



**Report: Medical Device Barriers to Entry for Start-Ups,
Entrepreneurs, & Suppliers**

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Table of Contents

Acknowledgments.....	3
Summary.....	3
Barriers for Entrepreneurs & Start-Ups.....	3
Assessing Market Potential.....	4
Determining Intellectual Property Position.....	4
Defining Regulatory Path to Clearance.....	4
Establishing a FDA / ISO Compliant Quality System.....	5
Defining & Addressing Appropriate Business Processes & Infrastructure.....	6
Planning Business & Product Development Efforts.....	7
Understanding the Impact of Industry Standards.....	7
Barriers for Medical Device Suppliers.....	7
Establishing a Quality System to Meet FDA, ISO, & Customer Requirements.....	8
Investing in Technology & Capital Equipment.....	8
Becoming Knowledgeable in Medical Device Supplier Requests.....	8
Conclusion.....	9

Medical Device Barriers to Entry for Start-Ups, Entrepreneurs, & Suppliers

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Summary

The medical device industry presents several barriers to entry that entrepreneurs and start-ups must consider and address. These barriers include:

- Assessing market potential.
- Determining Intellectual property position.
- Defining Regulatory path to clearance.
- Establishing a FDA / ISO compliant Quality System.
- Defining and addressing appropriate business processes and infrastructure.
- Planning Business & Product Development efforts.
- Understanding the impact of industry standards.

This report shall briefly expand on each of these issues that affect medical device entrepreneurs and start-up organizations.

Suppliers to the medical device industry are also faced with barriers and challenges to entry:

- Establishing a quality system to meet FDA, ISO, and customer requirements.
- Investing in technology and capital equipment to meet customer needs.
- Becoming knowledgeable in medical device supplier requests, including:
 - Material and product biocompatibility.
 - Packaging processes.
 - Sterilization requirements and processes.
 - Process controls, including:
 - Process validation.
 - Software validation.

Barriers for Entrepreneurs & Start-Ups

Medical Device Barriers to Entry for Start-Ups, Entrepreneurs, & Suppliers

Assessing Market Potential

First and foremost, the medical device product idea and technology must address a need. Market research and analysis should be thorough and identify end-user needs and define the intended uses for the product. The potential impact the device could have on the end-users and patients should be considered.

A competitive analysis should also be executed to determine other technologies and devices already on the market. This assessment will prove invaluable downstream in the process with regard to regulatory pathway and market release activities, as well as demonstrating competitive landscape for the product. It is important to determine how the product is similar to existing technologies and the differentiating features. This is important for market positioning, end-user acceptance, and addressing intellectual property issues.

Another important aspect of market analysis is determining who will pay for the product and technology. Reimbursement is an important factor and issue for many new technologies. Determine if reimbursement is an option. If not, determine if it is practical to establish reimbursement prior to market release. In some cases, end-users and patients may pay for the product.

Determining Intellectual Property Position

During market assessment, competitive technologies and products should be identified. Determine the existing intellectual property protection for these devices. Evaluate if the proposed product infringes on existing products. Further define how the product is different and whether intellectual property protection is an option. If so, investigate the patent process and consider filing provisional and other patents. At a minimum ensure that disclosures of the product are protected via a non-disclosure agreement.

Often times, start-ups and entrepreneurs have relationships with universities. Determine who owns the technology. In many cases, the universities may have intellectual property rights.

Defining Regulatory Path to Clearance

Understanding the regulatory pathway for a product and technology is critical. In the U.S., medical devices are regulated by FDA. FDA has established regulations that define minimum requirements for a product. The regulations are defined by device use and function. Start-ups should become familiar with the applicable regulations to the product.

Medical Device Barriers to Entry for Start-Ups, Entrepreneurs, & Suppliers

In order to obtain market clearance in the U.S., the product must receive market clearance from FDA. Medical devices fall into one of three classes—I, II, or III. As a general rule, the regulatory process and due diligence to demonstrate product safety and efficacy is directly proportional to device classification.

As a general rule, Class I devices represent the lowest risk and are the least regulated.

Class II devices generally require a submission, known as a 510(k), to FDA. The purpose of a 510(k) is to demonstrate that the product is substantially equivalent to a product already cleared by the FDA 510(k) process. The substantially equivalent product must have an identical intended use. It is also necessary to demonstrate the device is safe; this evidence is included as part of the 510(k) submission.

Class III products generally represent the highest risk devices. The path to regulatory clearance usually requires a clinical trial, followed by submission to FDA for market approval. The clinical trial must also be submitted to FDA as an Investigational Device Exemption (IDE) and must be approved prior to initiating the trial. After successful completion of the IDE clinical trial, a Pre-Market Approval (PMA) is compiled and submitted to FDA for approval.

The details described above represent classifications and a high-level overview of regulatory processes for the U.S. Other parts of the world have similar, yet slightly different device classifications and regulatory processes. If start-ups pursue regulatory clearance in Europe, Canada, and other parts of the world, compliance to ISO 13485:2003 should be considered.

Establishing a FDA / ISO Compliant Quality System

As mentioned above under regulatory pathway, regulations are a critical issue that medical device company must address. FDA defines quality system regulations in the code of federal regulations (CFR) part 820. ISO 9001 and ISO 13485 also define requirements for quality systems. FDA and ISO are very similar in their expectations.

Developing a complete quality system is time consuming and requires dedicated resources. Balancing quality system development with product development activities is important. For example, having a thorough a complete quality system without a product through development may not make sense.

