



Your Partner For Success

Experience at work for you

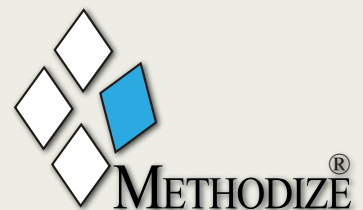
With over 35 years of combined Regulatory, Quality and Clinical experience, we have been helping companies all over the world gain U.S. and E.U. approval for their medical devices and In-Vitro Diagnostics products.

Anyone can read the regulations, we provide efficient and effective solutions to meet those regulations. Our services ensure that post market compliance is maintained through labeling advice and compliance with the applicable regulations.

Whether you're pondering the most effective way of pursuing a regulatory submission, starting up a clinical trial or need to meet a quality system regulation or international standard, Methodize is the one to call.

- ◆ ISO 13485 Consulting & Certification
- ◆ 510(K), IDE, PMA, Design Dossier and Technical File Preparation & Submission
- ◆ Regulatory Submissions
- ◆ Quality Systems & Compliance
- ◆ U.S. Agent for FDA Requirements
- ◆ E.U. Authorized Representative

Flexible solutions for your business needs



Please call for a free consultation ►►►

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Methodize provides a total end to end solution.

REGULATORY SUBMISSIONS & REPRESENTATION

Methodize understands the importance of getting a product to market as quickly as possible — without regulatory missteps that can cost thousands or millions of dollars in lost revenues.

Our key capabilities include: pre-market assessment, protocol reviews, statistical strategies, sample size calculation, regulatory applications, IDE, 510(k) and PMA support, investigational site monitoring, data entry, statistical analysis, data management, final reports, investigational site audits, sponsor audits, medical device clinical research training in good clinical practices (GCP), trial design, project management for clinical studies and more.

Audits

- ◆ In-house and Vendor QSR/ISO 13485 - ISO 9001:2000 Audits
- ◆ Conducting Mock FDA Inspections
- ◆ Conducting ISO Audits
- ◆ Performing Due Diligence Audits

QSR/CGMP Compliance Support

- ◆ Conducting in-house training for QSR and ISO

Compliance and Computer Validation

- ◆ QSR/CGMP Compliance Support
- ◆ Assisting in Developing Design Controls and Validation

CE Marking

- ◆ Design Dossier, Technical File Submissions
- ◆ ISO 13485 Certification and Gap Analysis

Canadian Approval

- ◆ CMDR, CMDCAS Assistance
- ◆ Product Licensing

FDA Assistance

- ◆ Assistance with Regulatory Strategies and Assessment
- ◆ Preparation of FDA Registration and Listing
- ◆ U.S. Agent for FDA Requirements
- ◆ E.U. Authorized Representation
- ◆ Liaison with FDA for Pre-submission or Special Meetings
- ◆ Assistance with FDA's GCP Requirements for Sponsors, Monitors, and Clinical Investigators
- ◆ GCP Audits/Monitoring and Data Integrity Audits
- ◆ Guidance of Briefing Package for FDA Meeting
- ◆ 510(k), IDE, PMA Preparation and/or Assistance
- ◆ Preparation and/or Assistance with Submission
- ◆ Amendments, Supplements and Required Reporting Records
- ◆ Development of Strategies for Advisory Committee Meetings



ISO 13485 CONSULTING & CERTIFICATION

ISO 13485 is the most commonly chosen path for medical device companies to meet the quality system requirements in Europe, Canada, Japan, Australia and other countries.

Methodize, Inc. has guided hundreds of medical device and IVD manufacturers through quality systems that meet the ISO 13485 standard. Our team of consultants will work closely with you to determine your unique business needs, develop a system to meet those needs, and ensure your quality system is implemented on schedule and on budget.

EUROPEAN AUTHORIZED REPRESENTATIVE

According to European law for medical devices, companies that do not have a physical location in the E.U. must appoint an Authorized Representative who is located within Europe.

As an official E.U. Authorized Representative, Methodize Inc. can act as your liaison with the National Competent Authorities to ensure your company meets the challenging and confusing European Regulatory Reporting requirements.

With offices in Galway, Ireland, Methodize Inc. has provided E.U. approvals to hundreds of companies who desire to sell their medical device in Europe.

