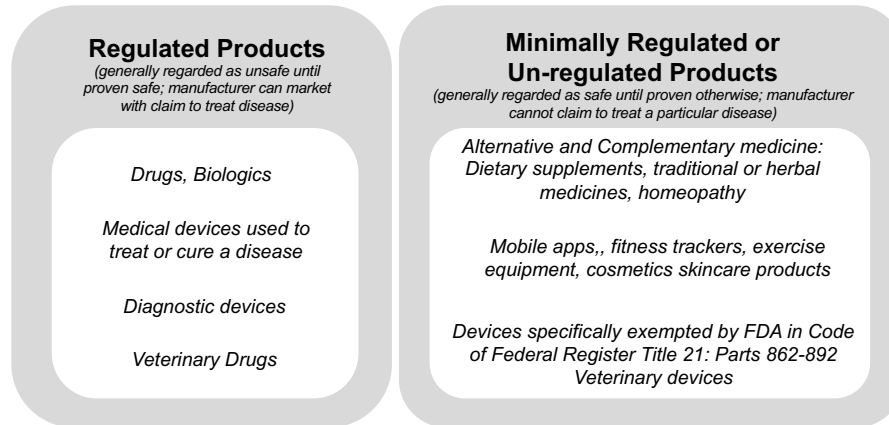


CHAPTER 1. BIOMEDICAL DRUG AND DEVICE INDUSTRY AND MARKETS

Q: What products are regulated and need approval or clearance by government agencies?



Q: What is included in regulated medical devices and drugs ?

- Regulated medical devices are classified as an instrument, apparatus, implement, machine, contrivance, implant, in vitro reagent, ... which does not achieve any of its primary intended purposes through chemical action within or on the body of man or other animals and which is not dependent upon being metabolized for the achievement of any of its primary intended purpose.
- Medical devices can be stand-alone software programs (SaMD – software as medical device) as a component of an apparatus or a standalone product that processes data and gives results.
- In vitro diagnostic tests and in vivo diagnostic imaging equipment products are also classified as medical devices
- Drugs are defined as a substance recognized by an official pharmacopoeia or formulary, intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease, and is a substance (other than food) intended to affect the structure or any function of the body. Drugs include biological or biotech drugs.
- Cell and tissue engineering products are usually regulated as drugs

Q. What are some overall trends in the industry that I can use to enhance my product idea?

- Mobile computing = handheld mobile devices always connected to the internet with significant handheld computing power are increasingly common around the developing

world so any software mobile app or smart device related app is instantly available globally once launched

- Ubiquitous sensors = phones and watches now have sensors with biometric measures for identifying individuals and tracking health patterns with secure storage and transmission of health data; continuous monitoring can yield very early diagnosis and enable preventive diagnostics
- Artificial intelligence/machine learning software is now accepted by US FDA and other regulatory bodies. This opens up large opportunities for smart devices and diagnostic stand-alone software. AI also plays a major role in drug discovery and new product development.
- Processing of audio and other sensory information to derive insights into health status on a real-time basis using local mobile sensors and computing devices

Industrialized life sciences – eg. next generation sequencing, mass production of proteins, automated LC/Mass spec and high throughput crystallography, etc. as new tools get developed for standardizing processes, invention and discovery get accelerated.

Q. How do I understand strategic positioning within an industry sector?

- Using Michael Porter's five forces analysis to understand competitiveness:
An industry sector can be understood in terms of competitiveness and power among entrants and stakeholders. Decision-making on approaching a specific market or changing strategy for a product or service can be chosen as an outcome of the analysis.
- Using industrial value chain analysis for more efficient differentiation or cost reduction:
Value chain analysis (also created by Michael Porter) is commonly used by business owners to review and break down each business process used by the company and identify strategic areas of strength and weakness. Note – supply chain analysis is about logistics to get raw materials into the factory and finished product delivered to the customers. Value chain analysis takes into consideration all company activities such as product design, research and development, advertising, and other marketing steps, divided into primary and secondary activities as shown in the figure below. Either product differentiation or cost reduction is chosen as the primary lens for the analysis.

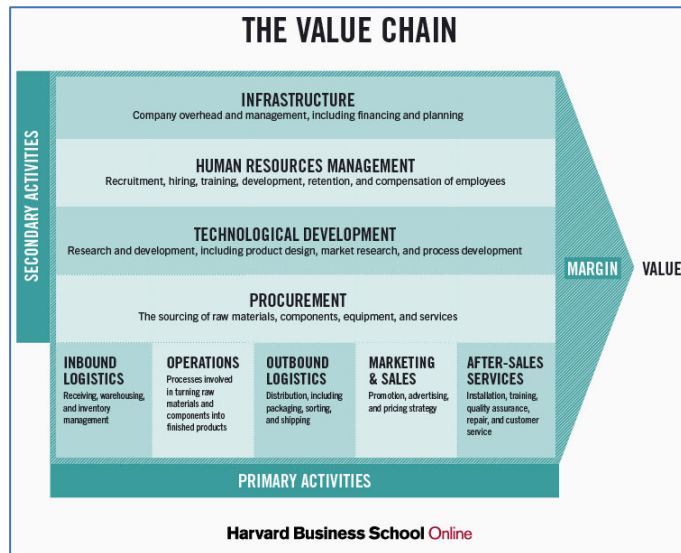


Figure from <https://online.hbs.edu/blog/post/what-is-value-chain-analysis>

Step 1: identify all the primary and secondary activities carried out by the company

Step 2: Determine cost and value of the activities

Step 3: Identify opportunities for competitive advantage by analysis through one of the lens above. I.e. either identify a low-cost provider for those activities that add less value, or focus on activities that create unique differentiation of product or service.