Companies should carefully evaluate and determine where the product is in its lifecycle and build a quality system accordingly. Quality systems can be built piecemeal and should focus on pertinent quality activities and regulations commensurate with the

Medical Device Barriers to Entry for Start-Ups, Entrepreneurs, & Suppliers

product lifecycle stage. Companies with early stage development products should establish and define procedures and processes for the following:

- Management Review.
- Design Controls (and its subparts).
- Risk Management.
- Document Control & Record Keeping.
- Supplier Selection (may have more importance for virtual companies).

FDA and ISO have established guidelines for developing quality systems. Start-ups should be familiar with these guidelines and regulations and develop a company quality plan to ensure procedures and processes are defined appropriately.

As the product progresses through its lifecycle, so too should the companies quality system. As a device approaches actual end use through a clinical trial and/or market release, a complete, thorough, and compliant quality system must be in place.

Defining & Addressing Appropriate Business Processes & Infrastructure

As with quality systems, start-ups should define business procedures, processes, and infrastructure commensurate with the lifecycle stage of the product. Early stage development companies should define and implement the following key business processes:

- Product Development Phases, Deliverables, & Milestones.
- Accounting systems, including purchasing.
- Confidentiality and non-disclosures.
- Organizational charts defining roles and responsibilities.

A common theme in FDA and ISO requirements is that management shall be engaged and responsible for product lifecycle activities.

Companies should also investigate and acquire business insurance. It is important to determine the cost of device failures and understand coverage options and limitations.

Business processes typically are not defined and regulated by FDA and ISO. Business processes and quality system procedures should compliment one another.

Medical Device Barriers to Entry for Start-Ups, Entrepreneurs, & Suppliers

Planning Business & Product Development Efforts

Planning must be addressed through all activities and stages of a business and product lifecycle. Planning should be a dynamic process and revised and updated. Design control regulations specify the requirements for design and development planning. Regulations and standards also define expectations for quality planning, regulatory planning, and risk management planning.

From a business perspective, companies should also engage in business strategy and planning activities.

Understanding the Impact of Industry Standards

There are a host of other issues medical device entrepreneurs and start-ups should consider. For many medical devices, industry standards have been developed that define expectations and requirements for a product. Regulatory agencies often recognize industry standards and expect companies to comply. Industry standards exist for quality systems, risk management, specific devices, biocompatibility, electrical safety, packaging, sterilization, and in many other areas. Common standards organizations include:

- ISO
- ASTM
- IEC
- BSI
- ANSI
- AAMI

Standards define accepted methods and should be complied with whenever possible. FDA and other regulatory bodies publish lists of accepted standards. Companies should thoroughly investigate the existence of applicable standards and utilize during the design and development efforts.

Barriers for Medical Device Suppliers

Suppliers to the medical device industry should consider many similar issues described above for start-ups and entrepreneurs.

Medical Device Barriers to Entry for Start-Ups, Entrepreneurs, & Suppliers

Establishing a Quality System to Meet FDA, ISO, & Customer Requirements

Medical device suppliers are also subject to meeting parts of FDA regulations and ISO requirements. One critical area to address is establishing a quality system. ISO has two possible choices of quality system standards that suppliers should consider: ISO 9001:2000 and ISO 13485:2003. From a supplier's perspective, both are very similar; ISO 13485 is specific to medical devices and more applicable to device manufacturers. Some customers, however, are insistent that suppliers are ISO 13485 certified. Regardless, medical device suppliers are recommended to pursue either ISO 9001 or ISO 13485 certification.

Some suppliers have an existing customer base and would like to include medical device clients. Many of these other industries (e.g. aerospace, defense, and automotive) are also regulated and require suppliers to become certified to appropriate quality system standards. The quality system standards applicable to non-medical industries are often very similar to FDA regulations and ISO 9001 and ISO 13485. In these cases, suppliers that desire entry into the medical device entry should not have too many issues regarding quality systems.

Investing in Technology & Capital Equipment

Medical device clients may require that supplier equipment is dedicated to medical device applications or that clean rooms are used or other special needs. These special requests are pertinent to ensuring the finished medical device is as safe as possible. Suppliers to the medical device industry need to be prepared for these situations.

Becoming Knowledgeable in Medical Device Supplier Requests

The medical device industry looks to suppliers for so many different parts and services. It is difficult to identify all issues for all types of suppliers. However, areas of concern for many medical device suppliers include biocompatibility, packaging, sterilization, and process control.

Suppliers of raw materials, components, and sub-assemblies need to be prepared regarding biocompatibility. Biocompatibility standards exist and define the types of testing and requirements based on end use body contact and duration. Suppliers should be educated and ready to assist medical device clients—especially start-ups and entrepreneurs regarding biocompatibility.

Medical Device Barriers to Entry for Start-Ups, Entrepreneurs, & Suppliers

Suppliers of packaging materials and services need to be prepared to address and assist clients with packaging design and validation. Packaging processes and equipment need to be properly qualified and validated, especially when packaging provides a sterile barrier for a medical device.

Suppliers of sterilization services need to be prepared to ensure sterilization processes adequately ensure products are sterile and that these processes are validated for the device in question.

All medical device suppliers should ensure proper process controls are in place. Processes that cannot be verified require validation. Many equipment includes some form of software. Suppliers also need to ensure that software is properly validated.

Conclusion

Companies pursuing entry to the medical device industry should go through proper planning and due diligence before doing so. It is easier to identify areas of improvement and concern prior to going too far down a path. Companies need to ensure the market need exists, regulations are being met, quality systems are in place, and that business infrastructure is ready to support the medical device endeavors.