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# TECHNOLOGY READINESS

Are You Ready for Formal Product Development?

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## Table of Contents

- 03 • Abstract
- 04 • Introduction
- 05 • Benefits
- 06 • Improving
- 06 • Sunrise Labs Approach
- 08 • Discussion of 'Phase 0'
- 11 • Conclusion



## ABSTRACT

New product development efforts are a significant investment. When product development is initiated before the technology is ready, time and money can be wasted while fundamental technology problems are addressed and the inevitable rework is executed. Performing a Technology Readiness Assessment is a methodology for evaluating how ready a new technology is for commercialization. These are then evaluated within the context of the business climate to make decisions on when is the right time to initiate formal product development. Performing early “Phase 0” development is a path towards increasing technology readiness to the level appropriate for the business to pursue commercialization.

### DISCLAIMER

The following white paper should be used for informational purposes only.

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## INTRODUCTION

New product development efforts are a significant investment. When product development is initiated before the technology is ready, time and money can be wasted while fundamental technology problems are addressed and the inevitable rework is executed. Performing a Technology Readiness Assessment (TRA) is a methodology for evaluating how ready a new technology is for commercialization. These are then evaluated within the context of the business climate to make decisions on when is the right time to initiate formal product development. Performing early “Phase 0” development is a path towards increasing technology readiness to the level appropriate for the business to pursue commercialization.

A 2015 survey of 200 medical device companies estimated a total cost of approximately \$31 million to bring a low-to-moderate risk device from concept to market, whereas high-risk products averaged \$94 million. Unfortunately, technology performance problems can be discovered at any stage in the development process causing increased costs and delayed schedules.

The National Aeronautics and Space Administration (NASA) developed Technology Readiness Levels (TRLs) as a method to assess technology readiness for space missions. NASA standardized this methodology in the 1990s and soon after, became adopted by other organizations that perform costly projects. In a 1999 report, the United States General Accounting Office (GAO) stated that the level of maturity of a new technology being incorporated into a product

development program is related to the success of the program; that is, the higher the level of readiness of critical technologies when incorporated into a product, the greater the profitability for a successful outcome.

A review of technology readiness provides an objective assessment of technical risks that may delay or prohibit market introduction. While there are no figures to represent how a Technology Readiness Assessment can produce project cost savings, a study conducted by the US GAO determined that delaying a program due to size and technology instability and immaturity can result in greater ROI.

This whitepaper outlines a method for evaluating technology readiness for new product concepts, and offers methods to improve the odds for successful commercialization by addressing the risks early.

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## BENEFITS OF PERFORMING A TECHNOLOGY READINESS ASSESSMENT

Integrating TRAs into the product development process can enable project framework standardization and actionable processes that reduce project risk, which can result in avoiding project delays and potential budgetary concerns. Project risks are then able to be objectively evaluated in the context of the business decision making process. Some projects can accept higher technology development risk if the benefits outweigh these risks.

In March 2007, the GAO issued a report on the results of a review of DOE projects performance which concluded that DOE's premature application of technologies was a reason for cost growth and schedule extension . Subsequently, the DOE Office of Environmental Management (EM) conducted several pilot TRAs in their projects using an adaptation of the NASA/DoD TRA model for evaluating technology maturity and reported that the benefits of using the TRAs processes include providing a structured, criteria-based, and clearly documented assessment .

Another study by the GAO provided detailed cost data of 62 U.S. DoD programs that use TRAs by providing three data points (total costs, technology maturity, and the average cost savings from technology stability and maturity) for determining the ROI. Among other findings, the ultimate result from this analysis is that return on assets (ROA) increases as risk increases and ROI% decreases, meaning that delaying a program due to size and technology instability and immaturity results in greater ROI .

