# MEDICAL DEVICE REGULATORY CONSULTING

Create Sustainable Business Growth
Comply to 21 CFR 820, MDR, ISO 13485 & ISO 14971

# FULL SERVICE FOR YOUR QUALITY, REGULATORY, AUDITING AND COMPLIANCE NEEDS

## Regulatory and Quality Assessments

Allow us to Assess your Regulatory and Quality needs.

## Regulatory Submissions and Registrations

EU CE Marking and Tech File/Design Dossier Creation and Maintenance.
510(k) Submissions to FDA, Pre-subs, Establishment Registrations, PMA Support, Notified Bodies, Device Listings, UDI, International Registrations (Latin America, Asia, Middle East)

## Gap Analysis

Regulatory Gap Analysis
CER Gap Analysis
MDSAP Gap Analysis
ISO 13485:2016 Gap Analysis
CE Mark Gap Analysis
MDR Gap Analysis

## MDD93/42/EEC and ISO 13485:2016 Quality Auditing, Audit Prep, and Audit Support, Audit Defense

Allow us to Audit your Quality System, prepare you for your next external audit, and support you during your next external audit.

## Clinical Evaluation Reports (CER)

MEDDEV 2.7/1 Rev 4
Clinical Literature Search
State of the Art Search
Regulatory Post Market Surveillance Review

## Qualification and Certificates

RAPS Certified
MDSAP
CER MEDDEV 2.7.1 rev. 4
MDR
ISO 13485:2016 Auditor
University Degree Educated

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