TRL Levels for Various "Products"

TRL Level	Pharmaceutical (Drugs)	Pharmaceutical (biologics, Vaccines)	Medical Devices	Medical IM/IT & Medical Informatics	Aerospace	Automotive	General Dept of Defense	Information Technology
1	Maintain scientific awareness; tech watch. Scientific literature reviews and market surveys initiated and assesed.	Maintain scientific awareness; tech watch. Scientific literature reviews and market surveys initiated and assesed.	Maintain scientific awareness; tech watch. Scientific literature reviews and market surveys initiated and assesed.	Identified potential medical solution to mission need. Defined data & knowledge representation issues.	Basic principles observed and reported.	• Basic Principles have been observed and reported. • Scientific research undertaken. • Scientific research is beginning to be translated into applied research and development. • Paper studies and scientific experiments have taken place. • Performance has been predicted.	Lowest level of technology readiness. Scientific research begins to be translated into applied research and development.	Transition from scientific research to applied research. Essential characteristics and behaviors of systems and architectures. Descriptive tools are mathematical formulations or algorithms.
2	Research ideas and protocols developed. Hypothesis(es) generated.	Research ideas and protocols developed. Hypothesis(es) generated.	Hypothesis(es) generated. Research ideas and protocols developed.	System concepts documented. Schema defined. Data and knowledge representation issues defined.	Technology concept and/or application formulated.	Speculative applications have been identified. • Exploration into key principles is ongoing. • Application specific simulations or experiments have been undertaken. • Performance predictions have been refined	Invention begins. Once basic principles are observed, practical applications can be invented. Applications are speculative and there may be no proof or detailed analysis to support the assumptions.	Applied research. Theory and scientific principles are focused on specific application area to define the concept. Characteristics of the application are described. Analytical tools are developed for simulation or analysis of the application.
3	Hypothesis testing and initial proof-of-concept (POC) demonstrated in limited number	Hypothesis testing and initial proof-of-concept (POC) demonstrated in limited number of in vitro and in vivo models.	Hypothesis testing and initial proof-of-concept (PoC) demonstrated in limited number of laboratory models.	Data and knowledge representation schema modeled.	Analytical and experimental critical function and/or characteristic proof of concept	Analytical and experimental assessments have identified critical functionality and/or characteristics. • Analytical and laboratory studies have physically validated predictions of separate elements of the technology or components that are not yet integrated or representative. • Performance investigation using analytical experimentation and/or simulations is underway	Active research and development is initiated. This includes analytical studies and laboratory studies to physically validate analytical predictions of separate elements of the technology.	Proof of concept validation. Active Research and Development (R&D) is initiated with analytical and laboratory studies. Demonstration of technical feasibility using breadboard or brassboard implementations that are exercised with representative data
4	PoC and safety candidate drug formulations or biologic/vaccine constructs are demonstrated in defined laboratory/animal model(s).	PoC and safety candidate drug formulations or biologic/vaccine constructs are demonstrated in defined laboratory/animal model(s).	PoC and safety candidate devices/systems are demonstrated in defined laboratory/animal model(s).	Prototype produced. HW/SW pieces work together. Models use real data/knowledge.	Component and/or breadboard validation in a laboratory environment	The technology component and/or basic subsystem have been validated in the laboratory or test house environment. • The basic concept has been observed in other industry sectors (e.g. Space, Aerospace). • Requirements and interactions with relevant vehicle systems have been determined	Basic technological components are integrated to establish that they will work together. This is relatively "low fidelity" compared to the eventual system.	Standalone prototyping implementation and test. Integration of technology elements. Experiments with full-scale problems or data sets.
5	Preclinical studies, including GLP animal safety & toxicity, sufficient to support IND applications.	Preclinical studies, including GLP animal safety & toxicity, sufficient to support IND applications.	Investigational Device Exemption (IDE) review by CDRH results in determination that investigation may begin. For 510(k), prelim findings suggest the device will be substantially equivalent to a predictive device.	Models are implemented into data/knowledge system & tested in lab environment. Actual interfaces specified.	Component and/or breadboard validation in a relevant environment (ground or space).	• The technology component and/or basic subsystem have been validated in relevant environment, potentially through a mule or adapted current production vehicle. • Basic technological components are integrated with reasonably realistic supporting elements so that the technology can be tested with equipment that can simulate and validate all system specifications within a laboratory, test house or test track setting with integrated components • Design rules have been established. • Performance results demonstrate the viability of the technology and confidence to select it for new vehicle programme consideration.	Fidelity of breadboard technology increases significantly. The basic technological components are integrated with reasonably realistic supporting elements so it can be tested in a simulated environment.	Thorough testing of prototyping in representative environment. Basic technology elements integrated with reasonably realistic supporting elements. Prototyping implementations conform to target environment and interfaces.
