Technology Readiness Levels

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

Drug Development

Level 1. Molecule identification.
A molecule with the potential for therapeutic effect has been identified.

Level 2 Synthesis or extraction of new molecules formulated.
Study for the development of new therapeutic agents has begun.
Models for pharmacology and toxicology have been designed.
Models of manufacturing have been developed.
New molecules have been produced.
GLP (Good Laboratory Practice) laboratories have been identified.

Level 3 Preclinical pharmacological/pharmacokinetic testing of compounds
Animals, cell cultures and tissues, as well as computer models, have been used to explore the pharmacological activity and therapeutic potential of compounds.
The potential beneficial activity of compounds has been determined.
Drug metabolism has been assessed.

Level 4. Preclinical dosage formulation and stability testing of compounds
The active compounds have the form and strength suitable for human use.
Dosage forms and strength have been determined.
Design of optimum drug delivery system have been initiated.

Level 5. Preclinical toxicology and safety testing of formulated compounds.
The potential risk for the compounds to man and the environment has been tested.
Information about dose-response pattern and toxic effect of the compounds has been obtained.
**Level 6. Phase I Clinical Trial**
The new compound has been tested in Healthy human subjects at small-scale basis. The tolerance level at different doses has been established. The pharmacological effects of the compound at anticipated therapeutic levels and the patterns of absorption, distribution, metabolism and excretion in humans have been determined.

**Level 7. Phase II Clinical Trial**
Controlled clinical testing of new compound has been conducted in a relatively small number of patients. New compound’s preliminary efficacy and short-term side effects or risks for particular indication or indications in patients with the disease have been evaluated.

**Level 8. Phase III Clinical Trial**
Controlled and uncontrolled clinical testing of the new product has been conducted in large patient populations. Additional information about effectiveness and safety to evaluate benefit-risk relationship of the new drug has been obtained.

**Level 9. Commercialization**
Clinical trials have been completed. The new drug has been approved and is available for physicians to prescribe.

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**Drug Development-Regulatory Readiness:**

**Level 1. Drug conception.**
A new potential drug has been identified.

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

**Level 3. Regulatory pathway definition.**
A completed regulatory pathway for the drug has been identified.
Design and quality control systems are in place.

**Level 4. Preparation for IND application**
Toxicology and pharmacological data has been gathered and a General Investigation Plan has been defined, in preparation for the Investigational New Drug Application.

**Level 5. Regulatory Review I**
An Investigational New Drug (IND) application has been filed, and has been approved by the U.S. FDA.

**Level 6. Preparation for NDA application.**
Scientific information about the drug, gathered during the drug discovery and development process, has been documented in preparation for a New Drug Application.
Level 7. Regulatory Review II.
A New Drug Application (NDA) has been filed, and has been approved by the U.S. FDA.

Level 8. Monitoring
Periodic reports to FDA have been submitted, including any cases of adverse reactions and appropriated quality-control records.

Drug Development-Business Readiness:

Level 1. Discovery and invention disclosure.
A new potential drug has 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 drug and possible competitors has 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 have been identified.
A marketing plan and a sales strategy have been developed.

Level 4 Initial financing.
Capital for pre-clinical testing has 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 made to the possible money sources.
Capital has been secured and negotiations with investors have been completed.
Comprehensive business plan is developed.

Level 6. Clinical Trials and manufacturing planning
Capital has been invested in clinical trials.
Manufacturing processes have been designed.
Promotional material has been submitted to FDA for approval.

Level 7. Commercialization
The device is ready for full scale manufacturing and launching.
Licensing agreements have been sought.
Marketing plan has been executed.