Simplexity®
PRODUCT DEVELOPMENT
Simplifying the Complex®

CAPABILITIES OVERVIEW

NSF
NSF-ISR
Registered to ISO 13485

- CLASS II MEDICAL DEVICE DESIGN
- INSTRUMENT PRODUCT DEVELOPMENT
- ROBOTIC SYSTEMS
- CONNECTED DEVICES
- MEDICAL WEARABLES

MEDICAL DEVICE DEVELOPMENT

Medical devices are subject to regulatory requirements that ensure a well-documented and reviewable design process — and ultimately, a safe product.

At Simplexity, our core design philosophy is that **the best solution is the simplest one to reliably accomplish your goals**. This guiding principle is particularly relevant in the medical device space, where reliability, safety, and intuitive design are of the utmost importance.

Our ISO 13485:2016 certified quality management system ensures consistent design and development of devices that are safe for their intended use.

SIMPLEXITY MEDICAL DEVICE EXPERTISE:

- Medical device product architecture and development
- Risk management
- Pre-production builds for design verification & usability testing
- DHF documentation
- Production and characterization test tools
- Robotic systems
- Wireless connectivity
- New product introduction (NPI)
- Design for manufacturing & assembly
- ISO 13485:2016 certified quality management system

COMMON CHALLENGES AND NEEDS that bring medical device clients to Simplexity:

- Medical device prototype development to support clinical trials
- Product architecture expertise for new medical devices
- Technology feasibility evaluation or isolated technical hurdle resolution
- Miniaturization of electro-mechanical designs
- Low power design – both electrical and firmware
- Proof-of-concept devices for technology demonstration & usability
- Characterization tools to execute design of experiments during device development
- Comprehensive program planning, phase-gate build objectives, risk assessment, development budget, product cost estimation
- Full medical device development
- New product introduction (NPI): contract manufacturing selection, tooling strategy, test planning
- Developing under quality system design controls and performing design verification
- Medical products developed in compliance with IEC 60601 and IEC 62304

SIMPLEXITY MEDICAL DEVICE EXPERTISE:

MOLECULAR DIAGNOSTICS	SMART MEDICAL DEVICES	CONNECTED WEARABLES AND MONITORING

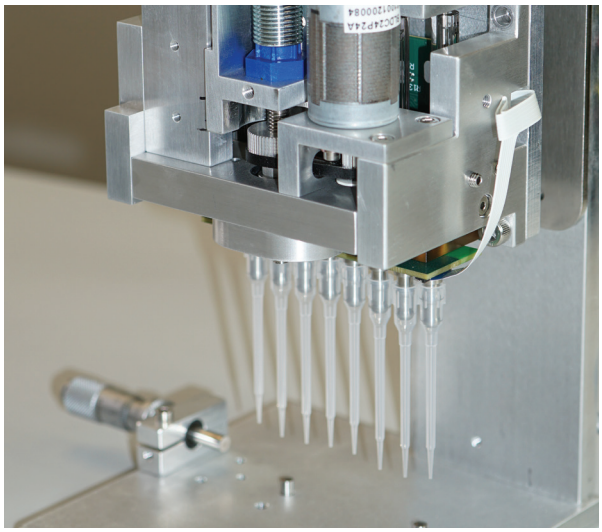
SIMPLEXITY'S CAPABILITIES

Simplexity® PRODUCT DEVELOPMENT

SUPPORTED PRODUCT CATEGORIES:

Our large, fast-ramp team of expert product engineers and project managers have worked with medical device clients to design products and systems in the product categories of:

- Medical wearables
- Patient monitoring devices
- Surgical tools
- Endoscopy and catheter-based devices
- Home health devices
- Low-power wireless communications



PRODUCT DEVELOPMENT COMPETENCIES:

As an engineering and technology-focused design company, we have assembled the best design team in the industry around our core competencies of product development and medical devices. These include:

Risk Management

- Hazard and risk analysis
- Class II documentation requirements
- Operating room environment considerations
- Fluid handling contamination concerns
- Biometric sensing
- Biocompatibility of materials
- Secure wireless data transfer

Product Design and Development

- Compact electro-mechanical design
- PCA & flex PCA design
- Sensors
- Components (motors, buttons, haptics, displays)
- Firmware and software integration
- Communications (Ethernet, USB, Wi-Fi, BLE)
- Low-power devices
- Optical systems

Process and Test Development

- Characterization testbeds
- Workflow analysis and automation
- Characterization DOE and test
- Design analysis
- Production process analysis
- Tolerance analysis

WHY SIMPLEXITY?

Simplexity has considerable experience with and understanding of the medical device development space and the unique requirements that must be met to achieve success. We look forward to partnering with your company's core technology experts, working shoulder-to-shoulder to enable the rapid transformation of novel concepts into reliable, safe products.

Medical device leaders choose Simplexity Product Development to accelerate and de-risk their product development. For almost 15 years, we have been a trusted partner in product commercialization, with a depth of expertise in product architecture, mechatronics, and complete system design for cost-effective manufacturing.

» Read Medical Device Development Case Studies

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