Roadblocks to Medical Device Certification and How to Avoid Them

Trusted Certification & Compliance Advisors for your Global Markets

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Medical Device Testing and Certification

Navigating the complex path from concept to market approval requires expertise in regulatory standards, testing protocols, and certification requirements.

Understanding these processes early can prevent costly redesigns and market delays.

Agenda

Introduction

Overview of Megalab Group and certification landscape.

Current Trends & Issues

Market challenges and evolving regulatory requirements.

Common Mistakes

Critical errors in design and certification planning.

Technical Considerations

Component selection, mechanical issues, and home healthcare requirements.

Avoiding Roadblocks

Best practices and proactive strategies.

Megalab: Your Comprehensive Testing

One-Stop Testing Solution

Comprehensive testing and certification services for both medical and non-medical devices under one roof

Electrical Safety

Leakage current, dielectric strength, ground continuity, and insulation resistance testing

EMC/Radio

Electromagnetic compatibility testing in state-of-the-art chambers with advanced measurement equipment

Environmental

Temperature, humidity, vibration, shock, and IP rating verification for various usage environments

Packaging

Transport simulation, drop testing, and packaging integrity verification for safe product delivery

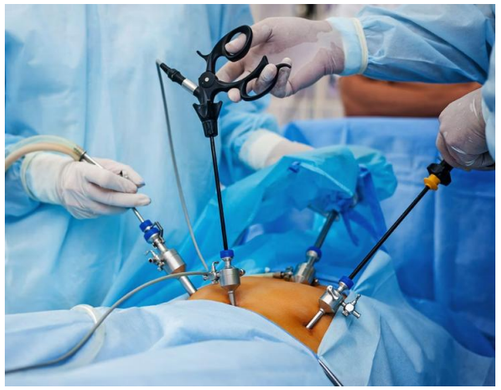
What is MegaStudio?

A Venture Studio that partners with healthcare professionals to transform medical device innovation ideas into commercially viable products.

Our Mission:

Provide the resources, expertise, prototyping & product development infrastructure to guide your ideas from concept to market, maximizing success in complex healthcare environments.

We bridge the gap between clinical expertise and commercial success, providing the technical and regulatory knowledge often missing in medical innovations.



Credit: https://www.apsf.org/article/con-supraglottic-airway-devices-safety-concerns-in-laparoscopic-surgery/

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How We Help

In-house Services:

- Product development planning
- Funding support
- Business planning
- Quality & regulatory strategy
- Testing & execution

Trusted Partner Network:

- Development execution
- Low-volume manufacturing
- Marketing
- Reimbursement analysis
- M&A planning

Photo credit: Congress of Neurosurgeons, 2023

Is Your Idea Feasible?

1

Unmet Clinical Need

Does your idea solve a real clinical challenge that impacts patient care or workflow in your specialty?

2

Practical Innovation

Is your idea based on a feasible, novel solution that can be integrated into existing healthcare systems or practices?

3

Clinical Expertise

Do you have firsthand experience and understanding of the problem your idea addresses, backed by your medical knowledge?

1

Patient or Provider Benefit

Will your solution deliver clear benefits, such as improved patient outcomes, increased efficiency, or cost savings for healthcare providers?

2

Regulatory Alignment

Is your idea feasible from a regulatory standpoint, and do you have a clear understanding of the necessary clinical trials or approvals?

3

Commitment to Development

Are you prepared to invest time and effort into developing and refining your idea, collaborating with experts to bring it to market?

Funding Challenges in Medical Device Development

Capital Access Barriers

- Longer development timelines than software startups
- Higher regulatory hurdles increase investment risk
- Early-stage funding gap for medical technologies
- Investors seeking quicker returns in other sectors

Strategic Funding Approach

- Identify targeted funding resources for medtech
- Leverage non-dilutive grant opportunities
- Partner with strategic industry investors
- Utilize Venture Studio and CAMEDA resources

Medical device development typically requires 3-7 years and $25-75 million from concept to market, making strategic funding planning essential from day one.

