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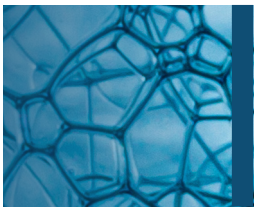
LIFE SCIENCES

Case Study

Private Equity Diligence of Multiple Excipient Manufacturing Operations & Integration Potential

Objective

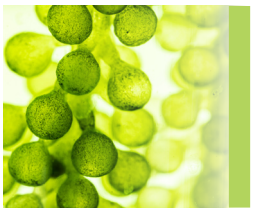
Identify and assess both expected and unexpected regulatory risks of two excipient manufacturing operations via on-site and desktop audits.



Challenge

Private equity investor required quality/compliance expertise to assess excipient manufacturing operations, ramifications from prior FDA enforcement actions, and quality systems across numerous facilities both on-site and through a desktop audit.

Engagement also involved a separate diligence of the quality/compliance status of its partner in the proposed investment, which had existing excipient manufacturing capacity, for its ability to integrate operations of the target company.



Solution

Assembled a team of former FDA investigators and experts specializing in quality and compliance systems. Together, the team of experts conducted an on-site audit and a desktop review of both the target company and the potential investment partner.

Outcome

Provided client with a detailed assessment of the target company's operations, progress around implementation/execution of Corrective and Preventive Action (CAPA) plans, enforcement trends and expectations in the excipient space, and recommendations for bringing operations into compliance in a comprehensive and efficient manner.

Also provided a separate assessment of investment partner operations, compliance status, and capacity to integrate with target company, including roadmap of necessary steps to ensure continued compliance post-acquisition.

Due Diligence Solutions

ELIQUENT's expanded due diligence platform leverages the unmatched experience and robust institutional knowledge of the firm's regulatory experts to empower decisions and drive value. Learn more at **ELIQUENT.com**