Technology Readiness Levels

Readiness: Biomedical Developments
(Developed with the USC Regulatory Science Program, School of Pharmacy)

Device Development

Level 1. Basic conceptual development
Basic concept of what the device will do and theoretical principle of how it will work are defined. Design inputs have been identified.

Level 2. Proof of concept
Research that validates basic idea and supports feasibility has been done. The design inputs have been defined. Device specifications are defined. A plan for the development of a prototype has been completed. The design process has not yet been initiated.

Level 3. Prototype development
A basic prototype has been designed and built. Development process has been documented.

Level 4. Pre-clinical research and benchmark testing
Validation tests of device. The device has proven to work under expected conditions in the laboratory. Toxicology and pharmacology studies have been done. Device design has been updated if deemed necessary. Manufacturability and production requirements have been defined.

Level 5. Animal Testing
An animal model has been chosen and animal testing has been done to corroborate the safety of the device and to validate design inputs.

Level 6. Clinical Trials
A detailed plan for human trials has been developed and executed. The safety and efficacy of the product has been tested. The device design has been validated.

Level 7. Commercialization
The device design has been completed and tested for safety and efficacy. The product is ready for manufacturing and launching.
**Device Development- Regulatory Readiness**

**Level 1. Device conception.**
The development has been identified as a medical device.

**Level 2. Regulatory Pathway Identification**
Applicable regulations have been identified.
A preliminary regulatory pathway for the device has been identified, along with the resources required to meet product specific regulations.

**Level 3. Regulatory Pathway definition**
A completed regulatory pathway for the device has been identified.
The appropriated notified body (NB) has been chosen.
The industry standards that the product will conform to have been identified.
Design and quality control systems are in place.

**Level 4. Animal Testing**
Appropriated Institutional Animal Care & Uses Committee approval has been obtained.
An application for exempt status (Investigation Device Exemption (IDE)) has been submitted.
Animal testing has been completed.

**Level 5. Preparation for Clinical Trials**
An Investigation Device Exemption (IDE) has been obtained.
Clinical studies protocols have been developed.
Procedures for inspections by regulatory authority on NB have been established.

**Level 6. Clinical Trials**
Clinical trials have been done after the approval by the Institutional Review Board (IRB).
Information required in preparation of FDA application/notification to market product has been collected.

**Level 7. Filing**
Pre-market notification 510K or Premarket Approval (PMA) has been filed.

**Level 8. Post approval**
Clearance for marketing of the device has been obtained.
Device has been marketed according to FDA and FTC advertising and labeling rules.
Post marketing device tracking has been performed (class III devices).

**Device Development: Business Readiness:**

**Level 1. Discovery and invention disclosure.**
Possible applications of the device have been identified.
A technology disclosure form has been filled and submitted to the USC Office of Technology Licensing (OTL).
Level 2. Preliminary market research and patent protection.
Preliminary technology and market assessment has been performed. Patent application has been reviewed and approved by the researcher and OTL. The Office of Technology Licensing has filed a provisional patent.

Level 3. Development of business model
A market for the device, and possible competitors have been identified. A risk assessment has been performed and a strategic position has been defined. A complete technology feasibility analysis has been done. Financial need has been quantified and initial funding sources identified. A marketing plan and a sales strategy have been developed.

Level 4 Initial financing.
Technical assistance for prototype development and capital for initial product development have been secured. Research of potential funding sources has been done.

Level 5 Access to money sources.
Disclosure agreements have been signed and presentations have been given to the possible money sources. Capital has been secured and negotiations with investors have been completed. Comprehensive business plan has been developed.

Level 6 Commercialization
The device is ready for manufacturing and launching. Marketing plan has been executed.