



**MaRS** | ENTREPRENEUR  
WORKBOOKS

**Emerging Life Sciences Series**

# Defining Your Target Product Profile: Medical Device Products

MaRS Discovery District, ©March 2011

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## Introduction

### What is a target product profile?

A target product profile (TPP) is a key strategic document that provides a summary of the following:

- the product under development
- the product's desired characteristics and features
- the studies and activities that must be completed to demonstrate the product's performance, efficacy and safety
- the features of the product that provide a competitive advantage

A well-designed TPP provides a structure to ensure that the company embarks on a product development program that is efficient and yet defines a listing of all relevant medical, technical and scientific information required to reach the desired commercial outcome. Historically, the US Food and Drug Administration (FDA) developed the concept of TPP to facilitate a communication strategy regarding a particular drug development program. However, many of the objectives provide sound guiding principles for the development of diagnostic products and medical devices.

### Benefits of a TPP

If used properly, a TPP can help address issues early in the product development process and prevent late-stage development failures. A TPP also provides various parties and stakeholders (e.g., management, board members, employees, advisors, investors, regulatory authorities, strategic partners) with a clear statement of the desired outcome of the product development program. This can be used later to help assess elements of the process and track progress. The TPP is a dynamic strategic document that should be revisited during the course of development. Much of the information discussed in the TPP should be incorporated into your [business plan](#).

A TPP serves as a:

- strategic planning tool
- communication tool for discussions with regulatory authorities
- communication tool for discussions with investors, partners, employees and other stakeholders
- tool for communicating, supporting and tracking changes during the lifecycle of the development program

The FDA TPP document was specifically developed for therapeutic products to provide a format for discussions between a sponsor and the FDA. Based on this framework, this workbook has been developed and customized to assist companies embarking on the development of new medical device products.



Medical devices include instruments, apparatus or implants intended for use in the cure, mitigation, diagnosis, treatment or prevention of disease. For medical devices related to *in vitro* diagnostic (IVD) products, see the [TPP workbook and template specifically designed for IVDs](#).

Health Canada and European regulatory authorities recognize four classes of medical devices based on the level of control necessary to assure the safety and effectiveness of the device. The US FDA recognizes three classes of devices. In general, Class I includes low-risk devices such as bandages, while Class III or IV devices (such as implantable pacemakers) present the highest risk and are subject to the highest level of regulatory scrutiny. The MaRS [Entrepreneur's Toolkit](#) offers documents about the medical device application processes in Canada, the US and Europe. These documents provide further detail on the requirements for assessing the safety, efficacy and quality of a device.



Read more about how medical devices are approved [in Canada, the US and Europe](#).

On February 8, 2011, the US FDA launched a new *Medical Device Innovation Initiative*, including [Innovation Pathway](#), a priority review program for new, breakthrough medical devices.

This workbook will help you put together a TPP for your medical device. Completing the TPP for your medical device will assist in the development of a regulatory strategy for the product. For devices that fall under the US FDA Class II guidelines for a 510(k) application, the TPP should be viewed as the first step in justifying the selection of the predicate device(s). For breakthrough medical devices that may qualify for programs such as the FDA's new *Innovation Pathway* pilot program, the TPP can serve as an outline for discussion with the FDA.

Five key features of a medical device have been selected for developing the TPP:

1. Intended use
2. Device description
3. Contraindications
4. Non-clinical testing
5. Clinical studies

These five sections were selected based on their importance when developing a [business plan](#). All sections provide an opportunity (see the accompanying workbook template) to describe the key [differentiating features](#) and competitive [positioning](#) of your product. The focus on competitive positioning will assist your company in communicating the value proposition as you embark on [raising capital](#) and preparing for strategic discussions with [partners](#).



## How to use these workbooks

### 1. Make it a team exercise—but make it quick!

We believe that much of the information you need is already known to your management team and advisors, so we recommend that you make the creation of your TPP a team effort. Remember, time is of the essence for high-tech start-ups and we encourage you to complete the workbook template thoroughly, but as efficiently as possible. The first version of your TPP should be no longer than eight to 12 pages. Use bullets and lists to accelerate the drafting of the first version.

