Borderless MedDev

Medical Device Regulatory Experts

Borderless MedDev works on a variety of projects all with the goal of facilitating access to the US and world markets for medical instrumentation for our clients. While each project is unique, we are able to utilize our depth of experience working with the FDA and other agencies throughout the world as well as ISO registrars to assure success.

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FDA Regulatory Clearances

- Regulatory Strategic Planning
- Organizing Pre-Submission Meetings
- 510(k) Submissions
- DeNovo Submissions
- 3rd Party 510(k) Submissions
- 510(k) Remediation
- Post Market Issues: Complaints and Recall Management
- Statistical Analyses

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ISO 13485/FDA Quality System Requirements

- Process Development
- Training
- Internal Audits
- Design Controls/ Design History Files
  - Risk Management
  - Usability
  - Labelling
  - EMC
  - Safety
  - Software documentation
  - Wireless registrations and testing expertise
  - Cyber Security
  - Coexistence
  - Interoperability
  - Biocompatibility
  - Mechanical Testing

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