' recommendations. This approach optimized resource allocation and reduced unnecessary expenses.

2. Continuous Consulting Support:

Beyond the initial project, the MBCA team remains a valuable consulting partner to the VP of Quality and the VP of IT. The MBCA team's expertise and willingness to assist with problem-solving and idea generation have made MBCA an essential resource within the company.

Conclusion:

The MBCA team was pivotal in transforming this client's Quality Management System. Their expertise in software validation, QMS customization, risk analysis, and ongoing support have not only resolved critical compliance issues but also positioned the company for sustained success in the industry. As a result, the VPs of Quality and IT plan to continue utilizing MBCA as their go-to Regulatory Compliance consulting partner to further enhance their quality, software, and compliance processes.