## PERFORMING A TECHNOLOGY READINESS ASSESSMENT

To determine whether a potential product has adequate technical maturity to effectively launch formal product development, the following steps should be considered:

- Determine the stage of maturity or immaturity of the current technology development and assign a TRL level
- Understand the implications of multiple technology and project risks
- Determine the tradeoff between business risks and rewards with technical and project risks
- Model and analyze to indicate whether the core technology fundamentals are capable of meeting the product requirements
- Evaluate whether the device can provide adequate performance over the expected range of conditions
- Determine whether the technology can scale to volume manufacturing and distribution
- Define the level of Technology Readiness required to initiate formal product development

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## IMPROVING THE LEVEL OF TECHNOLOGY READINESS

Once the TRA has been completed and the needed TRL determined to initiate commercialization efforts, an organized process can be performed that brings the technology to the desired maturity. This includes analysis and experimentation that provides a deep understanding of how to ensure proper functionality over the expected use of the product. Decisions are then objectively made regarding what risks need amelioration and which can be managed during normal product development.

Since they can incur significant project changes, fundamental issues are often best dealt with earlier in the development process. The needed maturity for each should be decided through creating greater understanding of their impact. Use proven, systematic processes to bring the technology to the necessary readiness.

## SUNRISE LABS APPROACH

On the path from concept to commercialization, there are many stages in the development process and associated levels of investment. Typically, business considerations drive product development decisions and vary depending on the size of the company. Decisions at startups are often hasty because of lack of funding and time, while decisions at larger companies are driven by senior or executive management goals or marketplace competition. In many companies, decisions are influenced by demanding timelines established

to please investors. Often, these pressures can rush projects into product development before core technology is well understood, and technical feasibility is established.

Balancing these demands leads to selecting the appropriate risk tolerance for a project by comparing the business rewards with the project technical risks.

For successful product commercialization, Sunrise Labs utilizes a Technology Readiness Assessment. This process begins by determining whether the technology is ready to enter formal product development or if performing further risk reduction activities is warranted. “Phase 0” is work performed to establish feasibility, reduce risk and bring the technology readiness to a point where it is reasonable to begin working on the commercial product.

The first step in evaluating the technology readiness is to formally and objectively look at each area where a new technology plays a critical role in the device. Sunrise Labs created a technology readiness level (TRL) assessment tailored for medical device development (see Figure 2).

## TRL

- 1 Basic principles are observed and reported
- 2 Technology concept and/or application is formulated
- 3 Analytical and experimental critical function and/or proof-of concept completed
- 4 Component, subsystem and/or breadboard validation in laboratory environment
- 5 Component, subsystem and/or breadboard validation in relevant environment
- 6 System designed and integrated
- 7 System performance demonstrated in a relevant environment
- 8 System and support services statistically demonstrate production scale up
- 9 System approved by FDA and/or has a successful clinical or market history

Figure 2: Technology Readiness Levels adopted for medical device product development

The TRL indicates stages that may or may not add risk. By evaluating the work ahead and the risk each stage incurs, TRLs are used to determine whether the risk is acceptable or requires amelioration before formal product development is initiated.

TRLs are applied to various subsystems and to the overall system. This underscores the importance of seeing a technology integrated into the specific system being designed before it can earn a high score.

Figure 3 shows an example of how the required TRLs at each progressive stage of development are defined. Using the TRLs to pace a project is safer than using a calendar based project schedule that may give the illusion of progress without the underlying foundation needed to succeed.



### DISCUSSION OF 'PHASE 0'

Performing a Phase 0 is a necessary approach when working with new technology to increase TRLs and reduce overall project risk. This collaborative process pools input from a wide range of perspectives (i.e., technological, clinical, regulatory, marketing, manufacturing, user and reimbursement) from different organizational groups to identify issues that might be overlooked. The Program Manager works with the client team to perform early risk evaluations, identify appropriate business model options, assess the maturity of the technology, and establish resources to complete the project within the existing budget and timeline.

Figure 3: Chart showing how the required TRLs at each stage of development may be defined.

