



ANDREWS COOPER | PRODUCT DEVELOPMENT

ebook

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Accelerating MedTech Development

BOOK 2 OF 4

**TEST ENGINEERING TO
SAFEGUARD DESIGN INTEGRITY**

TECH TALKS™ EBOOK SERIES

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Accelerating Complex MedTech Development Requires Diverse Expertise

Bringing a medical device from concept to market is a complex process. Beyond a great idea, it requires expert engineering, rigorous validation, regulatory compliance, and precision manufacturing—all while adapting to compressed timelines. For MedTech developers, these hurdles can feel overwhelming without the right support. Adding multidisciplinary engineering expertise to your team is essential to eliminate roadblocks and accelerate your journey to market.

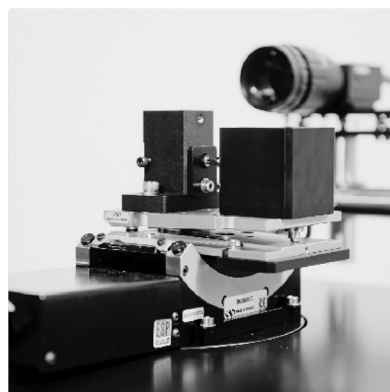
In this series, we address four critical questions for MedTech developers:

1. How does engineering expertise accelerate development and drive success?
2. How does test engineering safeguard design integrity?
3. How does engineering ensure regulatory readiness and compliance?
4. How does automation enhance device manufacturing?

Whether you're navigating early-stage design, validation, or scaling to full production, this series provides valuable insights. Learn how Andrews Cooper's (AC) multidisciplinary engineering expertise can help you succeed in the competitive MedTech landscape.

ABOUT ANDREWS COOPER

Andrews Cooper (AC) excels at advanced engineering for emerging technologies, specializing in Research & Development, Product Development, Hardware Testing, and Manufacturing Automation. We cater to ambitious, tech-focused companies seeking to innovate and lead their industries. With expertise in multiple engineering disciplines, our engineers function as force multipliers, propelling the development of HardTech solutions. With a focus on rapid development using proven methodologies, we de-risk the development process and integrate validation and testing to ensure high-quality, manufacturable products.



Looking for a snapshot of our testing capabilities? Visit our [Hardware Test page](#).



MEDTECH TEST ENGINEERING: Safeguarding Design Integrity, Compliance, and Patient Safety

MedTech devices are required to deliver consistent performance, adhere to stringent regulatory standards, and function reliably in real-world environments—all while maintaining cost-efficiency and timely market entry. Here, design integrity refers to a device's ability to fulfill its intended purpose consistently, delivering dependable outcomes while meeting safety standards. Compromising design integrity at any point can delay regulatory approval or lead to costly recalls.

To mitigate these risks, test engineering provides a structured, proactive framework to identify and resolve issues early, strengthening a product's reliability and compliance.

This eBook—the second in our series on Accelerating MedTech Development—explores how test engineering integrated into the product development lifecycle, actively preserves design integrity, ensuring product standards remain uncompromised despite complex design and regulatory demands.



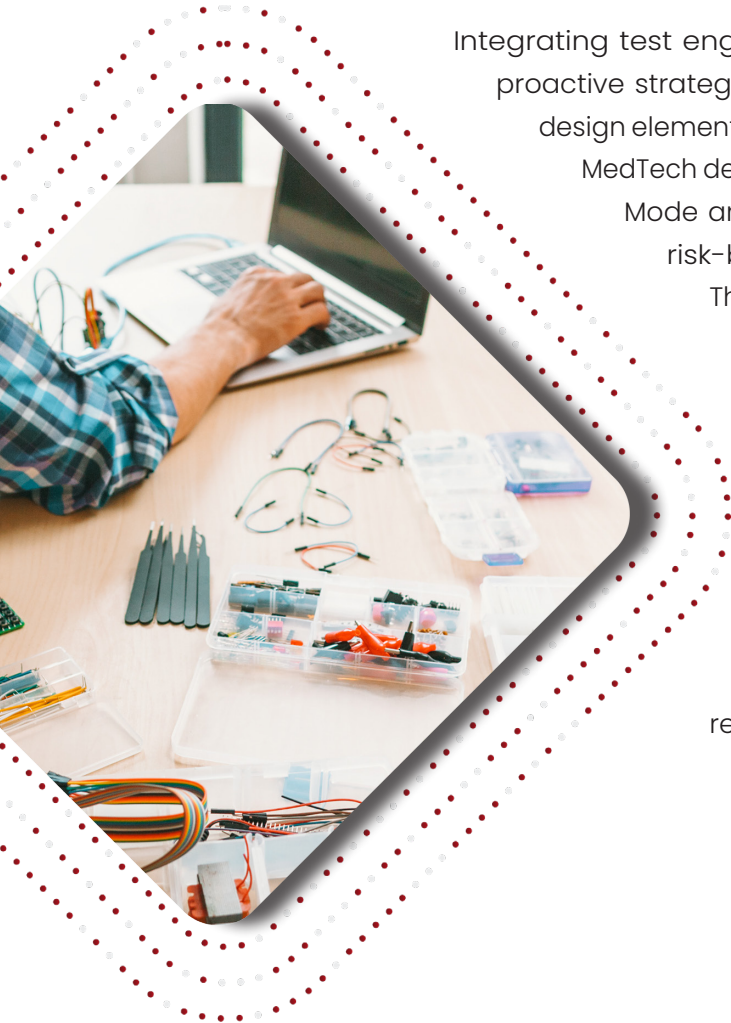
Test engineering provides a structured, proactive framework to identify and resolve issues early, strengthening a product's reliability and compliance.

