RESPONDING TO AN FDA-483 FORM

Lachman CONSULTANTS
Experience. Excellence.™

Experience Lachman's expert, responsive, and detailed guidance in addressing an FDA-483 Form.

YOUR PARTNER FOR TRUSTED AND TOTAL SUPPORT

At the conclusion of an FDA inspection, findings are presented as FDA-483s as required by Section 704(b) of the FDC Act. When an FDA-483 indicates that action is required look to Lachman to help resolve the list of observations or problems raised during an FDA audit. Lachman is the "go-to" firm when organizations are facing difficult challenges and has earned a solid reputation for delivering high-quality insight and recommendations to overcome FDA-483 issues. Working closely with Lachman's team of consultants enables you to respond quickly and clearly to FDA observations, and correct references cited by the investigators.

Lachman Consultants Provides the Highest Quality FDA-Related Services Including:

- Responding to an FDA Warning Letter
- Responding to an FDA 483 inspection
- Meeting with the FDA to resolve disputes
- Corrective and preventive action (CAPA) programs, including development, execution, monitoring, and project management

Lachman Consultants' Approach to Responding to an FDA-483 Form includes:

- Establishing a cross-functional team to formulate responses
- Corrections to any inaccurate statements in the FDA-483 Form
- Providing a corrective action plan with a realistic timetable for the completion of the corrective action
- A cover letter summarizing the company's commitment to sustainable compliance
- Tracking and documentation of a consistent CAPA system
- Holding inspection prep meetings periodically to maintain an ongoing awareness of key issues

LACHMAN CONSULTANTS ADVANTAGES AND BENEFITS:

- Optimum Regulatory Compliance
- Increase Operational Efficiencies
- Reduce Costs & Process Complexity
- Minimize Compliance Risks
- Accelerate Business Outcomes

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