Thomas Regulatory Resolutions

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TRR

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Scope of Services

- **Auditing:** MDSAP, Internal, Supplier, ISO 13485 2016, FDA, MDD, MDR
- **Regulatory Affairs:**Submissions, Assessments, Road Map, Reviews
- **Training**: ISO 13485, QMS Awareness, MDSAP, FDA, CE Mark, etc.
- **Regulatory Audit/Inspection Defense**FDA,Notified Body,MDSAP,ISO
- **Clinical Evaluation Reports (CERs)** per EU MEDDEV 2.7/1 Rev 4
- **Remediation:** FDA 483, Warning Letters, AE / MDR Reporting, Recalls
- **FDA:** 510(k), Establishment Registration, Small Business Applications
- **Int'l Market Registration & Licensing:**EU, LATAM, APAC, EEMEA, Etc
- **EU CE Mark:** MDD, MDR Transition, Tech File / Design Dossier
- **Bilingual** Spanish / Portuguese Fluency / Translation as needed.
- **LEAN Approach to reduce costs & leverage existing resources**