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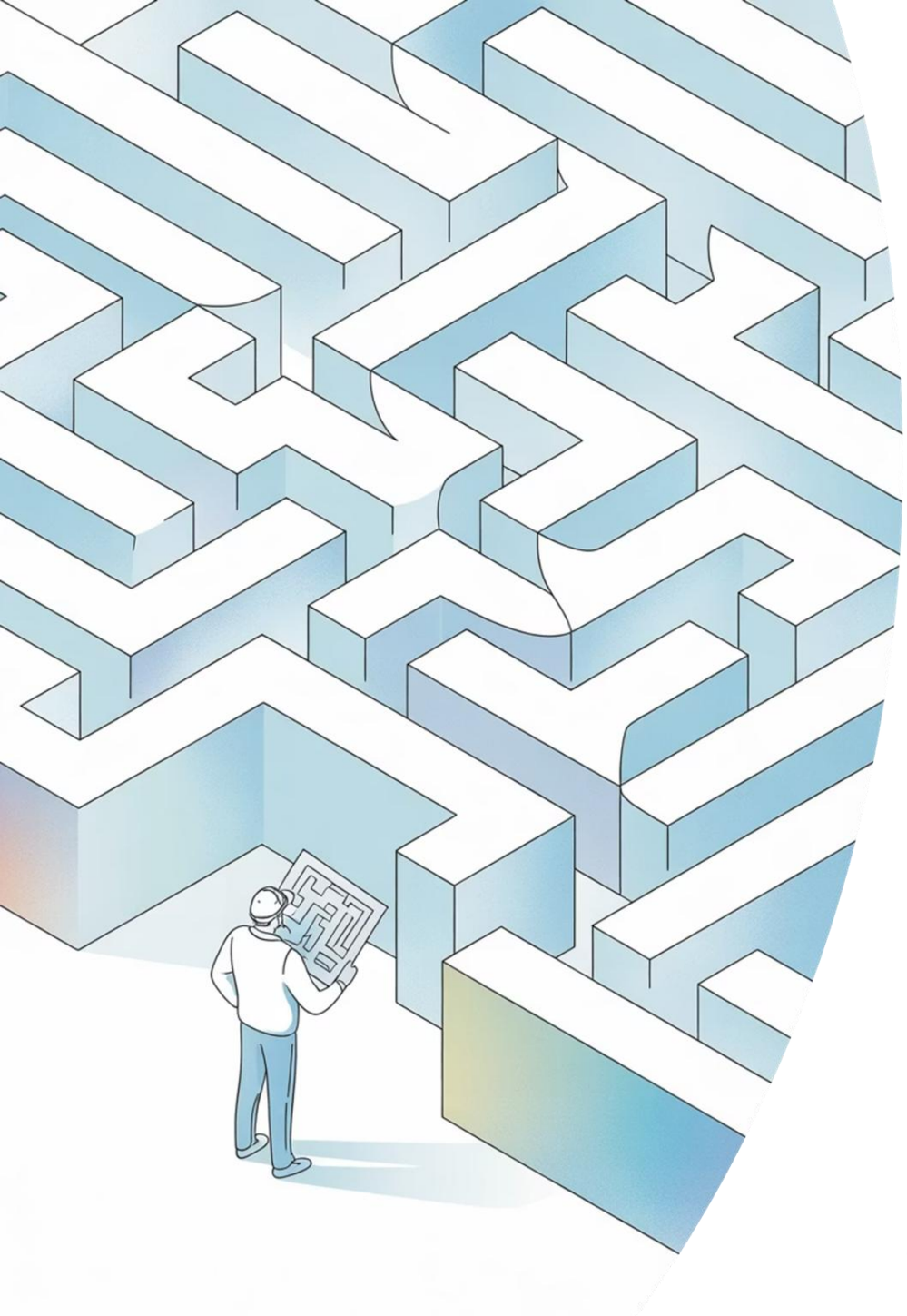
How We Help with Funding

We work with the institutions and groups you are affiliated with to secure grant funding, maximizing your time and effort in the application process.



Navigating the Knowledge Gap

Unknown Unknowns

You don't know what you don't know in the medical device space, creating blind spots in development planning