### 2. Record and test your assumptions

As you go through the exercises, record and highlight key assumptions. Identify assumptions that will be tested (and validated or invalidated) through further market research, as well as assumptions that will be tested through laboratory or clinical studies.

### 3. Use the icons for help

The MaRS workbooks are structured under the assumption that this is the first time you, the reader, have undertaken an exercise in of this nature. To help provide context for some of the ideas in these workbooks, we have clarified the ideas by defining key terms and offering real-world examples. In addition, we have provided links to articles provided by MaRS through the [Entrepreneur's Toolkit](#). For this reason, you may find it easiest to use these workbooks on a computer with an Internet connection.

Look for these icons:



denotes a key industry term that will recur in these workbooks



indicates an example drawn from a real-world business in order to illustrate an important idea



denotes a link to a more in-depth online article



appears wherever you are asked to record something while completing the exercises



## Before you start

The following six steps will help you gather the data needed in order to commence these workbook exercises.

Note that the following approach was specifically developed for new medical devices where competitor products exist. Creating a TPP for an innovative and potentially disruptive new class of medical device will help you organize your thoughts, outline the studies you will have to undertake and define milestones related to fundraising.

1. Broadly list all the potential usages of your proposed medical device. Rank the potential usages and select an initial intended use. The selection of the initial intended use is one of the most critical strategic decisions for an early-stage life-sciences company. Criteria to consider for selection of the initial intended use include:
  - a. Will the intended use validate the product's clinical benefit(s)?
  - b. Will the intended use clearly demonstrate a competitive advantage?
  - c. Does the intended use provide an efficient path to regulatory approval?
  - d. Does it lay the foundation for leveraging expanded usages of the medical device in the future?
  - e. Does the intended use target a real market opportunity with revenues that will support the company's future growth?

While you may not be able to answer all of these questions initially, the exercise of defining a TPP provides a structured platform to test the initial intended use against key metrics.

2. Once you have selected an initial intended use, identify the competitive products or treatment options that target the same market application. Contact your MaRS advisor for assistance with market intelligence.
3. Research competitive medical device products based on intended use, technology, contraindications, non-clinical testing and clinical studies. Detailed information on competitive medical devices can be found in a variety of documents including the "technical" or "product" manuals for the device. Product manuals, both for patient and physician use, can be found through product websites or by accessing the approval and 510(k) clearance summaries posted on the FDA website at <http://www.fda.gov/MedicalDevices/ProductsandMedicalProcedures/DeviceApprovalsandClearances/default.htm>.
4. Review and familiarize yourself with the competition. Highlight the areas where competitive products have limitations and your product will offer improved benefits.



5. Determine the non-clinical and clinical studies needed to demonstrate the safety and efficacy of your medical device and your [competitive differentiation](#). Even if you do not yet have a complete non-clinical and clinical testing plan, we recommend you outline the studies you plan to undertake, the anticipated outcome from those studies and a prospective development timeline.

## WORKBOOK:

# Defining Your Target Product Profile: Medical Device Products

## 1. Intended use statement

In completing this section of the TPP, you will create a concise summary of the medical device under development. Note that this section is not about technology platforms. Ultimately, the intended use statement should be consistent with your labelling, advertising and instructions for use.

In response to the following questions, provide a brief, focused description of your proposed medical device.

- What are the specific indications for the device?
- Who are the target patients?
- What anatomical sites does the device target?
- Where (e.g., home, clinic, hospital) will the device be used?



*In the corresponding section of the workbook template, write one or two brief sentences in response to the questions above.*

The following is an example of an intended use statement from the 510(k) summary of a product recently cleared by the FDA, the Masimo Disposable Ear Oximetry Sensors.



