Quality and regulatory for medical devices

MedTech Services Offering Essentials

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

Strong Knowledge

Thorough understanding of:

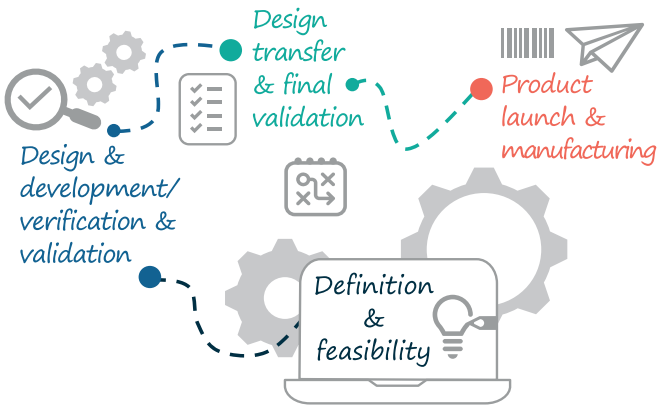
Business processes for managing communication between the different stake-holders involved in a project – such as: clinical, regulatory, Quality, PMS team, manufacturing, and commercial.

Advising clients on their processes or redefining and formalizing the processes with clients.

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

Our offering on Medical Devices:
Regulatory affairs, Device vigilance, Quality management, Clinical evaluation, Software as Medical Device, Risk Management, Usability Testing , Biocompatibility

Quality Services



Quality Assurance during the entire product lifecycle according to ISO 13485

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

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MDR Readiness Review

- GSPR Gap analysis
- Readiness assessment of Technical Documentation
- MDR CE marking support with accredited
- Notified Body
- UDI assessment, on UDI assignment and handling
- Risk management Review
- Biological Evaluation of medical devices

Regulatory Strategy

Regulatory Strategy Support in identifying best regulatory strategies for:

- Innovative Digital health solutions
- Medical Device Software – MDSW (embedded/ stand alone)
- IVD professional use – IVD self test use
- Combination Products (CTD file)

Post Market Surveillance

Support in Implementing Post Market surveillance, and in:

- Implementing PMS strategy
- PMS system/PMS plan
- Generation of PSUR
- Global & Local Literature search, safety alerts and PMSR/PSUR
- Support in internal CAPA management, and official reporting

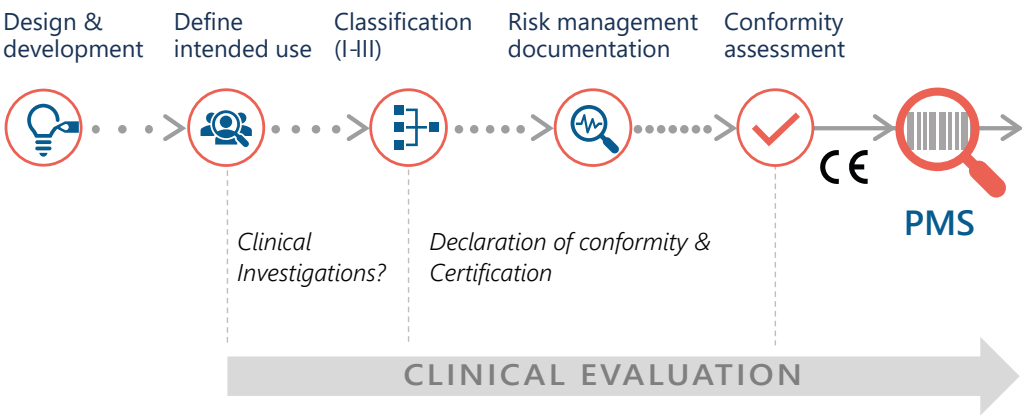
Clinical Reporting

Support in Implementing Clinical Evaluation Reporting, and in:

- Compliance to GCP – Align with ICH GCP (R2)
- Clinical Investigation (CI) according to Art 61 MDR
- Clinical Evaluation Reporting (CER)
- Clinical evaluation plan
- Relationship With Notified Body
- Post-Market Clinical Follow-up Studies (PMCF)
- Submissions and briefing package
- Medical expertise (aligned with ICH-GCP)

Updated on annual basis

Product overview, Summary of Safety Concerns, Risk minimization measures, Additional PMS activities, Plans for PMCF and CER, Safety communications, Annexes and References.



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