ebook

ANDREWS COOPER | MANUFACTURING AUTOMATION

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Accelerating MedTech Development

BOOK 4 OF 4

AUTOMATION THAT ENHANCES DEVICE MANUFACTURING

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.

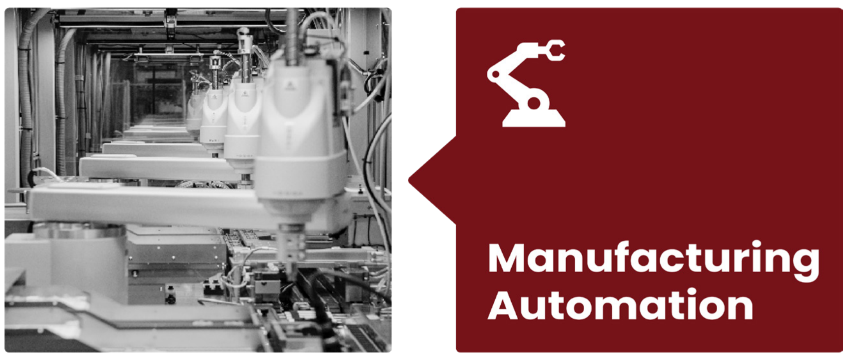
In this series, we address four critical questions for MedTech developers:

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 (AC) delivers product development and automation 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 Manufacturing Automation services? Watch our 1-Minute Video.

THE ROLE OF AUTOMATION IN MEDTECH DESIGN TRANSFER

Custom automation plays a transformative role in medical device manufacturing, enabling precision, scalability, and compliance at every stage of production. Advanced tools—such as vision-guided systems, modular workflows, and real-time monitoring technologies—streamline complex processes, reduce variability, and ensure consistent, high-quality outcomes. These systems are designed to meet the unique demands of MedTech devices, where intricate geometries, micro-scale components, and strict regulatory standards require exceptional control and accuracy.

Bridging Device Innovation & Production Readiness

However, developing a successful medical device manufacturing plan requires much more than advanced automation technologies. To bridge the gap between achieving an innovative device and full-scale compliant manufacturing, MedTech innovators must navigate a critical—and often underappreciated—phase of the product lifecycle: Design Transfer.

It requires a carefully orchestrated process of risk management, validation, and traceability to ensure that a product's design intent is fully realized in manufacturing. Understanding why design transfer is so challenging is the first step toward addressing its hidden complexities and achieving a seamless transition to production.

Navigating the Hidden Complexity of Design Transfer

At first glance, design transfer may seem deceptively simple. The FDA's 21 CFR Part 820 dedicates just a single sentence to it:

"Each manufacturer shall establish and maintain procedures to ensure that the device design is correctly translated into production specifications."

Yet this brief mandate belies the significant effort and complexity required to achieve a seamless and compliant transition, ensuring that a device's design is successfully translated into scalable, compliant manufacturing.

The focus of our eBook is to describe how to integrate automation early in the development of a medical device to achieve design transfer. This exploration includes why design transfer is challenging and how the right approach ensures crucial de-risking, validation, and traceability—all of which impact compliance and production readiness.

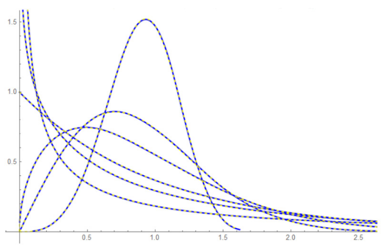
Why Design Transfer is Challenging

Transferring a MedTech product design to production can be just as complex as bringing it market. The challenges of design transfer often stem from common oversights that introduce unnecessary risks, inefficiencies, and quality gaps:

Challenge	Impact
Fragmented Collaboration	Misalignment between design and manufacturing teams leads to costly rework and manufacturability issues.
Delayed Risk Management	Identifying risks late in the process forces reactive solutions, increasing costs and jeopardizing timelines.
Insufficient Validation	Incomplete or ad hoc validation causes inconsistent tool performance, product defects, and audit challenges.
Poor Traceability	Missing or unreliable documentation prevents compliance demonstration, risking delays or recalls.
Adaptive Algorithms	Continuously refines processes based on live data, ensuring high-precision outcomes even as part variability changes.

