REGULATORY COMPLIANCE ASSOCIATES® INC
Wellness for Business®

Pre-Acquisition Technical Due Diligence

Client

Private Equity Firm

Industry

Medical Device

Business Challenge

Identifying the compliance, regulatory, technical, and operational risks associated with the purchasing a medical device company.

Background

A private equity firm was negotiating to purchase an established medical device company. Regulatory Compliance Associates® Inc. (RCA) was contracted to provide a technical due diligence analysis of facilities, manufacturing, quality, and regulatory systems, as well as the technical infrastructure.

Challenge

Under time constraints and with limited access to information, RCA needed to identify the compliance, regulatory, technical, and operational risks associated with the pending purchase. RCA also was charged with identifying remediation costs that could be used during deal negotiations.

RCA Approach

RCA planned and executed the due diligence process against a tight time-line. Regular communications were established with the client and other external due diligence teams, including legal, IT, and insurance.

- For each area of technical focus, checklists and cross-functional items were determined to ensure proper organization and thoroughness of the process
- An advance team conducted a preliminary evaluation, requested documents, and prepared the target site for the specialized due diligence team
- Due diligence was conducted at both domestic and international sites, and a report was submitted that included estimated cost to remediate the issues
- Post-report meetings with the client discussed risks, costs, potential action plans, and impact on deal negotiations

Results

RCA identified key business, technical, regulatory, and quality issues impacting the deal. The issues were risk mapped with remediation recommendations and accordant costs. The client used this data to discount the purchase price, negotiate escrow funds, and understand the way forward after deal closure.

"RCA planned and executed the due diligence process against a tight time-line."

References

1. FDA Code of Federal Regulations, Title 21, Part 820, "Quality System Regulation," April 1, 2010.

2. International Standards Organization, ISO Standard 13485: Medical devices—Quality management systems—Requirements for regulatory purposes. Second Edition, July 15, 2003