Early Test Integration & Risk Analysis for Baseline Metrics and Design Validation

Proactive Integration for Risk-Based Testing

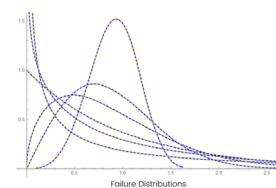
Integrating test engineering early in the design process establishes a proactive strategy to safeguard design integrity, ensuring that critical design elements are protected from the outset. For complex or high-risk MedTech devices, embedding test engineering into the Design Failure Mode and Effects Analysis (DFMEA) process enables targeted, risk-based testing aligned with potential failure modes. This approach not only strengthens device reliability but also ensures compliance with regulatory standards.

By incorporating test protocols from the beginning, teams can set baseline performance metrics, conduct stress testing, and validate that initial design choices align with both regulatory requirements and user needs. Early testing insights refine design parameters and shape downstream testing, creating a cohesive development process that reinforces product quality, reliability, and compliance.



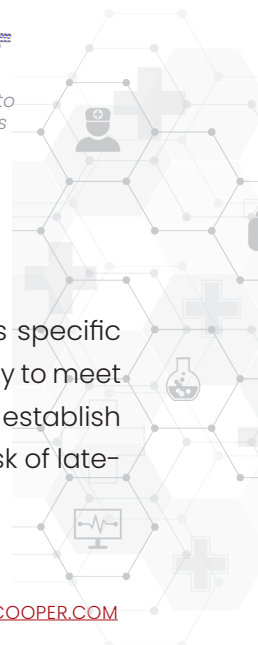
Identifying High-Priority Risks with a Collaborative Approach

When integrated early in the design phase, test engineering focuses on addressing the highest-priority risks identified through a comprehensive risk assessment. For instance, design engineers may need to address specific concerns with electronic sensors, signal quality, environmental durability, or long-term usability to meet stringent regulatory requirements. By working closely with the design team, test engineers establish a framework for targeted testing across the product development lifecycle, reducing the risk of late-stage failures and enhancing device resilience, compliance, and patient safety.



Failure distribution analysis to identify highest risk systems

> MORE..



CASE STUDY

Preserving design integrity and compliance for Cardiac Insight's Wearable ECG System



Cardiac Insight's Cardea SOLO

Challenges:

- Design and validate a wearable, low-power ECG monitoring system that reliably captures and transmits cardiac data over a seven-day period.
- Achieve regulatory compliance, accurate ECG signal capture, and seamless data transfer for clinical review, while ensuring patient comfort and durability through environmental changes.

Solutions:

- Signal testing optimized the ECG circuit for low power and validated intelligent power management for continuous monitoring.
- Battery capacity and power consumption were tested under simulated conditions to meet seven-day monitoring requirements.
- V&V testing minimized interference and enhanced signal clarity with a high-precision ECG amplifier and noise filtering.
- Compliance-focused testing ensured alignment with IEC 60601, AAMI, and ISO 10993 standards, verifying safety, biocompatibility, and durability.

Results:

AC's integrated MedTech engineering and V&V test solutions enabled the [Cardea SOLO](#) ECG device to meet stringent performance, regulatory, and clinical standards, preserving data integrity across diverse conditions for a full seven-day monitoring period.

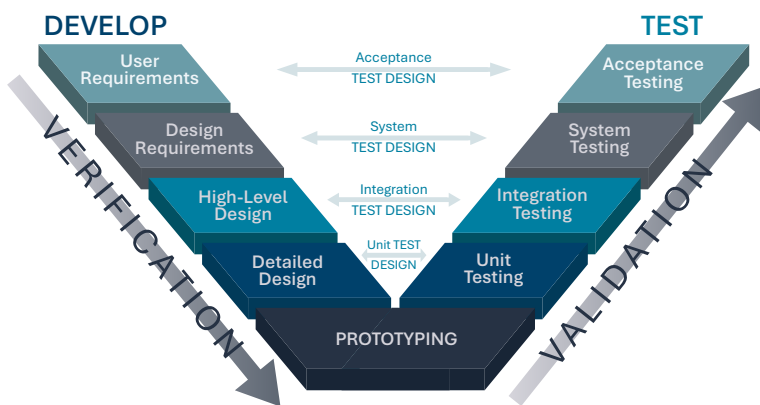


Read the full Case Study on the Cardea Solo Wearable ECG

> MORE..