The Need to Engage Early & With the End Result in Mind

Addressing these challenges requires an early and proactive approach where product design and production planning happen in tandem. MedTech Developers must begin with the end in mind if they expect a seamless transition from product development to full-scale manufacturing. Automated assembly and manufacturing processes have regulatory requirements such as risk management, process validation, traceability and data integrity that need to be understood at the very start of the design transfer process. This understanding should be a gating milestone to any capital procurement efforts.



Failure Distributions

More MedTech Insights: Interested in how FMEA of high-risk components impacts expected service life and regulatory compliance?

MORE..

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Integrating Automation: 3 Steps to Achieving Design Transfer Compliance

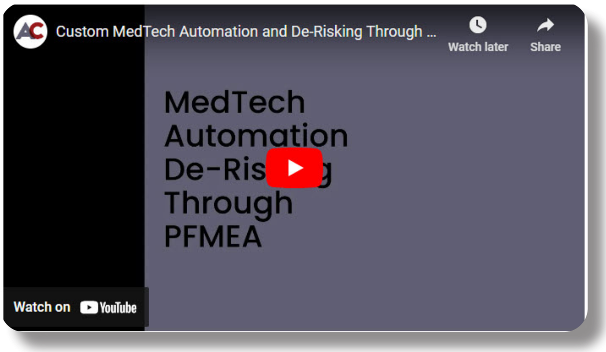
The design transfer process consists of several activities that require compliance with regulated standards, including process control, device master records, device history records, and the data integrity and retention therein. When set up correctly, automated manufacturing and assembly systems can streamline compliance by integrating systems that manage these areas into a unified workflow. This ensures regulatory requirements are met with precision, consistency, and audit-ready documentation.

Step 1: Assess Risks with PFMEA

Design transfer begins with identifying potential risks during the process development phase. Process Failure Mode and Effects Analysis (PFMEA) is a structured approach for evaluating and mitigating failure modes before production starts.

This proactive methodology ensures that critical risks are addressed in the manufacturing process, reducing the likelihood of defects and improving overall reliability. This is a key driver for the design of automated equipment and software. A risk-based approach is also directly aligned with subsequent equipment and process qualification efforts.

Engineering Focus	Compliance Impact
Early Risk Identification	Highlights failure points to improve product safety and reliability.
Proactive Mitigation	Implements preventative measures during design to reduce defects.
Regulatory Alignment	Meets FDA and ISO expectations for risk-based compliance strategies.



Learn more about AC's de-risking approach to MedTech manufacturing in this 3-minute video.

Step 2: Validate Systems & Processes

Once risks have been identified and mitigated, validation ensures that systems and processes meet compliance requirements. Validation activities, such as Installation Qualification (IQ), Operational Qualification (OQ), and Performance Qualification (PQ) protocols, confirm reliability and readiness for production.

Proving the confidence and reliability levels of automated processes, including sampling strategy and acceptance criteria, is also a key part of process validation activities.

> "We develop our factory acceptance test protocols to mirror industry standard IQ/OQ/PQ/SWV formatting and methodologies."

Jack Link
AC Automation Senior Project Manager & MedTech Specialist

Engineering Focus	Validation Process	Compliance Impact
Design Qualification (DQ)	Map user requirement specifications (URS) and risk mitigation to the technical design of automated systems and equipment.	Accounts for all requirements before production begins.
Process Validation (IQ, OQ, PQ)	Configure factory and site acceptance testing in protocols that mimic industry-standard IQ, OQ, and PQ.	Provides audit-ready documentation and ensures consistent, repeatable tool performance. Turnkey protocols can be leveraged by the device OEM's internal quality systems.
Software Validation	Create test scripts to ensure functionality, risk management, and 21 CFR Part 11 compliance.	Ensures system functionality, traceability, data security, and regulatory compliance.

