MEDICAL DEVICES

Lachman CONSULTANTS
Experience. Excellence.™

Experience excellence in technical, regulatory consultation and guidance services for medical devices.

CONSULTATION, SERVICES & SUPPORT FROM A TRUSTED PARTNER

Every Lachman Consultants client who receives services and support for their Medical Devices experiences excellence at the highest levels of quality and satisfaction. Through a vast array of expertise and knowledge, we provide effective compliance and regulatory services for medical devices in areas such as cardiology, orthopedics and invitro diagnostics as well as combination devices like auto-injectors, patch delivery systems and pre-filled syringes. In addition, Lachman also offers consultation and guidance for a wide range of other devices, including monitoring and measuring systems and Software as a Medical Device (SaMD).

The Lachman team has an outstanding record of client facilitation, which incorporates design history file building, quality systems audits and due diligence, full support in pre-application preparation, validation-specific review guidance and more.

Lachman Consultants Medical Devices Services and Features:

- General Audits
- FDA Response and Remediation
- FDA Pre-Approval
- FDA Inspection Support
- Due Diligence Reviews
- Medical Device Reporting
- Supplier Qualification
- EU MDR Requirements
- ISO13485 Support Services

Multi-disciplinary groups of accomplished FDA and industry experts are assembled from Lachman's Compliance, Regulatory, and Science and Technology Practice Groups. Each comprehensive team is selected and assigned on a project-specific basis, each according to your unique set of circumstances, needs and objectives.

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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