Making an effective transition to EU MDR and IVDR Compliance

The medical device manufacturing industry is undergoing a series of unprecedented regulatory changes due to evolving EU regulations.

Trusted partner for your **Digital Journey**

Atos | Syntel

With a focus on clinical evidence, transparency and traceability, the EU Medical Device Regulation (MDR) and In Vitro Diagnostic Regulation (IVDR) will impact nearly every area of the medical device sector, including clinical, regulatory, manufacturing, supply chain, and post-market surveillance.

Atos Syntel solution

Through our work with top medical device manufacturers, Atos Syntel has built a strong team of regulatory consultants to address the EU MDR / IVDR needs of our global clients. We have capabilities in R&D, product engineering, manufacturing, clinical, quality, regulatory, labeling, packaging and PMS functions, as well as a deep understanding of the latest regulatory developments and their impact on these workstreams.

Our solutions combine deep domain knowledge with expertise in end-to-end project delivery and program execution. With our global reach and a large pool of trained, cross-functional teams, Atos Syntel can help you comply with regulations and industry standards by planning, designing and implementing a solution customized to your organization's unique needs.

EU MDR / IVDR service offerings

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Post Market Surveillance (PMS)

- PMS planning and reporting
- Periodic update safety report (PSUR)
- Trend reporting
- Manufacturer incident reporting (MIR)

Regulatory Affairs

- EU MDR consulting
- Technical file gap assessment
- Tech file remediation/STED
- Product registration support
- Coordination with notified bodies/HAs

Quality

- Gap assessment and QMS consulting
- QMS-ISO 13485:2016 implementation
- Risk management (ISO 14971)
- Audits and inspection readiness
- Record management, SOP updates

Research and Development

- Product design and drawings
- DHF remediation, V&V
- Technical documentation
- PMCF and PMPF support
- CEP/CER and PEP/PER updates
- MEDDEV 2.7.1 Rev 4 implementation

Supply Chain

- Labeling and packaging gap assessment
- Label change implementation
- Artwork management
- Packaging design and development
- Contract management
- Supply chain documentation

IT Support

- eIFU website development
- UDI implementation
- EUDAMED interface development
- IT support for labeling, PLM, QMS, PMS/PV
- Computer system validation
- Data insights and analytics

Business benefits

- **Improved scalability,** with the size, scale and training capabilities to ramp-up a large team within 2-3 weeks
- Access to a team of **skilled, experienced medical device professionals** versed in CDRH, MDR, GxP and other medical device and diagnostic standards
- **Stringent QA processes** that adhere to your standards and regulatory imperatives
- **Innovation team,** with accelerators and frameworks to support continuous improvement and process efficiency
- **Added flexibility,** with the ability to support a variety of operations/delivery models and pricing strategies
- **Significantly reduced cost,** with a blended onsite/offshore delivery model and competitive rates

Atos Syntel in action

EU MDR Labeling Gap Assessment for a Fortune 500 U.S. healthcare services company which develops and manufactures medical devices for patient care, cardiovascular, surgical, diagnostics and durable medical equipment.

Project Highlights:
- 3 franchises in scope
- 100+ labels/ IFUs
- 20+ SOPs/WIs
- 3 symbol libraries

Key Benefits:
- 30%+ faster time to market
- 30%+ cost savings
- Up-to-date symbol libraries, SOPs, EU MDR checklists
- Improved knowledge sharing through cross-functional workshops

Labeling Change Management for a top-5 multinational medical device, pharmaceutical and consumer packaged goods manufacturer with $70 billion in annual revenue.

Project Highlights:
- 10+ franchises in scope
- Estimated 100,000+ labels within the first 2 years
- Onsite/offshore support

Key Benefits:
- 100% SLA adherence
- 25%+ productivity gains
- 99%+ quality and regulatory compliance through automation, tools and accelerators

PMS Plan and PSUR Development for a manufacturer of pharmaceuticals, OTC products and medical devices (contact lenses, intraocular lenses, ophthalmic surgical equipment and aesthetic devices) marketed in more than 90 countries.

Project Highlights:
- 5 business units in scope
- 150+ technical files for creation of PMS plan and reports

Key Benefits:
- 30%+ efficiency gains through process standardization, data consolidation and clean-up
- Achieved MDD and EU MDR compliance
- 100% SLA adherence
- 40%+ cost savings

Clinical Evaluation Plan and Report (CEP/ CER) Development for a diagnostic systems manufacturer focusing on the diabetes market, specifically blood glucose monitoring systems.

Project Highlights:
- Remediation of clinical evaluation and risk assessment procedures
- MEDDEV 2.7.1/Rev 4 updates
- Template creation for CER/CEP, PER/PEP

Key Benefits:
- Achieved MEDDEV 2.7.1/ Rev 4 and EU MDR compliance
- Operational improvements through process re-engineering
- Updated SOPs, templates, regulatory checklists

Our Medical Device and Diagnostics (MDD) practice

Atos Syntel has more than a decade of experience delivering digital transformation solutions for leading global clients. We focus on supporting quality, regulatory and compliance needs, and helping transform business processes to meet industry standards and regulatory guidelines.

Our team has in-depth expertise providing services for a wide range of therapeutic areas, including cardiovascular, gastroenterology, ophthalmology, endocrinology, surgery, oncology, orthopedics and others.

Atos Syntel blends onsite leadership consultants, a talented offshore delivery team, and technology, regulatory and process expertise to deliver large-scale programs across the device segment.

Our solutions

Device Engineering
- New product development
- Sustenance engineering
- Reliability engineering

Quality and Regulatory
- Quality assurance
- Risk management
- Regulatory affairs

Labeling
- Label lifecycle management
- System implementation
- GS1, UDI compliance

Packaging
- Packaging design and development
- Packaging validation

Clinical Evaluation
- Clinical investigation support
- Clinical evaluation planning and reporting
- PMCF support

PMS and Vigilance
- Complaint management
- Device vigilance
- Trend reporting

About Atos Syntel

Atos Syntel is a leading global provider of integrated IT and knowledge process services. As a trusted partner to many of the world's biggest brands, we help accelerate their digital journeys, increase enterprise agility and business performance, evolve their platforms to "Digital native" standards, and deliver the scale and flexibility required in today's dynamic business environment.

Atos Syntel is a member of the Atos Group, a global leader in digital transformation with 110,000 employees in 73 countries and annual revenue of over € 11 billion. The Group operates under the brands Atos, Atos Syntel and Unify, and is listed on the CAC40 Paris stock index.

Atos Syntel unites Atos's scale, market presence and capabilities in Orchestrated Hybrid Cloud, Big Data, Business Applications and Digital Workplace solutions with Syntel's industry focus, global delivery model, and core and digital services powered by intelligent automation.

To learn more, visit us at: **www.atos-syntel.net**

Let's start a discussion together