

## **Anexo A:**

# **Technologies Readiness Level por tipo de Proyecto y Manufacturing Readiness Level**

### TRL: Adaptación para desarrollos Farmacéuticos

Fuente: EIT Health (European Institute of Innovation and Technology).

TRL	Definition
1	Review of scientific knowledge base (Adopted from US DoH&HS)
2	Research ideas and protocols are developed
3	Hypothesis testing and initial proof of concept (PoC) is demonstrated in a limited number of in vitro & in vitro models
4	PoC and safety of candidate drug formulation is demonstrated in a defined laboratory or animal model
5	Pre-clinical studies, including GLP animal safety & toxicity, sufficient to support IND application
6	Phase 1 clinical trials support proceeding to phase 2 clinical trials. Investigation New Drug (IND) application submitted to an reviewed by FDA (CDER)
7	Phase 2 clinical trial is completed. Phase 3 clinical trial plan is approved by FDA (CDER)
8	Phase 3 clinical trial is completed. FDA (CDER) approves New Drug Application (NDA)
9	Post marketing studies and surveillance

### TRL: Adaptación para Dispositivos Médicos

Fuente: EIT Health (European Institute of Innovation and Technology).

TRL	Definition
1	-
2	Research ideas and protocols are developed.
3	Hypothesis testing and initial proof of concept (PoC) is demonstrated in a limited number of in vitro & in vitro models.
4	PoC and safety of candidate device or system is demonstrated in a defined laboratory or animal model.
5	MD-CDRH review of investigational Device Exemption (IDE) results is sufficient to begin investigation.
6	Class III device safety is demonstrated. 510 (k) data demonstrates substantial equivalency to predicate device.
7	Final product design is validated and final prototypes are produced and tested.
8	FDA (CDRH) approves the Premarket Approval (PMA) for medical device or applicable 510 (k) for devices.
9	Post marketing studies and surveillance.

## TRL: Adaptación para Software

Fuente: EIT Health (European Institute of Innovation and Technology).

TRL	Definition
1	Concept/pre-alpha: script is more of an abstract idea than an actual working program. Through this stage the coding starts and changes to functions are being made until a working draft is created.
2	
3	
4	Alpha testing of the software by one or a few in-house developers or testers ("White-box").
5	"Black-box" alpha testing for selected external end-users or in-house users/testers not associated with the development.
6	Beta testing for invited end-users ("Black-box").
7	Open beta testing - open for anyone who signs up ("Black-box").
8	v1.0 - Final stable release to the end-users.
9	v1.x, v2.x, etc - continuous development and improvement.

**Alpha:** Working script, probably lots of bugs, might not have all features, but the core of the program is running and can be tested extensively.

**Beta:** Program near completion, all feature working, may be some bugs that may not have shown up in alpha testing.

**White-box:** Tests internal structures or working of a program, as opposed to the functionality exposed to the end-userby.

**Black-box:** examining functionality without any knowledge of internal implementation. The tester is only aware of what the software is supposed to do, not how it does it.

Para apoyar interpretación de niveles 1-3 se utiliza definición y descripción del gobierno de Australia publicada en reporte Technical Risk Assessment of Australian Defence Projects elaborada por Defence System Analysis Division.

TRL	Definition	Description
1	Basic principles observed and reported	Lowest level of software readiness. Basic research begins to be translated into applied research and development. Examples might include a concept that can be implemented in software or analytic studies of an algorithm s basic properties.
2	Technology concept and/or application formulated	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. Examples are limited to analytic studies.
3	Analytical and experimental critical function and/or characteristic proof of concept	Active research and development is initiated. This includes analytical studies to produce code that validates analytical predictions of separate software elements of the technology. Examples include software components that are not yet integrated or representative but satisfy an operational need. Algorithms run on a surrogate processor in a laboratory environment.

### TRL: Adaptación para Practise-based Technologies (PBT)

Fuente: Nasa; Technology Readiness Assessment Guide - DoE; Defense Acquisition Guidebook

TRL	Definition	Description
1	Basic principles observed and reported.	Scientific knowledge generated underpinning hardware technology concepts/applications.
2	Technology concept and/or application formulated.	Invention begins, practical application is identified but is speculative, no experimental proof or detailed analysis is available to support the conjecture.
3	Analytical and experimental critical function and/or characteristic proof of concept.	Analytical studies place the technology in an appropriate context and laboratory demonstration, modeling and simulation validate analytical prediction.
4	Component and/or bread-board validation in a laboratory environment.	A low fidelity system/component breadboard is built and operated to demonstrate basic functionality and critical test environments and associated performance predictions are defined relative to the final operating environment.
5	Component and/or bread-board validation in a relevant environment.	A mid-level fidelity system/component brassboard is built and operated to demonstrate overall performance in a simulated operational environment with realistic support elements that demonstrates overall performance in critical areas. Performance predictions are made for subsequent development phases.
6	System/subsystem model or prototype demonstration in relevant environment.	A high fidelity system/component prototype that adequately addresses all critical scaling is built and operated in a relevant environment to demonstrate operations under critical environmental conditions.
7	System prototype demonstration in an operational environment.	A high fidelity engineering unit that adequately addresses all critical scaling issues is built and operated in a relevant environment to demonstrate performance in the actual operational environment and platform (ground, airborne or space)
8	Actual system completed and qualified through test and demonstration.	The final product in its final configuration is successfully demonstrated through test and analysis for its intended operational environment and platform (ground, airborne or space)
9	Actual system proven through successful mission operations.	The final product is successfully operated in an actual mission.

### TRL: Adaptación para Practise-based Technologies (PBT)

Fuente: Defence System Analysis Division – Gobierno de Australia.

TRL	Definition	Description
1	Basic principles observed and reported	Scientific, behavioural and market research paper studies.
2	Technology concept and/or application formulated	Practical, speculative applications invented. Potential user communities identified.
3	Analytical and experimental critical function and/or characteristic proof of concept	Active R&D initiated. Critical elements identified and demonstrated with innovative users.
4	Component and/or breadboard validation in laboratory environment	Basic elements integrated to form core PBT. Initial design prototype and tested.
5	Component and/or breadboard validation in relevant environment	Prototype "implementation mechanisms" (IM) demonstrated along with core PBT for users in simulated environments (e.g. workshops).
6	System/Subsystem model or prototype demonstration in a relevant environment	Implementation mechanisms (IM) refined and integrated with core PBT and demonstrated in relevant environments.
7	System/Subsystem model or prototype demonstration in an operational environment	Implementation needs of mainstream users identified and integrated into prototype. Operational use by relevant users demonstrated across the community.
8	Actual system completed and qualified through test and demonstration	Technology adopted and distributed for widespread use across the community of practice.
9	Actual system proven through successful mission operations	Technology is used routinely within community of practice. Best practices, quality assurance and body of knowledge are in place.

## MRL: Manufacturing Readiness Level

Fuente: U.S. Department of Defense.

Reporte: Manufacturing Readiness Level (MRL) Deskbook, Version 2.0

<b>MRL</b>	<b>Definition - v2.0</b>
1	Basic Manufacturing Implications Identified
2	Manufacturing Concepts Identified
3	Manufacturing Proof of Concept Developed
4	Capability to produce the technology in a laboratory environment
5	Capability to produce prototype components in a production relevant environment
6	Capability to produce a prototype system or subsystem in a production relevant environment
7	Capability to produce systems, subsystems, or components in a production representative environment
8	Pilot line capability demonstrated; Ready to begin Low Rate Initial Production
9	Low rate production demonstrated; Capability in place to begin Full Rate Production
10	Full Rate Production demonstrated and lean production practices in place