EdgeOne medical

YOUR END-TO-END SOLUTION FOR COMBINATION PRODUCTS

- Device Selection & Development Strategy
- Design History File Development (Remediation)
- Risk Management File Development (Remediation)
- Release Testing & Complaint Investigations
- Regulatory Strategy & Submission Authoring (FDA & CE)
- In-House Combination Product Testing
  - Custom Fixture Development
  - Test Method Development & Validation
  - Verification & Validation Testing
  - Aging (Stability) Testing

The trusted partner to emerging pharma and top 20 global biopharmaceutical companies

A TRACK RECORD OF SUCCESS SINCE 2012

125+ Customers Served

250+ Test Method Validations Completed

60+ FDA and Critical Submission for Combination Products

EdgeOne it!™

E1M is the only company I found who focuses on design and device verification in a laboratory equivalent of GMP without direct interest in manufacturing the product itself. They follow all the controls, documentation, procedures and validation the FDA expects, and are led by an impressive founder who is responsive, thoughtful and knows her stuff.

Principal Engineer
Top 10 Pharmaceutical Company

ISO 13485:2016 CERTIFIED | FDA & EMA REGISTERED

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