

Medical Device Development

Bring your products to market quickly and confidently with the product development, quality management, testing, compliance, and regulatory support you need.



www.aversan.com/medical-devices

PRODUCT DEVELOPMENT

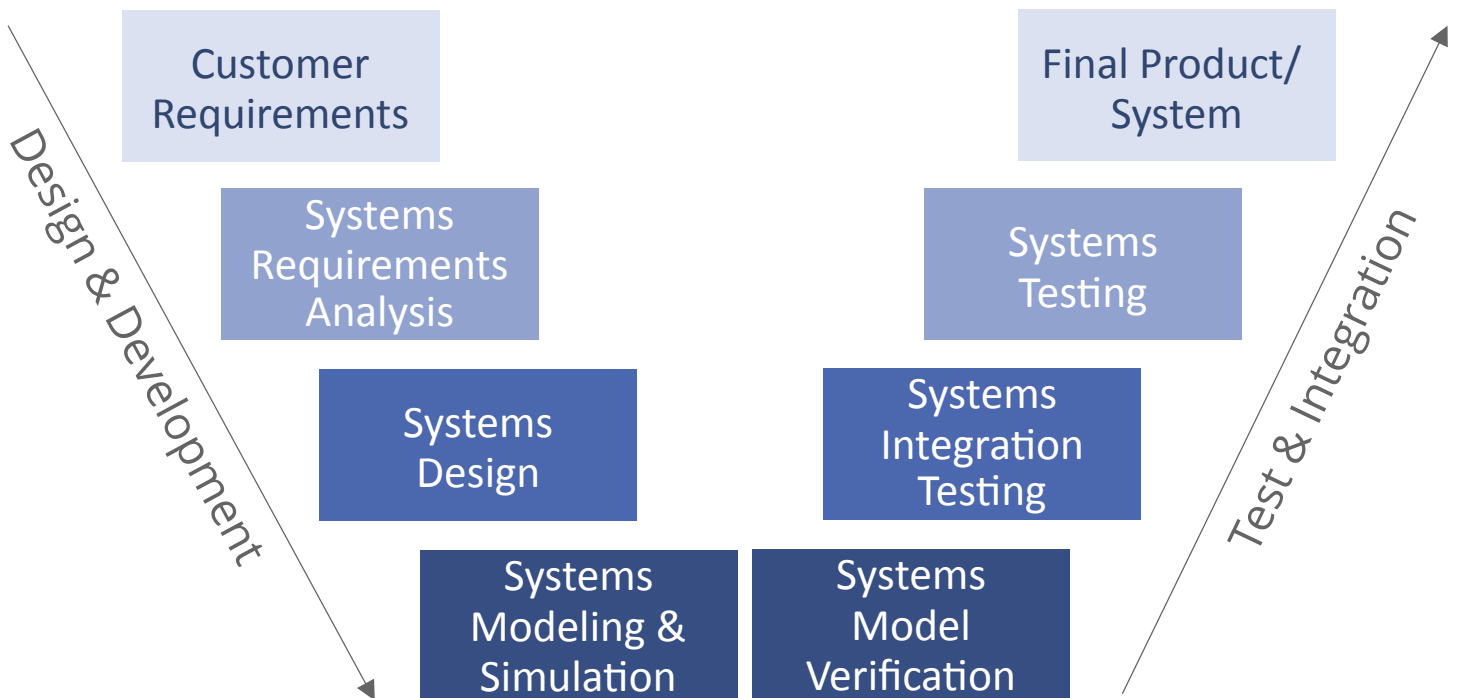


Regulatory experts and embedded systems engineers can help you meet your objectives while staying cost effective in a highly competitive market. Aversan develops electronic hardware and embedded software which meet the highest regulatory standards for medical devices.

- ✓ Embedded Systems Design & Development
- ✓ Board Design / ASIC / FPGA / VLSI / SoC Design
- ✓ Mechanical & Hardware Design and Build
- ✓ GUI Design and Development
- ✓ Software Application Development
- ✓ Firmware / Middleware Development
- ✓ Privacy and Security (HIPAA, PHIPA, PIPEDA)
- ✓ Systems Integration & Device Connectivity
- ✓ Design Inputs Gap Analysis
- ✓ Design Verification & Validation
- ✓ DHF, DMR, DHR Assessments

Quality Management System implementation, support and upgrades (ISO 13485, ISO 9001)

Regulatory compliance support (ISO 13485, IEC 62304)



VERIFICATION & VALIDATION



Bring your product into compliance through verification and validation services. Driven by a robust Quality Management System, experienced and certified engineers work to fully qualify medical devices.

Software Verification

- Unit and white box testing
- Regression testing
- Performance testing
- Tools validation

Mechanical Verification

- Hardness/compression
- Thermal analysis
- Corrosion & fracture mechanics

Electrical Verification

- EMC testing
- IEC 60601-1 3rd standard edition

System Integration Verification

- Verification of enterprise EMR, EHR, or HIS connectivity using HL7 and FHIR
- Verification of real-time data collection using ISO/IEEE 11073 standards
- RS-232, WiFi, Bluetooth, RFID verification

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TEST AUTOMATION

Enable quick regression campaigns for hardware and software systems with automated test processes, and empower development teams to bring products to market quickly and confidently.

- ✓ Automated Testing Framework for software and user interface testing
- ✓ Automated Test Equipment for hardware design verification and factory acceptance testing
- ✓ Automated testing to support validation of design control inputs and outputs
- ✓ Manual to automated test conversions

Providing test automation solutions to major public and private organizations including Cancer Care Ontario, the Province of British Columbia, Laborie, and Honeywell for more than ten years.

[Read more about our projects >>](#)

REGULATORY SUPPORT

Global Market Launch

- Define regulatory pathways (US FDA, Health Canada, EU)
- Regulatory & clinical path strategy
- Technical filing & regulatory submissions

Certification Support

- CE Mark, NRTL Mark
- Pre-compliance testing (i.e. electrical & mechanical safety testing and alarm testing).
- Project management services between client and certification entities.

Risk Management

ISO 14971, IEC 14971 standard:

- Root cause analysis and failure mode event analysis (FMEA)
- Cybersecurity risk management

Software Process Lifecycle Creation

Align with the requirements of IEC 62304, ISO 14971, IEC 60601 (including any collaterals or particulars that are applicable to the subject device).

QUALITY MANAGEMENT

Our engineering and regulatory experts develop Quality Systems with ISO 13485 & FDA compliant processes, along with the training and support to facilitate audit preparations, market launches and certifications like CE, NRTL (i.e. UL, TUV).

- ✓ Quality Management System (QMS) Planning
- ✓ QMS Development
 - Design Controls
 - Risk Management
 - Document Control & Records Management
 - Supplier Management
- ✓ Mock Audits
- ✓ CAPA Resolution
- ✓ Post-Market QMS Support
- ✓ Gap Analysis from ISO 13485:2003 to ISO 13485:2016
- ✓ Transition from ISO 13485:2003 to ISO 13485:2016

CONTACT US

Learn more about our services, ask a question, or request a presentation.

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