PLG
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Quality and Regulatory for Medical Devices

MedTech Services Offering Essentials

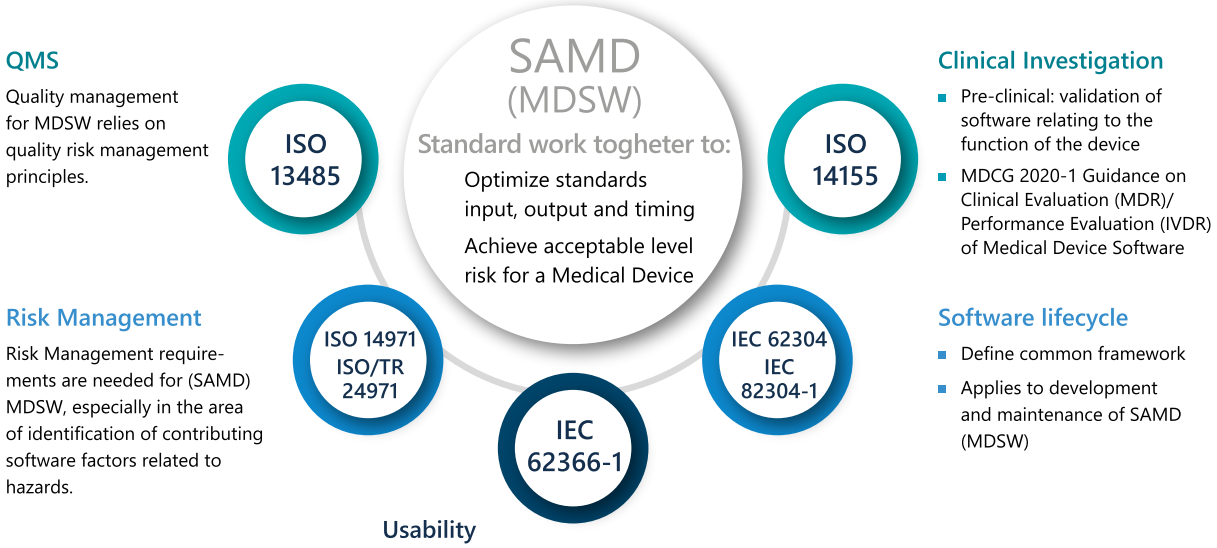
Full product lifecycle support from Design to Post Market Medical Devices, Combined Devices, SaMDs

Thanks to cross-functional expertise in regulatory, safety, and quality, information management in Medical devices and the pharma environment, PLG develops pragmatic strategies consulting for new challenges facing companies placing Medical devices, Combined devices, and Startups with innovative solutions.

Our added values

- In guiding you through regulatory challenges, design control, MDR and IVDR transition, we deliver tailored services according to specific regulatory pathways, ultimately leading to global market access.
- Thorough understanding of business processes for managing communication between the different stake-holders involved in a project – such as clinical, regulatory, Quality, PMS team, manufacturing, and commercial.
- Advising clients on their processes or redefining and formalizing the processes with clients.

Role of international standards



QMS

Quality management for MDSW relies on quality risk management principles.

Clinical Investigation

- Pre-clinical: validation of software relating to the function of the device
- MDCG 2020-1 Guidance on Clinical Evaluation (MDR)/ Performance Evaluation (IVDR) of Medical Device Software

Risk Management

Risk Management requirements are needed for (SAMD) MDSW, especially in the area of identification of contributing software factors related to hazards.

Software lifecycle

- Define common framework
- Applies to development and maintenance of SAMD (MDSW)

Usability

- Identification of user interface
- Knowing or preventing hazards/ hazards situation
- User interface risk control measure and usability evaluations

PLG supports your MedTech device, ensuring its success to the market for safe and effective use.

Regulatory Services

MDR Readiness Review

GSPR Gap analysis

Readiness assessment of Technical Documentation and Declaration of Conformity (Labelling, and IFUs)

UDI assessment

Risk management file review

Change to Economic Operators Agreements Review, including European Authorized Representative (EC REP) agreement

Post Market Surveillance

Support in Implementing Post Market surveillance, and in:

Implementing PMS system/PMS plan

Generation of PSUR

Management CAPA

Complaints and market experience

Monitoring of trends

Global & Local Literature search, safety alerts and PMSR/PSU

Regulatory Strategy

Support in identifying best RA strategy for approaching EU MDR and US FDA market with:

Registrations within EU for EU and Non-EU Manufacturers (class I to III), SAMD, drafting different pathways to handle SW development, cGMP compliance of Medical devices, Combined devices and SAMDs.

Quality Services

- Quality Management system (QMS)
- Document control implementation support
- Design control management supporting DHF and DMR
- Manufacturing and production processes
- Standard Operating Procedure (SOP) development
- Support for Supplier quality and purchasing controls
- Post Market Surveillance implementation
- Implementation of full set of Validation templates

Digital Health

Scope

Mobile health (mHealth), health information technology (IT), wearable devices, telehealth and telemedicine, and personalized medicine.

Digital health technologies use computing platforms, connectivity, software, and sensors for health care and related uses.

PLG provides support in implementing clinical evaluation reporting and in Technologies intended for use as a medical product, as companion diagnostics, or as an adjunct to other medical products (devices, drugs, and biologics).

What are the benefits of Digital Health Technologies?

Digital health offers real opportunities to improve medical outcomes and enhance efficiency.

Providers and other stakeholders are using digital health technologies in their efforts to:

- Reduce inefficiencies
- Improve access
- Reduce costs
- Increase quality
- Make medicine more personalized for patients

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PLG supports FDA Registrations of MedTech Devices

The marketing pathways include:

- Premarket Notification (510(k), original, special , traditional)
- Most exempt from premarket submission (Class I)
- Premarket Application (Class III)
- De Novo
- Humanitarian Use Exemption (HDE)
- Breakthrough program submission

How to access the US Market

Medical devices marketed in the United States are subject to the regulatory controls in the Federal Food, Drug, and Cosmetic Act (FD&C Act) and the regulations in Title 21-Code of Federal Regulations (21 CFR) Parts 1-58, 800-1299.

The regulatory controls and marketing pathways are based on the risk of the device the regulatory controls needed to ensure reasonable assurance of safety and effectiveness.

The voluntary Breakthrough Devices Program is also intended to provide patients and health-care providers timely access to medical devices by speeding up development, assessment, and review for premarket approval, 510(k) clearance, and De Novo marketing authorization.

Breakthrough Devices must meet the FDA's rigorous standards for device safety and effectiveness to be authorized for marketing.

The Breakthrough Devices Program reflects FDA's commitment to device innovation and protecting public health.

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