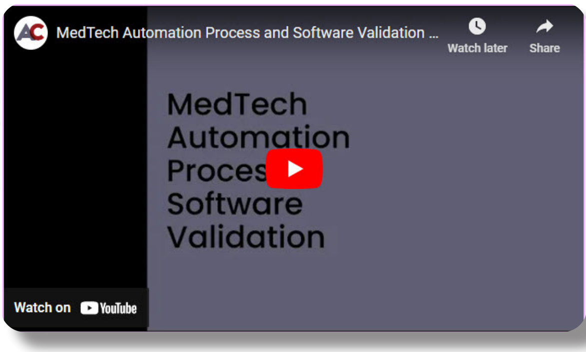
Step 3: Enable Traceability and Compliance

Automation simplifies compliance through robust traceability mechanisms. Systems designed with 21 CFR Part 11 compliance automatically capture and document key data, creating an unbroken audit trail for regulatory submissions and post-market surveillance.

> "We review all possible opportunities for non-conforming product escapements as a foundation to our automated process development, aligning with regulatory expectations for risk-based decision making."

Jack Link
AC Automation Senior Project Manager & MedTech Specialist

Engineering Focus	Compliance Impact
In-Line Data Capture	Ensures accurate documentation of process parameters in real time.
Audit-Ready Records	Provides traceable documentation aligned with 21 CFR Part 11 standards.
Integrated Quality Monitoring	Prevents non-compliance by detecting defects during production.

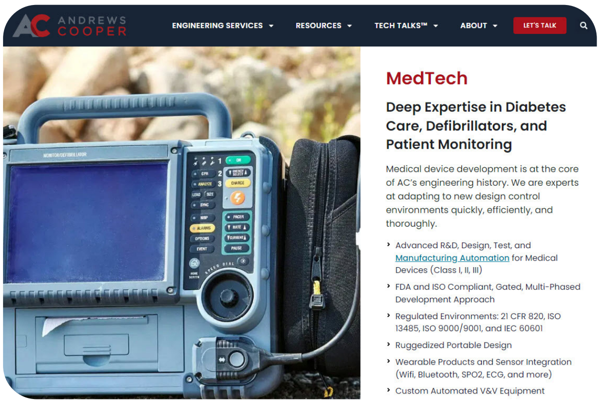


Learn more about AC's approach to MedTech validation in this 3-minute video.

AC Engineering: Your MedTech Compliance Design & Development Partner

Navigating medical device development requires expert support at every stage to drive innovation from concept to production. By integrating compliance into every phase of development and manufacturing, AC engineers streamline development while tackling regulatory processes in parallel. Through decades of expertise in design, risk mitigation, and regulatory compliance, AC accelerates your path to market with confidence and precision. Contact us today to bring your MedTech vision to life.

Find more on MedTech



Visit our MedTech page at Andrews-Cooper.com

Watch our 1-minute video

Harry Richards describes how AC de-rsks and prepares your device for success in our 1-Minute Video.

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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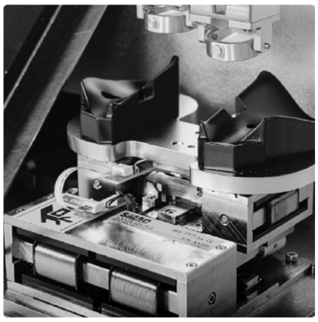
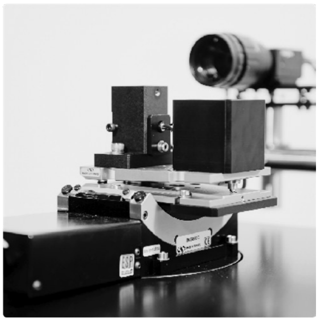
R&D Accelerator



Product Development

Hardware Testing



Manufacturing Automation

Integrated Engineering Teams

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