

Commercialization Strategy for Innovative Products: The Importance of Considering Regulatory Implications

By Donna Mitchell-Magaldi, M.S.

After designing an innovative product and gaining a granted patent, it is time to assess market and commercialization feasibility. The following are common questions that arise at this point in the process: What is the market size? Who is the competition and what competitive products do they sell? What is their current market share? What distributors will I use and how do we effectively market this great new product? All of these questions are important and will help gain an understanding of the market landscape.

However, there are even more pressing concerns at stake: What are the possible regulatory pathways you will need to navigate in order to get your innovative product approved and on the market, and what are the potential financial burdens associated with compliance?

Regulatory authorities such as the U.S. FDA, Chinese FDA, and European Union have different definitions for medical devices, drugs, combination devices, cosmetics, etc. Deciding which definition applies to the product at hand will help determine the regulatory pathway needed to gain product approval for the appropriate market. This is an important consideration (in addition to market size, competitive landscape, etc.) because it could identify other significant challenges in commercializing your innovation.

For example, consider that the aforementioned innovative product is to be used for a medical application. The regulatory pathway will be determined according to the product definition and its uses, indications, and instructions. . Is it a medical device, a drug, a cosmetic, or a natural product? What is its intended use? For example, if the innovative product meets the definition of a medical device (below), the appropriate regulatory pathway would need to be adhered to (often requiring a 510(k) or PMA) for approval in the U.S. as a medical device.

FDA definition of a medical device:

A medical device is "an instrument, apparatus, implement, machine, contrivance, implant, in vitro reagent, or other similar or related article, including a component part, or accessory which is:

- *recognized in the official National Formulary, or the United States Pharmacopoeia, or any supplement to them,*
- *intended for use in the diagnosis of disease or other conditions, or in the cure, mitigation, treatment, or prevention of disease, in man or other animals, or*
- *intended to affect the structure or any function of the body of man or other animals, and 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 purposes."*

Depending on the risk associated with the device, the FDA may also require clinical data from clinical trials, which can be very expensive.

If the product meets the definition of a drug, it will require extensive clinical trials and be very expensive to proceed through the regulatory pathway, which involves an IND (investigational new drug) application and NDA (new drug application) for market approval in the U.S.

FDA definition of a drug:

A drug is defined as:

- *A substance recognized by an official pharmacopoeia or formulary.*
- *A substance intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease.*
- *A substance (other than food) intended to affect the structure or any function of the body.*
- *A substance intended for use as a component of a medicine but not a device or a component, part or accessory of a device.*

If however, the product is intended to be rubbed, poured, sprinkled, or sprayed on, introduced into, or otherwise applied to the human body, for cleansing, beautifying, promoting attractiveness, or altering the appearance, it will be considered a cosmetic and will not need FDA regulatory approval. If the product is considered a natural product (i.e., dietary supplement) it also will not require FDA approval to gain market entrance. However, both cosmetics and dietary supplements are nevertheless regulated by FDA. These items have extensive regulations related to content, labeling, and good manufacturing practices, which must be considered and followed for successful market entry.

Anticipating the likely regulatory pathway the innovative product must follow for market entry will allow make it easier to move forward with overall commercialization strategy assessment. For example, a small start-up or technology transfer office may have determined their regulatory pathway to be very expensive, forcing them to consider waiting for additional funding prior to commercialization, or looking for partnership or licensing opportunities with larger companies prior to commercializing their product.

Larger companies have the luxury of greater financial resources, but usually have many projects in the pipeline. Being able to demonstrate an understanding of the regulatory pathway for new products may help these corporations to prioritize more innovative products within their product pipeline, in order to concentrate on commercializing projects/products with larger potential revenues and minimal financial risks.

When evaluating and creating a viable commercialization strategy for innovative products, it is vital to evaluate the possible regulatory pathways in addition to the competitive and marketing landscape. This process will provide the necessary information to more fully evaluate the commercialization feasibility and anticipate the possible financial burden associated with meeting regulatory compliance. The ability to anticipate possible regulatory challenges allows more time to develop viable solutions to enable patent holders to move forward with commercializing their innovative product.

How can Nerac help?

Nerac's medical device team helps business development teams identify unmet medical needs, new market opportunities and challenges, and clinically effective therapeutic approaches during early stage vetting. We provide the vital support needed to make informed Go/No-Go decisions.

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providing an attractive choice for clients seeking rapid response research and advisory services for smaller, mission-critical engagements that require highly experienced expert advisors

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About the Analyst

Donna Mitchell-Magaldi, MSRA, Project Manager/Analyst

Donna Mitchell-Magaldi has over 16 years experience working with medical device companies. As an Analyst at Nerac, Donna has experience working with various medical device industries such as cardiovascular, dentistry, wound care, medical imaging, endodontics, biomonitoring and medical sensors, orthopedics, gastrointestinal and more. Over the last several years, Donna has been assisting medical device clients with meeting the MEDDEV 2.7.1 Rev. 3 "Guideline on Medical Devices Clinical Evaluation: A Guide for Manufacturers and Notified Bodies" and other regulatory issues, market analysis, prior art research, research to support R&D initiatives, patent landscape, FDA clinical literature support, CFDA clinical evaluations to support medical device regulatory submissions and much more. Ms. Mitchell-Magaldi has wide-ranging expertise, encompassing medical device regulatory; dentistry (devices, equipment, procedures, dentifrices, hygiene, impressions, prosthetics, implants, orthodontics, periodontal); medical devices (including imaging diagnostics, catheters, shunts, and syringes); radiography; environmental topics (the effects on wildlife and habitation, strategies to protect endangered ecosystems, species, and food-chain effects); ecology (population dynamics, animal behavior and organism biology); and laboratory analysis (trace metal analysis, IACUC, lab safety, inductive couple plasma and atomic absorption).

Academic Credentials

M.S. Regulatory Affairs, Northeastern University
B.S. Biology, Eastern Connecticut State University

Professional Memberships:

Regulatory Affairs Professional Society (RAPS)
American Medical Writers Association (AMWA)
MedTech
BioScience Network of Connecticut- CURE

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