MEDICAL DEVICE IVD SaMD

DESIGN, TESTING, REGULATORY & QUALITY PARTNER

End-to-end medical device lifecycle support for 20+ global markets

NexorTest

- Engineering Support
- Compliance Testing
- Cybersecurity Testing
- Product Compliance & Validation
- Process Compliance Validation
- Labeling
- Packaging
- Product Compliance & Validation
- Global Regulatory Consulting
- Authorized/ Legal Representation Support
- QMS (ISO13485)
- Clinical/Medical Writing
- Post Market Surveillance

Facts

300+ Compliance Tests Executed	20+ Designs Completed
15+ HA Submissions	20+ Countries AR/LR support
>90% On Time Completion	300+ Customers
30% Typical Cost Reduction	

What sets us apart

- Faster time-to-market
- Single accountable partner
- Qualified & expert teams
- Multi-region support
- Cost effective business model

Engineering Support

- Electrical Engineering
- Product Design Development
- Hardware Engineering
- Embedded Systems Development
- PCB Design and Development
- Prototyping and Product Realization

Compliance Testing

- EMI/EMC Testing (EN/IEC/ISO 60601-1-2)
- Electrical Safety Testing (EN/IEC/ISO 60601-1)
- Reliability & Safety Testing
- Material Testing
- Biocompatibility Testing (ISO 10993)
- Software Lifecycle (ISO 62304)
- Cybersecurity Testing
- Human Factor studies (IEC 62366)

Cybersecurity Testing

- Pen testing
- Threat modeling
- Algorithm safety frameworks
- Vulnerability assessment

Product Compliance & Validation

- DHF Gap Analysis
- DHF Remediation
- Test method validation
- V&V support & documentation
- Design Drawings
- ECN/ECO management
- CAPA & RCA support
- Reliability improvement
- Benchmarking Support

Process Compliance Validation

- Design transfer support
- Manufacturing documentation
- DMRs, DHRs
- GxP implementation
- (GMP, GLP, GCP)
- Process validation (IQ/OQ/PQ)
- PFMEA
- Statistical process control analysis
- Stability studies report

Labeling

- Gap Analysis
- Label Design &Management
- UDI support
- Lifecycle Management
- IFU Gap Analysis
- IFU Development
- Global labeling strategy and compliance checks
- EU MDR, UK MDR, and country-specific labeling
- Artwork review and change impact assessment

Packaging

- Packaging design & Development
- Prototyping
- Regulatory Advice & Support
- Packaging Validation
- Process Development

Global Regulatory Consulting

- Regulatory pathway assessment and market access strategy
- Regulatory classification assessment
- Market specific approval strategies
- Global submissions support
- Technical documentation
- IEC 62304 lifecycle documentation
- Software risk management and usability engineering
- Submission support
- Gap Assessment
- Remediation
- Regulatory authority interaction support
- Sustenance
- Standard Assessment

Authorized/Legal Representation Support

- LR/AR support globally in the 20+ countries.
- Change of legal representative support.
- Interaction in local language with the Health Authorities in APAC, LATAM, and Europe regions.
- EU PRRC, UKRP, Swiss AR, EAR, US Agent and IAA support
- Liaison with the Health Authorities (HA) for submissions, queries, and feedback.

QMS (ISO13485)

- QMS establishment support
- QMS gap analysis
- QMS Remediation
- Support Country specific QMS
- QMS Assessment
- Development
- Maintenance
- Quality Audits
- Supplier Audits
- MDSAP support
- CAPA and quality improvements

Clinical/Medical Writing

- Scientific Literature Reports
- Promotional Materials
- Scientific Journals
- Clinical Evaluation Plans and Reports (CEP, CER)
- PMS plans and reports, PSURs, SSCPs
- PMCF planning and execution support
- Literature review and clinical evidence strategy
- Response to notified body clinical findings

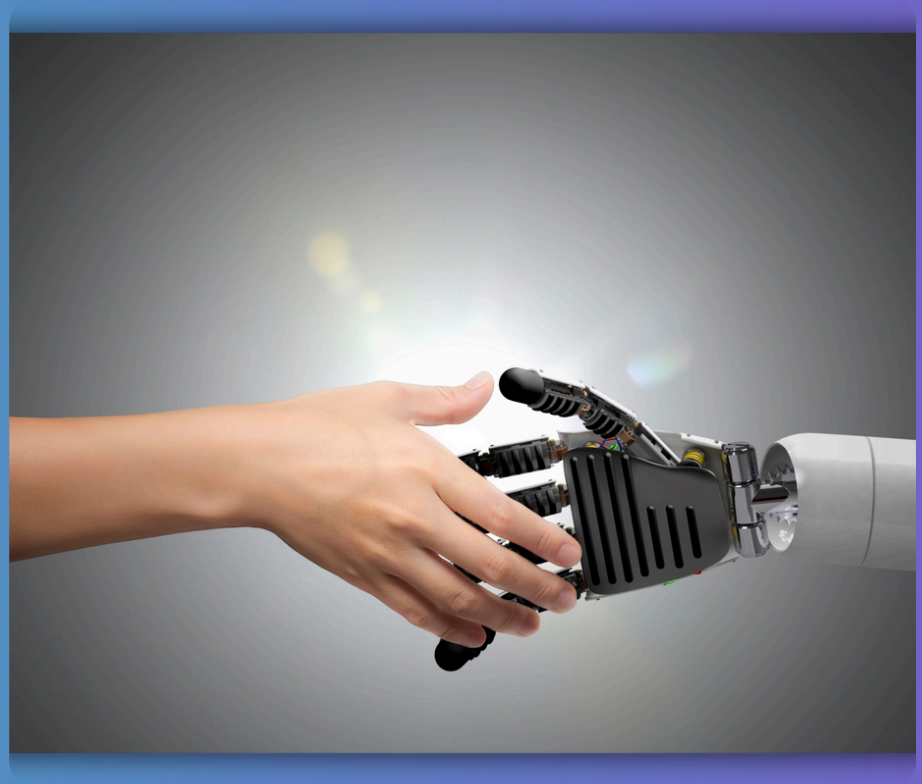
Post Market Surveillance

- Complaint Management
- Vigilance
- Regulatory Reporting
- Periodic safety updates
- PMS Plan & reports

ABOUT US

Key challenges we solve

- Constantly evolving global medical devices, IVD and SaMD regulations
- EU MDR and UK MDR transitions
- SaMD and AI/ML regulatory ambiguity
- Clinical evidence generation and justification of gaps
- Increasing post-market surveillance and vigilance burden
- Delays in approvals due to incomplete or misaligned submissions



Industries we support

- Medical Devices
- In vitro diagnostic devices (IVDs)
- Software and AI-based medical devices
- Wearables and patient monitoring systems
- Combination products
- Companion Diagnostics

Global Reach

USA	UK	Europe	India	Indonesia	Israel	Singapore	Malaysia	Egypt	Morocco	Canada
South Africa	Algeria	China	Turkey	Serbia	Saudi Arabia	UAE	Argentina	Brazil	Australia	New Zealand

Schedule a free call to speak with our regulatory expert for a strategy discussion.