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Each project has risks associated with bringing its technology to fruition. Understanding where risks lie is not always obvious. Risks can come from a needed innovation, technical limitations of components, unexpected environments or use, failure modes, rare events, etc. Compounding the difficulty of evaluating risk is that expertise is not always readily available for all of the technologies in the project.

The following steps provide a methodology to discover, clarify and reduce project risks and provide a descriptive discussion of each stage in the Phase 0 process:



#### Step One: Analysis

This initial stage is focused on performing a thorough analysis of the system which includes theoretical calculations, modeling, literature review, experimentation, brainstorming and analysis that increase confidence and facility with the fundamental principles.



#### Step Two: Deep Technical Dive

Once the basic review is completed, perform a collaborative, deep technical dive to find underlying issues that have not been explored or missed from step one. Specifically examine exceptions and outliers during this step if they will be encountered in real life situations.



#### Step Three: Solve Hard Problems

If there are results that are promising but not good enough, continue development until an adequate level of performance is achieved. It can take 80% of the time to get the last 20% of performance



#### Step Four: Build Proof of Concept Devices

The next step is building a proof-of-concept prototype that provides empirical evidence of assumptions and validates analytical results.



### Step Five: Test Over a Broad Range of Conditions

Following successful proof-of-concept work, the device elements are tested with reasonably realistic environments. For example, these environments can include various temperatures, blood types, reagent conditions, electronic sensors, humidity, power inputs, patient populations, etc. Data collected through well-designed experiments will increase the experience and understanding of real world issues that may arise. There can be unexpected discoveries as the outcome of this process.



### Step Six: Perform a Sensitivity Analysis

Use Sensitivity Analysis to prioritize programmatic efforts. Based on the data collected during step five, determine how sensitive the system performance is on each independent variable. Create a Pareto chart and determine which need to be addressed. For example: accuracy is directly affected by volume dispensing accuracy, introduces the most error and therefore needs to be improved



### Step Seven: Work with Experienced People

Having team members who have direct experience in the field is one of the most important factors leading to understanding and reduction of risk. They have dealt with issues that aren't obvious to first time users. Consider bringing in outside expertise or product development partners to take advantage of their experience; an early design review can provide a fresh perspective to help catch potential issues early in the project.



### Step Eight: Iterate Until it Works and TRL Meets the Goal

Analyze critical requirements and investigate unresolved issues that can derail the project later or until they are no longer considered significant risks. While fundamental risks remain, there are also implementation and execution risks -- resolve both types of risks adequately



## CONCLUSION

Technology readiness Assessments are not widely used in medical product development. TRAs help ensure technology is mature enough to meet product requirements at the early stages in the development lifecycle and before the full product development team is engaged. With the number of medical devices being introduced into the market each year expected to grow and the cost of development remaining high, medical device manufacturers should consider adopting a Technology Readiness Assessment method to provide an objective assessment of technical risks that may delay or prohibit market introduction. Performance of Phase 0 activities before initiation of formal product development offers to reduce technical, cost and schedule risk and improve business outcomes.



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## ABOUT SUNRISE LABS

Sunrise Labs is a full service product development and engineering services provider specializing in complete product development for medical devices leveraging ISO-13485 certified processes. Our clients' success stories reflect our strengths in systems engineering, project management, and a full range of technical disciplines to turn novel ideas into commercially viable products.

The Sunrise Labs' team boasts extensive project experience in medical device and life science instrumentation development, with deep expertise in software and electronics spanning portables, wireless, battery powered devices connected to mobile phones, tablets, and back-end systems. Our project portfolio includes patient monitoring solutions, imaging, cardiac, neuro, and IVD applications.

Sunrise Labs is located an hour north of Boston in Auburn, New Hampshire with a satellite office in California. We proudly employ over 60 dedicated employees in a high performance culture based on engineering excellence, mutual respect, ethics, and integrity.

Visit our website at [www.sunriselabs.com](http://www.sunriselabs.com), or contact us to learn more.

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