Medical Device AI/ML Compliance

Regulators such as FDA and national bodies now expect lifecycle approaches for AI/ML-enabled devices: Good Machine Learning Practice (GMLP), documented Predetermined Change Control Plans (PCCPs), transparent data governance, and robust post-market performance monitoring.

Manufacturers struggle with iterative model updates, traceability of training/validation data, clinically defensible performance, reproducible validation, cybersecurity, and explaining model behaviour to clinicians and regulators.

wega can be you trusted partner to turn regulatory requirements into a clear, auditable program that fits your product and business model. Reduce time-to-market and regulatory friction by incorporating AI/ML compliance into your SDLC, QMS, and evidence generation strategy.

Our Services Include:

- Regulatory strategy & pathway
- GMLP implementation & data governance
- EU AI Act Compliance
- Predetermined Change Control Plans (PCCP) & lifecycle planning
- Post-market surveillance
- Training, audits & in-house enablement

Pillars of AI/ML SaMD

Data Management	Reference Dataset	Generalisability	Performance Evaluation
Develop and document dataset management plans covering provenance, versioning, and access control	Design and qualify reference datasets aligned with clinical context and labelling claims	Assess representativeness and diversity of training data to ensure fairness and generalisability across patient populations and devices	Build risk-based evaluation strategies tailored to intended use and model type

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360° Services in Life Science, Pharma, and Healthcare Informatics