### **Example: Intended use statement—Masimo Disposable Ear Oximetry Sensors**

In November 2010, Masimo Corp. received 510(k) clearance for a disposable oximetry sensor. The intended use statement<sup>1</sup> is:

*"The Masimo Disposable Ear Sensors are indicated for single patient use for continuous non-invasive monitoring of functional oxygen saturation of arterial hemoglobin (SpO<sub>2</sub>) and pulse rate (measured by an SpO<sub>2</sub> sensor) for use in adult and pediatric patients, (weighing >30 kg), who are well or poorly perfused, in hospitals, hospital-type facilities, mobile, and home environments."*

Compare the above with the intended use statements for the two predicate devices. For the first predicate device, the Masimo Resuable Ear Sensor, the intended use statement<sup>2</sup> reads:

*"The additional Masimo series of sensors are intended for continuous noninvasive monitoring of functional oxygen saturation of arterial hemoglobin (SpO2) and pulse rate (measured by an SpO2 sensor) for adult, pediatric, and neonatal patients in hospitals, hospital-type facilities, mobile and home environments.*

For the second predicate device, the LNCS Oximetry Sensors, the intended use statement<sup>3</sup> reads:

*"The LNCS oximetry sensors are intended for continuous noninvasive monitoring of functional oxygen saturation of arterial hemoglobin (SpO2) and pulse rate (measured by an SpO2 sensor) for adult, pediatric, and neonatal patients in hospitals, hospital-type facilities, mobile and home environments."*

Sources:

<sup>1</sup> [http://www.accessdata.fda.gov/cdrh\\_docs/pdf10/K101031.pdf](http://www.accessdata.fda.gov/cdrh_docs/pdf10/K101031.pdf)

<sup>2</sup> [http://www.accessdata.fda.gov/cdrh\\_docs/pdf/k012992.pdf](http://www.accessdata.fda.gov/cdrh_docs/pdf/k012992.pdf)

<sup>3</sup> [http://www.accessdata.fda.gov/cdrh\\_docs/pdf5/K051212.pdf](http://www.accessdata.fda.gov/cdrh_docs/pdf5/K051212.pdf)

The similarities between the intended use statements for the new device and the two predicate devices are no accident. Clearance for a Class II device using the FDA 510(k) pathway requires the new device to be substantially equivalent to the predicate device.

According to the FDA<sup>1</sup>:

"A device is substantially equivalent if, in comparison to a predicate it:

- has the same intended use as the predicate; **and**
- has the same technological characteristics as the predicate;
- or**
- has the same intended use as the predicate; **and**
- has different technological characteristics and the information submitted to FDA:
  - does not raise new questions of safety and effectiveness; **and**
  - demonstrates that the device is at least as safe and effective as the legally marketed device."

In the example provided above, the main difference between the new device and the predicate are the disposable sensors.

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<sup>1</sup>FDA US Food and Drug Administration. (2010, September 3). *Premarket Notification (510k)*. Accessed March 10, 2011, from <http://www.fda.gov/MedicalDevices/ProductsandMedicalProcedures/DeviceApprovalsandClearances/default.htm>



**Consider the following points (if applicable) with regard to your own product:**

- Does the intended use statement of a predicate device(s) adequately describe the intended use for your product?
- What changes to the intended use or indications for use would expand the market opportunity for your product relative to the competition?

## 2. Device description

In completing this section of the TPP, you will create a concise summary and explanation of the medical device. In response to the following questions, keep your answers brief:

- Does the device employ new technology or is the technology fundamentally similar to a predicate device?
- How many component parts are there to the medical device?
- Does the device include software?
- What are the key design features?
- Are any additional devices required to achieve the desired clinical outcome?



*In the corresponding section of the workbook template, write brief responses to the questions above.*

Review the example of Medtronic’s recently approved Revo MRI™ SureScan™ pacing system.



### **Example: Device description—Revo MRI™ SureScan™**

On February 8, 2011, the FDA announced the approval of the first heart pacemaker designed to be used safely during certain magnetic resonance imaging (MRI) exams. Prior to approval of this device, MRI scans were contraindicated in the US for patients with pacemakers. The device manual includes the following descriptions:

*"Medtronic Revo MRI SureScan Model RVDR01 implantable pulse generator (IPG) is a multiprogrammable, bipolar, implantable dual chamber device that monitors, detects, and treats atrial tachyarrhythmia episodes. It also detects bradycardia pacing and monitoring of ventricular tachycardia (VT) episodes. The device senses the electrical activity of the patient’s heart using the sensing electrodes of the implanted leads. It then analyzes the heart rhythm based on selectable sensing and detection parameters. If the device detects an atrial tachyarrhythmia, it*