6	Phase 1 clinical trials completed, data support proceeding to Phase 2 clinical trials. IND application prepared and submitted.	Phase 1 clinical trials completed, data support proceeding to Phase 2 clinical trials. IND application prepared and submitted.	Class III device safety demonstrated, support proceeding to clinical safety and effectiveness trials. For 510(k), info and data support production of final prototype and final testing in a military operational environment.	System tested with interfaces & support systems in relevant or simulated operational environment. Configuration Management approach developed.	System/subsystem model or prototype demonstration in a relevant environment.	A model or prototype of the technology system or subsystem has been demonstrated as part of a vehicle that can simulate and validate all system specifications within a test house, test track or similar operational environment. • Performance results validate the technology's viability for a specific vehicle class.	Representative model or prototype system, which is well beyond that of TRL 5, is tested in a relevant environment. Represents a major step up in a technology's demonstrated readiness.	Prototyping implementations on full-scale realistic problems. Partially integrated with existing systems. Limited documentation available. Engineering feasibility fully demonstrated in actual system application.
7	Phase 2 clinical trials completed. Phase 3 clinical study plan approved.	Phase 2 clinical trials completed. Phase 3 clinical study plan approved.	Class III clinical end points and test plans are agreed upon by CDRH. For 510(k), final prototype and/or initial commercial-scale device is produced and tested in a military operational environment; info and data support preparation of 510(k).	System is operationally integrated and tested with target applications in operational environment with end users.	System prototype demonstration in an operational environment.	Multiple prototypes have been demonstrated in an operational, on-vehicle environment. • The technology performs as required. • Limit testing and ultimate performance characteristics are now determined. • The technology is suitable to be incorporated into specific vehicle platform development programmes.	Prototype near, or at, planned operational system. Represents a major step up from TRL 6, requiring demonstration of an actual system prototype in an operational environment such as an aircraft, vehicle, or space.	System prototyping demonstration in operational environment. System is at or near scale of the operational system, with most functions available for demonstration and test. Well integrated with collateral and ancillary systems. Limited documentation available.
8	Phase 3 clinical trials completed. Approval of New Drug Application (NDA) for Drugs by Center for Drug Evaluation & Research (CDER)	Phase 3 clinical trials completed. Approval of the Biologics License Application (BLA) by Center for Biologics Evaluation & Research (CBER)	CDRH approval of Premarket Approval (PMA), or as applicable, 510(k)	Development Test & Evaluation (DT&E) of the HW/SW system in its intended environment. Demonstrated it meets design specifications. Validated in several operational environments.	Actual system completed and qualified through test and demonstration (ground or space).	• Test and demonstration phases have been completed to customer's satisfaction. • The technology has been proven to work in its final form and under expected conditions. • Performance has been validated, and confirmed.	Technology has been proven to work in its final form and under expected conditions. In almost all cases, this TRL represents the end of true system development.	End of system development. Fully integrated with operational hardware and software systems. Most user documentation, training documentation, and maintenance documentation completed. All functionality tested in simulated and operational scenarios. Verification and Validation (V&V) completed.
9	Post marketing studies/surveillance. Post marketing studies may be required	Post marketing studies/surveillance. Post marketing studies may be required	Post marketing studies/surveillance. Post marketing studies may be required	Product successfully used in military mission as part of Initial Operational Test and Evaluation (IOT&E). Logistical demonstration successfully conducted.	Actual system proved through successful mission operations.	The actual technology system has been qualified through operational experience. • The technology has been applied in its final form and under real-world conditions. • Real-world performance of the technology is a success. • The vehicle or product has	Actual application of the technology in its final form and under mission conditions, such as those encountered in operational test and evaluation.	Fully integrated with operational hardware/software systems. Actual system has been thoroughly demonstrated and tested in its operational environment. All documentation completed. Successful operational experience. Sustaining engineering support in place.