Complex Ecosystem

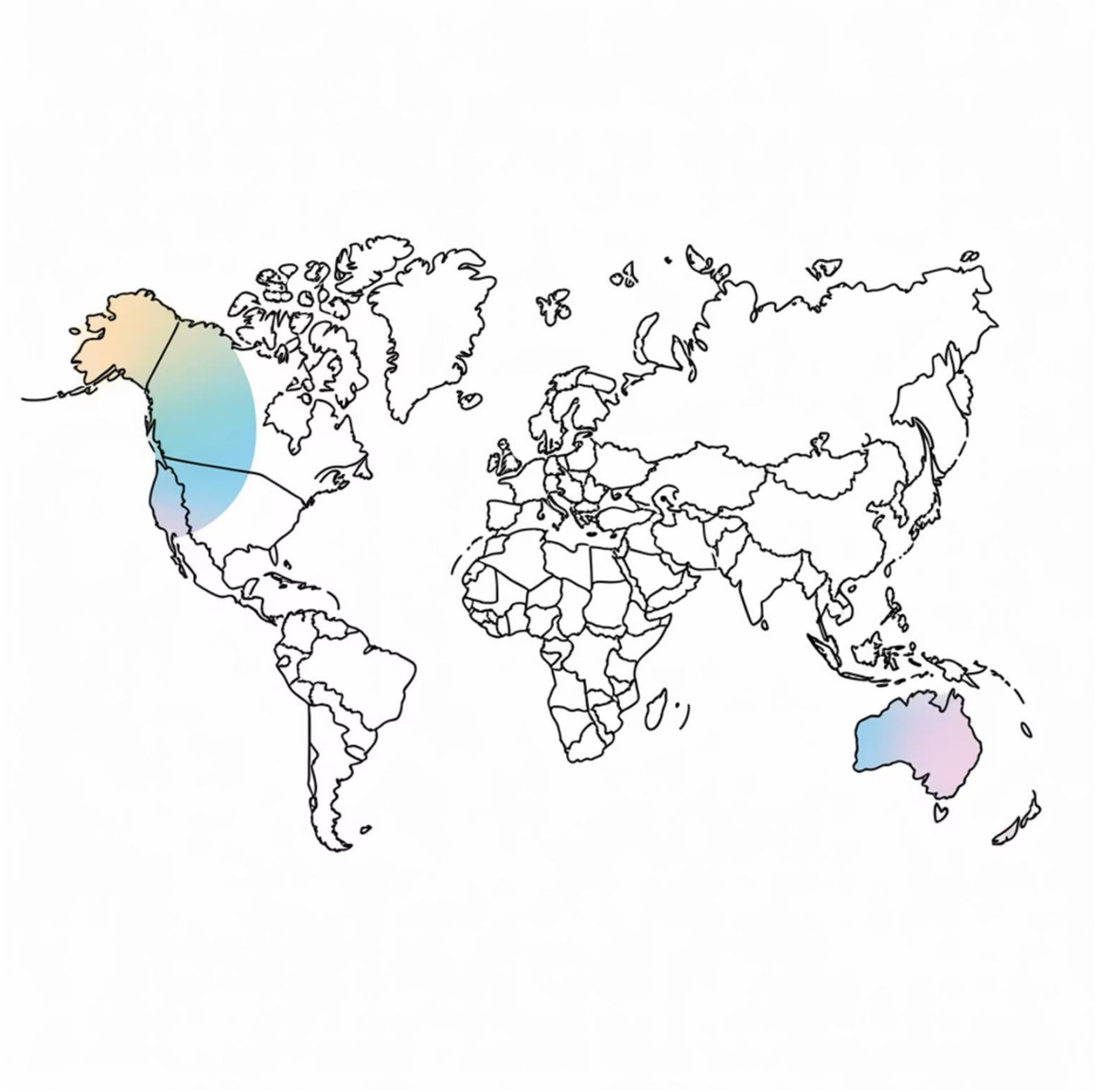
Navigating suppliers, standards, and regulatory bodies requires specialized expertise

Technical Standards

Standards are complicated with specific testing requirements that impact design decisions

> The most expensive mistakes in medical device development stem from regulatory and compliance knowledge gaps that could have been addressed early in the design process.

Global Market Entry Considerations



International Standards

IEC standards are harmonized, but implementation varies significantly by region and country.

EMC Testing Differences

EMC testing requirements differ by market and device classification, necessitating tailored approaches.

In-Country Testing Mandates

Some countries require specific in-country testing with local laboratories for certification.

Unique Registration Processes

Each regulatory body has its own distinct registration processes and

⚠ **Critical planning question:** Which markets will you target first, second, and third? This sequence impacts your testing strategy and budget allocation.

Essential Medical Device Standards

EMC: IEC 60601-1-2 ed 4.1

Electromagnetic Compatibility standard ensuring:

- Device does not interfere with other equipment
- Device is immune to emissions from other equipment
- Performance remains within specifications during electromagnetic disturbances

Safety: IEC 60601-1 ed 3.2

Electrical safety standard addressing:

- Protection against electric shock
- Fire prevention measures
- Mechanical hazards
- Protection against excessive temperatures

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Particular and Collateral Standards

Additional Product-Specific Standards

The "-2" standards address specific requirements for particular device types:

- IEC 60601-2-X series covers specific medical devices
- Examples include standards for infusion pumps, ventilators, surgical equipment
- These standards fall on top of the general standard