*delivers programmed atrial ATP therapy to the patient's heart. If the device identifies a bradyarrhythmia, it delivers bradycardia pacing therapy to the patient's heart."*

*"The Revo MRI SureScan device, along with the SureScan leads, constitutes the implantable portion of the SureScan pacing system."*

*"The MRI SureScan feature permits a mode of operation that allows patients with a SureScan device to be safely scanned by an MRI machine while the device continues to provide appropriate pacing. While programmed to On, the MRI SureScan operation disables arrhythmia detection, magnet mode, and user-defined diagnostics."*

It should be noted that the regulatory approval includes a "MR Conditional" symbol, meaning that the Revo MRI SureScan pacing system is designed to allow patients with the implant to undergo MRI scans only under specified MR conditions of use.

Source: [http://www.accessdata.fda.gov/cdrh\\_docs/pdf9/P090013c.pdf](http://www.accessdata.fda.gov/cdrh_docs/pdf9/P090013c.pdf)

**Consider the following points (if applicable) with regard to your own product:**

- Are there technical features of the device that may restrict the use of the device to certain environments?
- How compatible is the device with other treatment or diagnostic modalities such as MRI examinations?

Consider the example of the device selected by the FDA as the pilot project for its new *Innovation Initiative*.



**Example: Device description—*Innovation Initiative* pilot project: A brain-controlled, upper extremity prosthetic**

The February 8, 2011 press release from the FDA states:

*"The FDA has accepted its first submission [to the Innovation Initiative] from the Defense Advanced Research Projects Agency (DARPA) to review a brain-controlled, upper extremity prosthetic designed to restore near-natural arm, hand and finger function to patients suffering from spinal cord injury, stroke or amputation. The arm system uses a microchip implanted on the surface of the brain to record neuronal activity and decode the signals to actuate motor neurons that control the prosthesis."*

The intent of the *Innovation Initiative* is to support the development of transformative and pioneering medical devices.

Source: <http://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm242629.htm>

**Consider the following points (if applicable) with regard to your own product:**

- Is your device radically different from any legally marketed medical device?
- Does your medical device significantly improve the diagnosis or treatment of a life-threatening or irreversible debilitating disease or condition?
- Does your medical device diagnose or treat a condition for which no approved treatment or diagnosis exists?

### 3. Contraindications

This section will summarize situations in which the device should not be used because the risk(s) outweigh any possible benefit. Together with the indications for use, the contraindications will provide guidance on the size of the addressable market for your product.

In completing this section of the TPP, create a concise summary in response to the following question: What conditions would put the patient in a situation where the risk of your medical device would outweigh the benefit?



*In the corresponding section of the workbook template, write a brief list of points in response to the question above.*

Review the example of Wright Medical's CONSERVE<sup>®</sup> Plus Total Resurfacing Hip System with regard to contraindications.



### **Example: Contraindications—CONSERVE® Plus Total Resurfacing Hip System**

Wright Medical markets the CONSERVE Plus Total Resurfacing Hip System for use in patients who are relatively younger and who may not be suitable for traditional total hip replacement due to an increased possibility of their requiring future hip joint revisions. Contraindications that might exclude younger patients from receiving the CONSERVE implant include:

- Patients with a family history of severe osteoporosis or severe osteopenia.
- Patients who are skeletally immature.
- Women of child-bearing age (due to the unknown effects of metal ion release on the fetus).
- Patients who are obese and/or who have a BMI greater than 35.
- Patients who are immunosuppressed with a disease such as AIDS, or persons receiving high doses of corticosteroids.
- Patients with known or suspected metal sensitivity (e.g., to jewellery).

Source: [http://www.accessdata.fda.gov/cdrh\\_docs/pdf3/P030042c.pdf](http://www.accessdata.fda.gov/cdrh_docs/pdf3/P030042c.pdf)

### **Consider the following points (if applicable) with regard to your own product:**

- Has hypersensitivity to an ingredient of your device been reported or demonstrated?
- Are there concomitant therapies that would put a patient at risk?
- Are there conditions related to age or gender that would substantially increase the risk to the patient?