Stage-by-Stage Testing for Verification and Validation (V&V)

Verification and Validation (V&V) are core processes that confirm a medical device meets design specifications (Verification) and fulfill real-world user needs (Validation). Test engineering supports V&V by developing and executing targeted tests that assess device safety, functionality, and compliance at each stage, ensuring that every design element aligns with regulatory and operational requirements.



This V&V approach aligns testing with development phases, facilitating continuous refinement while reinforcing design integrity. Testing checkpoints across Unit, Integration, System, and Acceptance Testing levels enable early issue detection, incremental improvements, and risk mitigation at each development stage, guiding the product toward reliable market readiness.

V&V Stage	Focus	Example of Test Role
User Requirements	Validates usability and safety meet essential user needs	Usability tests for a wearable glucose monitor confirm ease of use, comfort, and reliable readings for patient operation.
Design Requirements	Ensures technical specifications align with user needs and regulatory standards.	System tests for an AED validate battery life and shock delivery per IEC 60601, ensuring emergency readiness.
High-Level Design	Verifies reliable subsystem interactions to support device functionality.	Integration tests for an ECG device ensure sensors and processors provide continuous, accurate monitoring.
Detailed Design	Confirms component durability and regulatory compliance to support safety.	Battery tests for a pacemaker validate durability and biocompatibility for long-term implant use under ISO standards.
Prototyping	Assesses overall functionality and usability in real-world settings.	Final tests on a home diagnostic device ensure accurate readings and ease of use for non-clinical users.

Test Engineering Tailored for MedTech Compliance Standards

Compliance with stringent ISO and IEC standards is essential for medical devices to ensure safety, efficacy, and reliability. Test engineering plays a crucial role in meeting regulatory requirements such as these:

Standard	Purpose	Test Engineering Role
ISO 13485	Quality management system for consistent product quality.	Process validation ensures each manufacturing step consistently meets quality criteria.
ISO 14971	Framework for identifying and mitigating device risks.	Design Failure Mode and Effects Analysis (DFMEA) identifies and prioritizes potential failure modes early in development.
IEC 60601	Ensures electrical safety and EMC compliance for medical devices.	Electrical safety and EMC tests validate insulation, grounding, and compatibility with other medical equipment.
IEC 62304	Regulates software lifecycle processes for medical device software safety.	Software reliability testing assesses fault tolerance, ensuring software performs safely and consistently.
IEC 62366	Guides usability engineering to minimize user errors and improve device intuitiveness.	Usability testing confirms the device interface is intuitive and minimizes the risk of operational errors in clinical settings.

Standards like these form the regulatory foundation for medical device test engineering, ensuring that each protocol and test outcome meets rigorous safety, usability, and functionality criteria.

Strategic test engineering supports Process Failure Mode and Effects Analysis (PFMEA) in manufacturing by supplying essential data to identify and reduce risks in production. This approach helps preserve the design’s integrity through to the final product, minimizing variability and non-compliance.



Advancing MedTech with Strategic Test Engineering

Test engineering is more than a verification step; it's a proactive approach to sustaining MedTech design integrity. By integrating testing early and upholding rigorous protocols throughout development, engineering teams can deliver compliant, reliable devices optimized for real-world use.



Discover how our strategic testing solutions support your MedTech product's journey from concept to market, ensuring safety, compliance, and lasting reliability.

Regardless of where you are in your product lifecycle, improve your speed to market with AC's engineering teams in [Research & Development](#), [Product Development](#), [Hardware Testing](#), and [Manufacturing Automation](#).

Let us know how can we support your current needs and solve your ambitious challenges.



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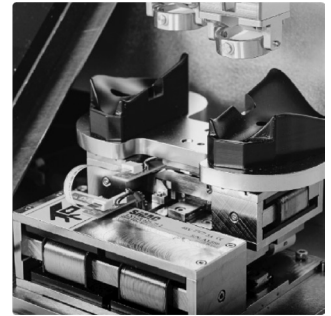
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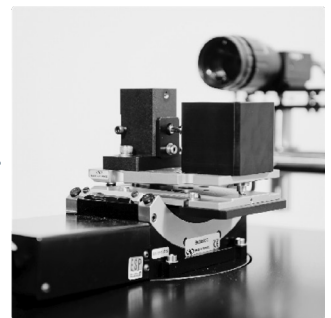
**R&D
Accelerator**

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**Product
Development**

A white icon of a cube with a cursor arrow pointing to it, representing hardware testing.

**Hardware
Testing**

A white icon of a robotic arm, representing manufacturing automation.

**Manufacturing
Automation**

A white icon of three stylized human figures, representing integrated engineering teams.

**Integrated
Engineering
Teams**



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