Home Use: IEC 60601-1-11

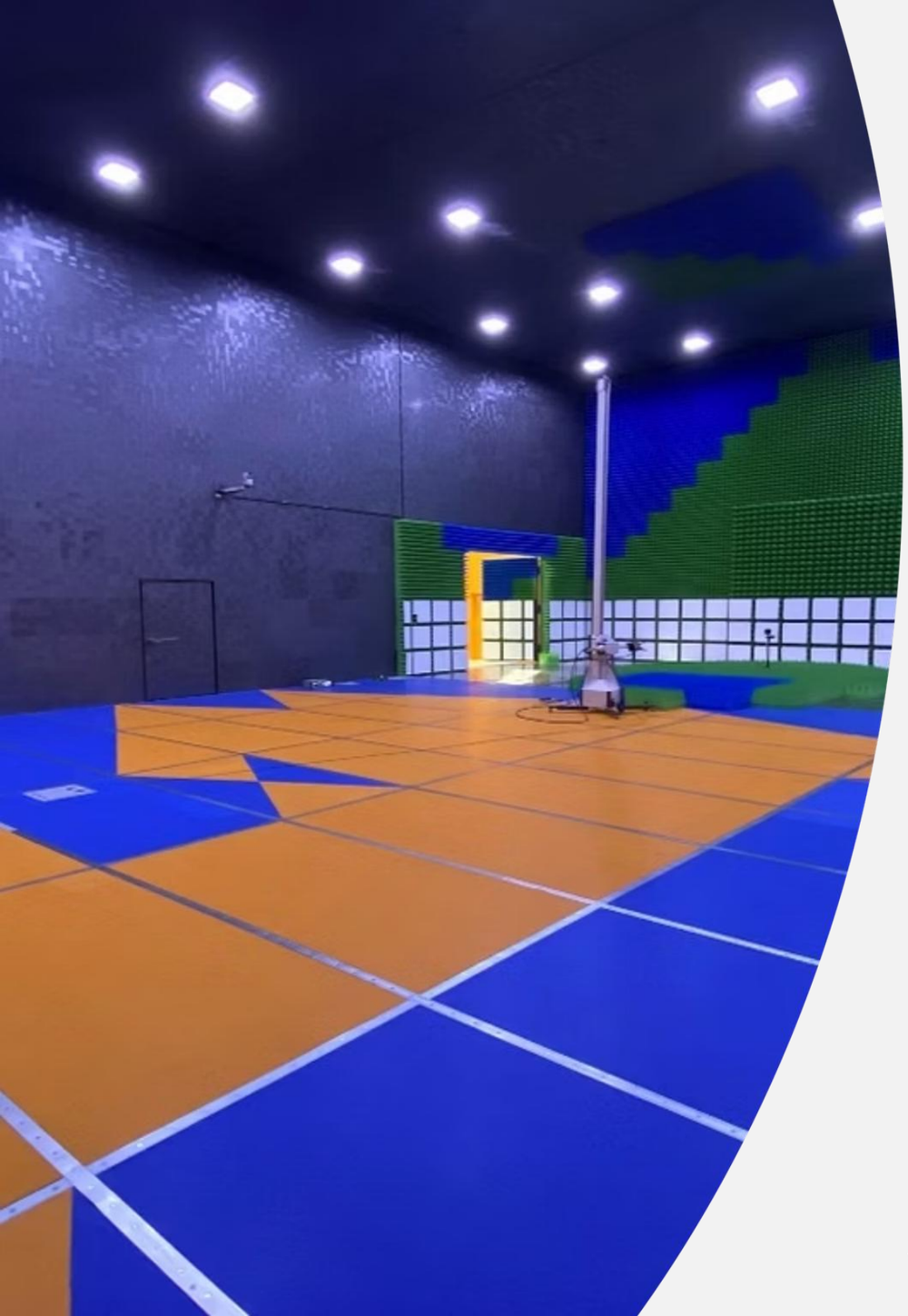
Special considerations for devices used in home environments:

- Heightened safety requirements for lay users
- More robust environmental specifications
- Simpler user interfaces and maintenance

IP Testing

Ingress Protection ratings specify environmental protection:

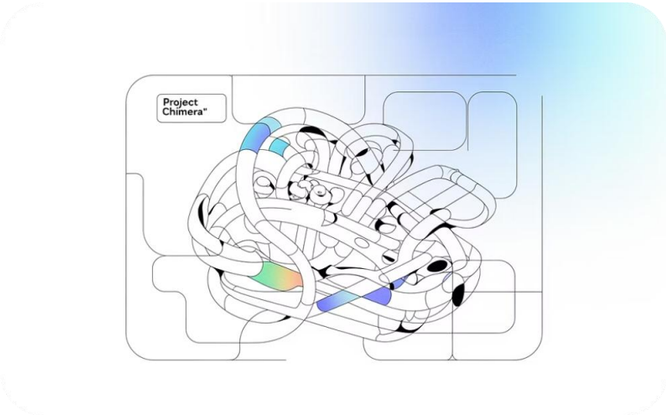
- First digit: Protection against solid objects
- Second digit: Protection against liquids
- Home use devices often require higher IP ratings



Advanced Testing Capabilities: 10-Meter EMC Chamber

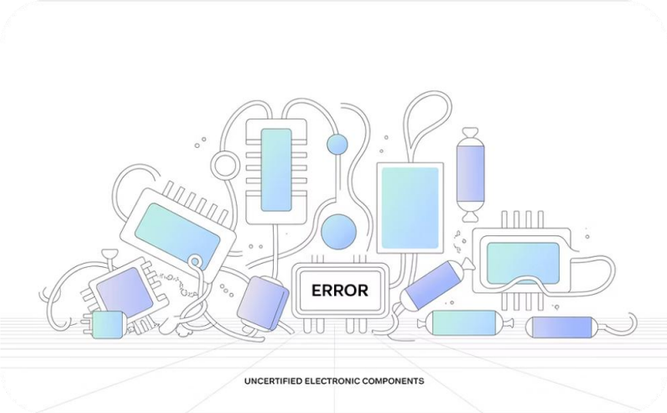
Our state-of-the-art 10-meter EMC chamber provides precise, controlled testing environments for evaluating electromagnetic emissions and immunity. This facility allows us to simulate real-world electromagnetic conditions while eliminating external interference that could compromise test accuracy.