Include only known hazards, not theoretical possibilities, in this section. For example, if a hypersensitivity to an ingredient in a device has not been demonstrated, it should not be listed as a contraindication.

## **4. Non-clinical testing**

For medical devices, non-clinical test methods can include *in vitro* (bench) testing, *in vivo* (animal) testing and computer simulations (modelling). Typically the non-clinical



testing section for a device should include information on sterility, toxicology, immunology, biocompatibility, stress, wear and shelf-life.

In completing this section of the TPP, you will create a concise summary of the non-clinical testing for your medical device. In response to the following questions, keep your answers brief and focused and list the related studies (completed or planned):

- Will your medical device need to be sterile? If yes, how will sterility be achieved and confirmed?
- Have the toxicology profiles of the component parts of your device been reported?
- Will any additional toxicology tests be required?
- Will animal models for efficacy and safety be required prior to treating patients?
- What are the possible consequences of failure of the device?
- How will the device be tested for robustness and safety?



*In the corresponding section of the workbook template, write a brief list of points in response to the questions above.*

Review the following example of the Bard® LifeStent® XL Vascular Stent.



### **Example: Non-clinical testing—LifeStent® XL Vascular Stent**

The non-clinical testing for Bard’s LifeStent XL Vascular Stent included evaluating the conditions for use of the stent with MRI examinations. The following information is included the product’s summary labelling information:

*"Non-clinical testing has demonstrated that the LifeStent Vascular Stent is MR conditional. It can be scanned safely under the following conditions:*

- *Static magnetic field of 1.5-Tesla or 3-Tesla.*
- *Spatial gradient field of 1000 Gauss/cm or less.*
- *Maximum whole-body-averaged specific absorption rate (SAR) of 1 W/kg for 15 minutes of scanning. For landmarks superior of the umbilicus, a whole body SAR up to 2 W/kg may be applied.*
- *In a configuration where the patient’s legs are not in contact with each other."*

Non-clinical tests and computer modelling were performed to test for potential worst-case temperature rise in the stents during MR scanning.

Source: [http://www.accessdata.fda.gov/cdrh\\_docs/pdf7/P070014S010c.pdf](http://www.accessdata.fda.gov/cdrh_docs/pdf7/P070014S010c.pdf)



**Consider the following points (if applicable) with regard to your own product:**

- What *in vitro* tests would identify performance concerns or device failures?
- Can computer simulations (modelling) be used to predict hazard probabilities across a broad patient population and a wide range of clinical scenarios?

## 5. Clinical studies

The requirements for clinical studies for medical devices depend on the nature of the device and the classification of the device. Clinical studies are most often conducted for devices in support of a “Premarket Approval” (PMA) in the US or equivalent applications in other jurisdictions. In addition, a percentage of 510(k) applications in the US require supporting clinical data. Clinical evaluation may also be required for certain modifications or new intended uses of legally marketed devices. All clinical evaluations of investigational devices must be cleared by the respective jurisdictions in which the studies are to be conducted.

In completing this section of the TPP, you will summarize any clinical studies required to support your regulatory submission and your labelling and marketing strategies.

In response to the following questions, keep your answers brief and focused:

- What is the clinical evidence to support the indication for use?
- What is the safety profile?
- How will the endpoints in the study support the competitive [positioning](#) and [marketing strategy](#) for the new device?



*In the corresponding section of the workbook template, create bulleted summaries in response to the questions listed above. List any assumptions and studies that will validate (or invalidate) the assumptions.*



*Read about the application processes for the approval of a new medical device [in Canada, the US and the EU](#).*

**Consider the following and implement as applicable in the design of your clinical studies:**

- Plan carefully, as poorly designed clinical trials can significantly delay the development of even the most promising medical devices.



- Invest time and effort to review clinical studies that have been completed and reported for competitive products.
- Review the clinical studies that supported the approval of competitive products.
- Seek guidance from statisticians to ensure that your studies will include sufficient numbers of patients to demonstrate the selected endpoints.
- Consider meeting with regulatory authorities to discuss the clinical development of your product.
- Select and include endpoints that not only will achieve regulatory approval but will differentiate your product from the competition and support your marketing efforts.