COMBINATION PRODUCTS

Lachman CONSULTANTS
Experience. Excellence.™

Experience excellence in technical, regulatory consultation and guidance services for combination products.

CONSULTATION, SERVICES & SUPPORT FROM A TRUSTED PARTNER

Lachman Consultant Services, Inc. (Lachman Consultants) offers a wide range of consulting services for areas that include medical products, SaMD, materials and components, processes and mechanical engineering and manufacturing, as well as testing and validation. Our team of experts provides consultative services for combination products such as auto injectors, pre-filled syringes, patch delivery systems and many others.

Lachman Consultants supports clients with compliance guidance that includes due diligence review, general auditing, quality assessment remediation work for 483 or warning letters, as well as design history file building and documentation. We offer a full menu of regulatory services that includes traditional 510k, de novo filing under 510k and Premarket Approvals.

Lachman Consultants Combination Products Services and Features:

- Harmonization of Drug/Biologic - Device Development
- Due Diligence Assessments
- Quality Systems Audit to 21CFR Part 4
- Quality Assessment Remediation Work for 483 or Warning Letters
- Design History File Remediation
- 510k Submissions
- Assistance on NDA/BLA submissions
- Premarket Approval (PMA)
- Validation Review
- Preparation for Application
- FDA-Related Services
- Develop and Enhance Laboratory Controls
- Optimize Product Formulation and Processes
- Assess Product Stability

LACHMAN CONSULTANTS ADVANTAGES AND BENEFITS:

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

516-222-6222 516-683-1887 info@lachmanconsultants.com lachmanconsultants.com