Common Certification Mistakes



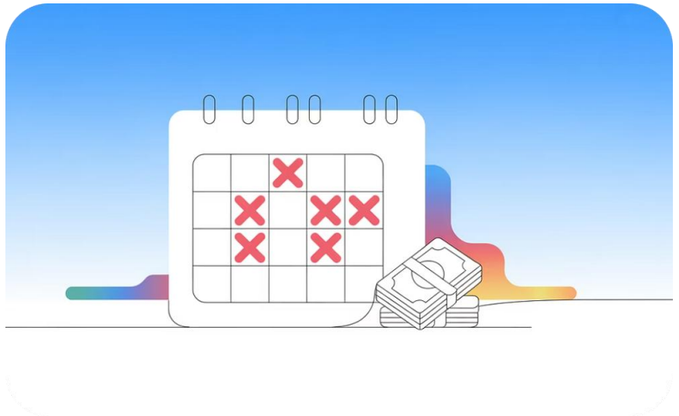
Design Oversight

Not designing the product with certification requirements in mind from the beginning, leading to fundamental issues.



Component Selection

Using uncertified or inappropriate components that do not meet rigorous medical device standards, causing compliance failures.



Costly Consequences

Avoidable failures leading to extensive redesigns, significant market delays, and substantial increases in overall development costs.

> Building certification requirements into your design process from day one can reduce development time by up to 40% and significantly lower overall costs.

Electrical Safety Test

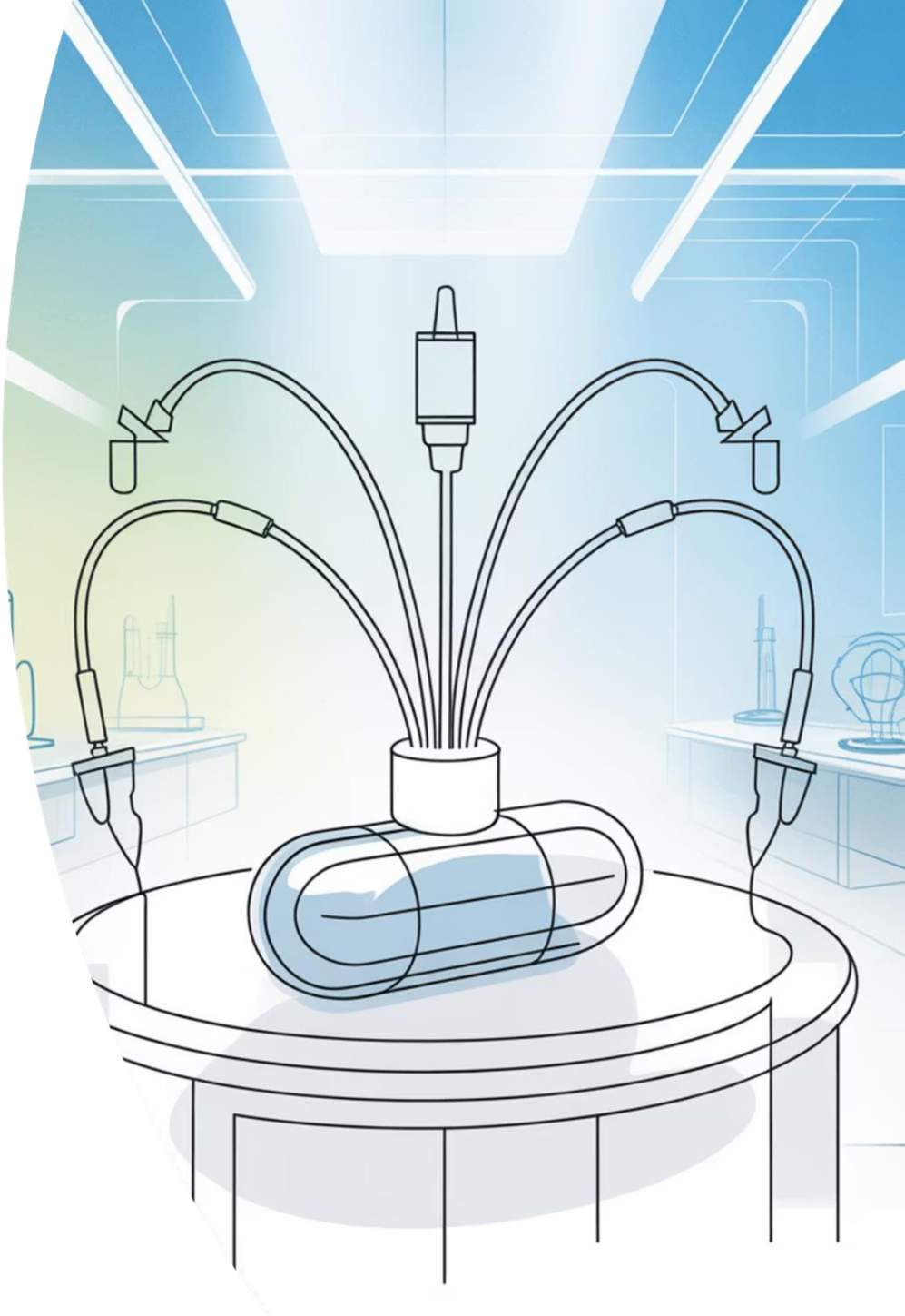
- Improper grounding configurations
- Inadequate insulation between circuits
- Poor PCB layout with insufficient creepage/clearance
- Low-quality components with high leakage characteristics

