

COMBINATION PRODUCTS

ADVANCE. CONFIDENTLY.

Lachman
CONSULTANTS
(IRELAND)



Experience. Excellence.™

BEST IN CLASS CONSULTANCY AND ADVISORY:

- ▶ Harmonisation of Drug/Biologic - Device Development
- ▶ Quality Management Systems Assessment to 21CFR Part 4
- ▶ EU MDR Requirements
- ▶ Regulatory Citation Response and Remediation
- ▶ Design History File Remediation
- ▶ Regulatory Submissions (i.e. 510K, NDA/BLA)
- ▶ Design Control Remediation
- ▶ Premarket Approval (PMA)
- ▶ Preparation for Application
- ▶ Scientific and Analytical Development and Support
- ▶ Product Development and Optimisation
- ▶ Supplier Quality Audits
- ▶ Due Diligence Assessments

COMPREHENSIVE CAPABILITIES. PROVEN EXPERIENCE.

Optimum
Regulatory
Compliance

Increase
Operational
Efficiencies

Reduce Costs
and Process
Complexity

Minimise
Compliance
Risks

Accelerate
Business
Outcomes

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