REGULATORY COMPLIANCE ASSOCIATES® INC
Wellness for Business®

Time, Distance and Technology for a Private Equity Due Diligence

Client

Private Equity Firm

Industry

Pharmaceuticals

Business Challenge

Study regulatory, operational, and quality aspects of a target enterprise.

Project Time-line

8 Days

Background

Wanting to purchase a medical enterprise, a private equity firm contacted Regulatory Compliance Associates® Inc. to perform a technical due diligence analysis of a target company within an extremely tight time-line. The acquisition target had multiple operations in North America, Europe, and East Asia. The nature of the target enterprise presented potential for risks within the operational structures and disciplines on multiple levels.

Challenge

With this type of company the risks could be technical, operational, or legal, and arise from a range of regulated areas. This added to the complexity of ensuring that all relevant areas were identified and successfully evaluated. In addition, the private equity firm asked RCA to assess expansion capabilities and develop an understanding of any structural limitations that could affect the financial transaction or provide leverage during the deal negotiations.

RCA Approach

RCA immediately identified that a cross-functional team of technical and regulatory subject matter experts would be needed. Within 24 hours, technical functions were matched with skilled resources to study the regulatory, operational, and quality aspects of the target enterprise.

Working with the client and the material in the data room, this team quickly identified the critical risk areas and prioritized the order in which to assess the different operations. A comprehensive checklist was prepared to support the facility visits and the corporate headquarters assessment.

With preparation complete and time limited, the RCA team was given the go ahead to initiate the on-site corporate and facilities visits. Across a total of eight days, the team successfully completed nineteen facility visits and a corporate office assessment.

The private equity firm was provided with timely updates that they were able to integrate into the ongoing negotiations.

All findings and recommendations were compiled into a final report, resulting in a successful negotiation. Providing the client with dependable and consistent information on a daily basis, RCA supported the client with recommendations that contributed to a successful negotiation.

Result

RCA leveraged our personnel with extensive subject matter expertise to successfully provide a comprehensive mapping of the technical, regulatory, quality, and industry findings, culminating in a final report for the equity firm to utilize in negotiating the sale. We were able to provide expert council in a number of areas and, in particular, to quantify the range of potential health and safety liabilities.

Additionally, risk mapping and assessment of remediation costs, expansion capability, and infrastructure needs enabled the client to successfully negotiate the purchase price of the medical enterprise.

"Over eight days, RCA teams successfully completed nineteen worldwide facility visits and a corporate office assessment."

References

1. FDA Code of Federal Regulations, Title 21, Part 210, "Current Good Manufacturing Practice in Manufacturing, Processing, Packaging, or Holding of Drugs," April 1, 2010.

2. FDA Code of Federal Regulations, Title 21, Part 211, "Current Good Manufacturing Practice for Finished Pharmaceuticals," April 1, 2010.

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

4. U.S. Department of Health and Human Services, Food and Drug Administration, "Guidance for Industry, Process Validation: General Principles & Practices," January, 2011.

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

6. International Standards Organization, ISO Standard 11135: 1: Sterilization of health care products—Ethylene oxide—Part 1; Requirements for development, validation, and routine control of a sterilization process for medical devices. 2007.

7. International Standards Organization, ISO Standard 11137-1: Sterilization of Healthcare Products—Radiation—Part 1: Requirements for development, validation and routine control of a sterilization process for medical devices. 2006.

8. International Electro-technical Commission, "International Standard—IEC, 60300-3-1," Second Edition, 2003.