Types of Leakage Current Measurements:

Earth Leakage: Current flowing through protective earth conductor

Touch Current: Current flowing from device enclosure through a person to ground

Patient Leakage: Current flowing from applied parts through patient to ground



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Mechanical Test Failures

Section 9.1 Compliance Issues

Common failures in conforming to IEC 60601-1 mechanical requirements:

- Medical carts sliding due to improper wheel selection
- Failure to meet stability requirements in transport mode
- Inadequate stability in non-transport mode
- Insufficient tip resistance under load conditions
- Improper mounting systems that create instability
- Failure to withstand push, impact, and drop tests

These issues not only result in certification failures but also create serious safety risks for patients and healthcare providers.

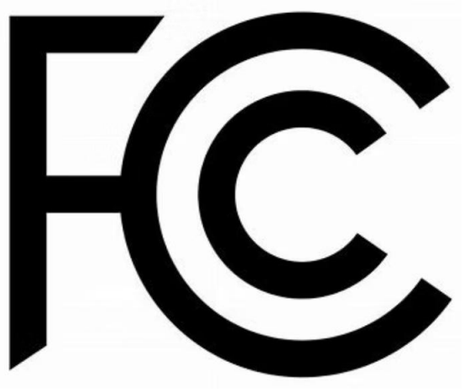
⚠ **Design Tip:** Always use medical-grade wheels with locking mechanisms and ensure your device remains stable during all anticipated use conditions, including maximum load configurations.

EMC Test Planning: A Critical Oversight

Test Plan Requirements for IEC 60601-1-2 ed 4.1

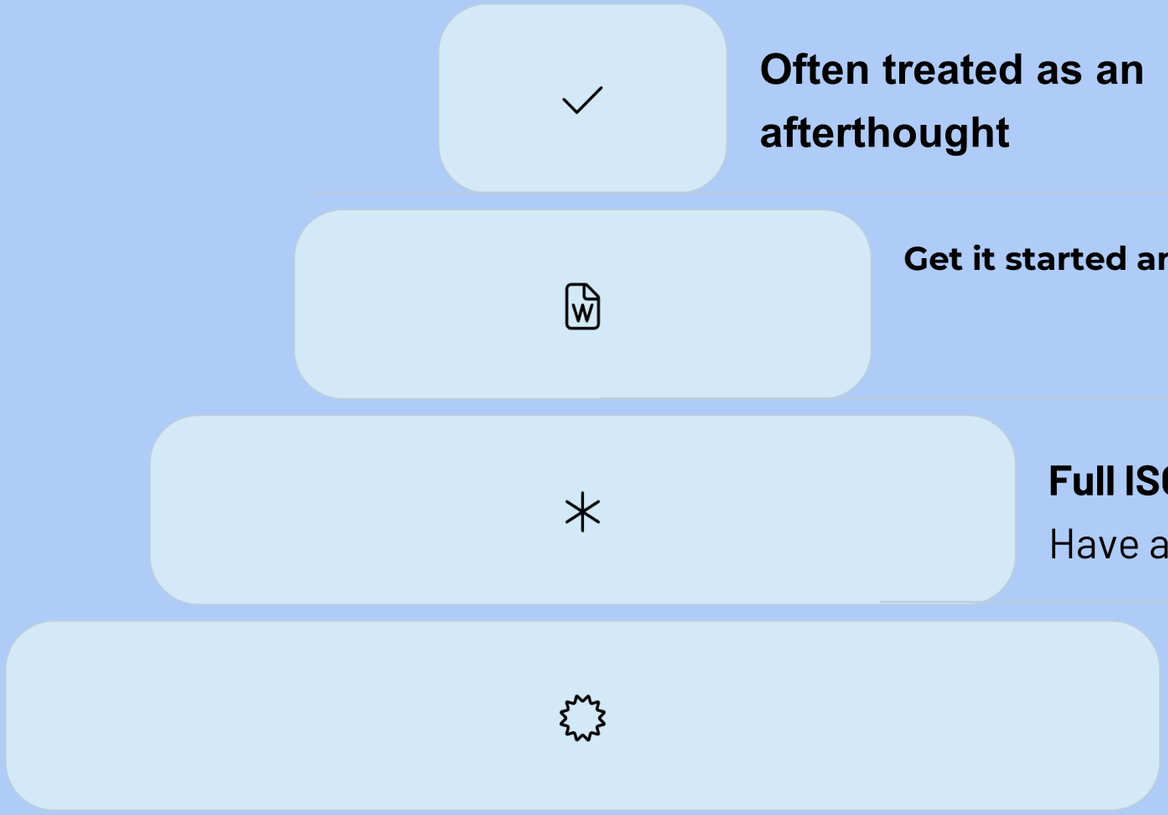
- Comprehensive documentation required before testing
- Must define essential performance characteristics
- Establish specific pass/fail criteria for each test
- Identify risk control measures for EMC hazards
- Document intended electromagnetic environment

