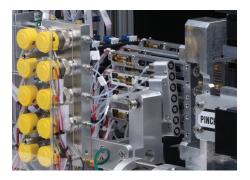
CAPABILITIES OVERVIEW





- INSTRUMENT PRODUCT DEVELOPMENT
 MECHATRONICS
- FLUIDIC/MICROFLUIDIC
 OPTO-MECHANICAL
- VALUE ENGINEERING
- VALUE ENGINEERING





SIMPLEXITY BIOTECH EXPERTISE:

- Instrument architecture and development strategies
- Laboratory instrument product development
- Cartridge-to-instrument interfaces optimization
- Value engineering
- System integration and testbed delivery
- Production and characterization test tools
- New product introduction (NPI)
- Robotic systems
- Wireless connectivity
- ISO 13485:2016 certified quality management system

MOLECULAR DIAGNOSTIC INSTRUMENTS

Designing novel molecular diagnostic instruments requires a unique blend of systems design expertise and biological process understanding.

Simplexity helps clients navigate this complex development landscape through close collaboration with their assay and consumable team, establishing a well-defined interface and setting the common objective of designing a successful instrument.

COMMON CHALLENGES AND NEEDS that bring biotech clients to Simplexity:

- Product architecture expertise for new instrument platforms
- Technology feasibility evaluation or isolated technical hurdle resolution
- Proof-of-concept devices for technology demonstration
- Design of cost-reduced and design-optimized next-generation
 products
- Automated workflow testbeds for assay and cartridge development
- Production test tools for monitoring critical performance metrics
- Characterization tools to execute design of experiments during instrument development
- Comprehensive program planning, phase-gate build objectives, risk assessment, development budget, product cost estimation
- Manufacturing strategies with customer interests in mind (contract manufacturing selection, tooling strategy, test planning, quality management)
- Designing to medical device standards as required

SIMPLEXITY BIOTECH EXPERTISE:



• MOLECULAR TESTING



SIMPLEXITY'S CAPABILITIES

SUPPORTED PRODUCT CATEGORIES:

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

- Liquid handling instruments
- Point-of-care diagnostics instruments
- PCR instruments

- Library preparation instruments
- Sample preparation instruments
- · Cell therapy manufacturing tools

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 molecular diagnostics. These include:

Subsystem Development Complete motion subsystems

- (gantries, robotic arms, actuators, cartridge loaders)
- Thermal systems (thermocycling, precision temperature control)
- Fluidic systems (pumps, valves, manifolds, tubing)
- Opto-mechanical systems
- Optical systems
 (machine vision, alignment and inspection, barcode readers)
- Magnetic systems

Process and Test Development

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

Cartridge Interfaces

- Pneumatic
- Sonication
- Magnetic
- ThermocyclngOpto-mechanical

Valve actuation

- Communications
 Ethernet WiFi
 - USB Bluetooth Low Energy (BLE)
 - RFID Cellular

WHY SIMPLEXITY?

Simplexity understands the challenges of designing molecular diagnostics instruments. We speak your language. Working shoulder-to-shoulder with you, we are focused on transforming your novel idea or benchtop proof-of-concept prototype into a well-designed, integrated instrument ready for the marketplace.

Biotech instrument 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 Molecular Diagnostic Case Studies

simplexitypd.com

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