> The test plan isn't just paperwork—it's a strategic document that allows you to set reasonable pass/fail criteria based on your device's actual clinical function rather than arbitrary technical standards.



Strategic Advantage: A well-crafted EMC test plan can save significant time and resources by preventing unnecessary redesigns when minor issues arise during testing.

Not Implementing a QMS System



Often treated as an afterthought

Get it started and grow as you scale, Crawl, Walk Run approach.

Full ISO accreditation can be implemented too early or too late.

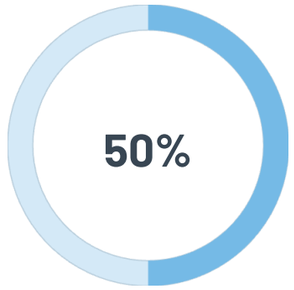
Have a prototype ready

Full ISO Implementation

Complete system implementation before manufacturing scale-up

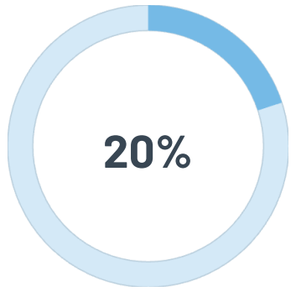
Companies with mature QMS systems typically achieve 3-5x higher valuation multiples during acquisition.

Prevention Strategy: Avoiding Certification Roadblocks



Without Pre-compliance

Certification failure rate



With Pre-compliance

Reduced Failure rate

Key Prevention Strategies:

- Early expert engagement
- Pre-compliance testing
- Safety construction review
- EMC pre-scans
- Early QMS consultation

Early engagement with certification experts can reduce development costs by up to 30% and accelerate time-to-market by

The Value of Early Expert

Feasibility Assessment

Evaluate product viability and identify potential regulatory roadblocks before significant investment

Free Initial Consultation

We don't charge for initial engineering meetings to discuss your device and certification path

Cost Transparency

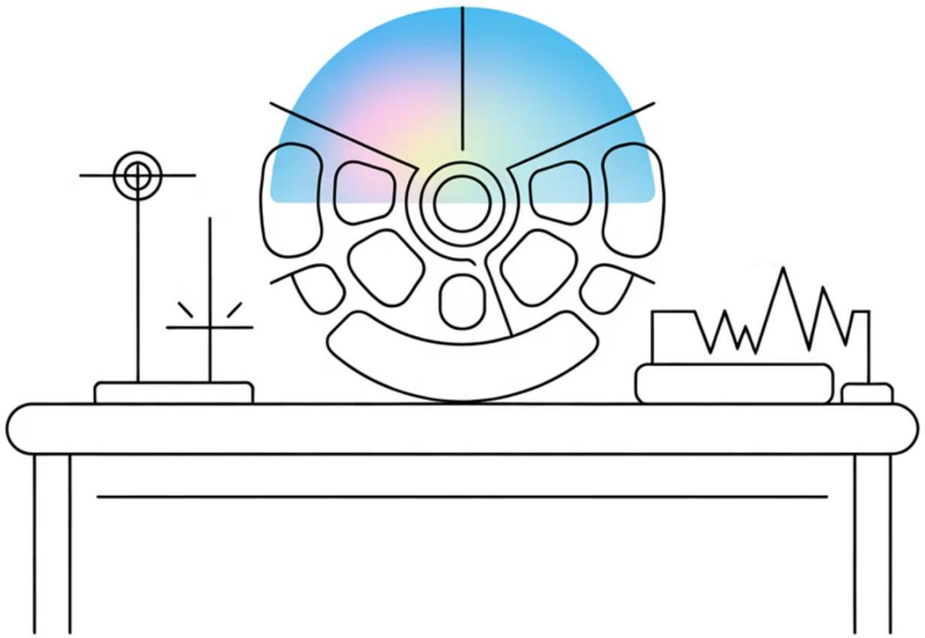
Understand general certification costs upfront for better budget planning

Standards Clarification

Determine applicable standards and testing requirements specific to your device

Early consultation typically saves 3-6 months in development time and 15-25% in overall product development costs.

Pre-compliance Testing Services



EMC Pre-scan Options:

Half-day assessment: Quick identification of major emission issues

Full-day assessment: Comprehensive emissions and limited immunity testing

Safety Construction Review:

- Thorough examination of prototype design
- Identification of potential safety hazards
- Component selection evaluation
- Documentation review

Preliminary Testing:

- Leakage current measurements
- Dielectric strength (hipot) testing
- Basic mechanical evaluation

QMS Consultation Services

Flexible Engagement Models

Our QMS services can be provided on an hourly basis for specific needs or as a comprehensive project-based engagement for full system development.

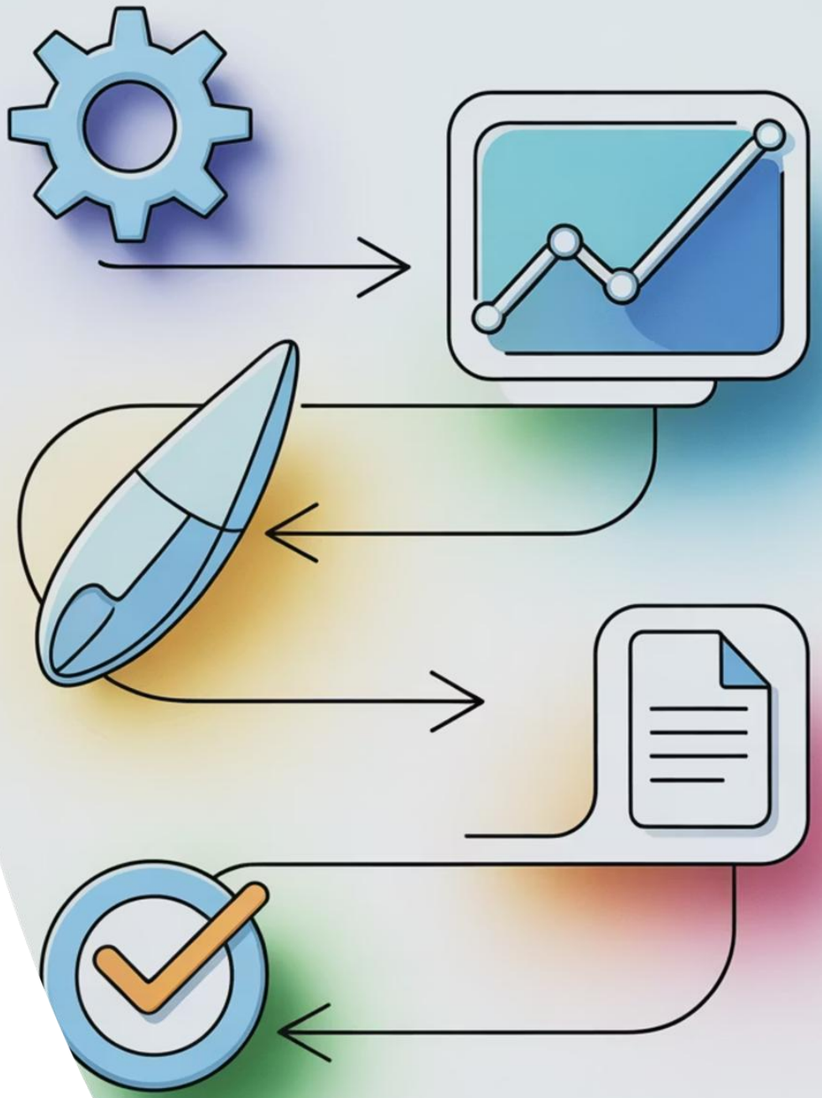
Device Classification

We help determine your device's risk classification in target markets, which directly impacts the regulatory pathway and QMS requirements.

QMS Roadmap

Develop a staged implementation plan aligned with your product development timeline, ensuring regulatory compliance without overwhelming your team.

A properly implemented QMS is not just a regulatory requirement—it's a competitive advantage that improves product quality, reduces defects, and builds customer confidence.



Questions?

Contact Us

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Thank you for your attention. We look forward to helping you navigate the certification process and bring your medical device to market successfully.

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