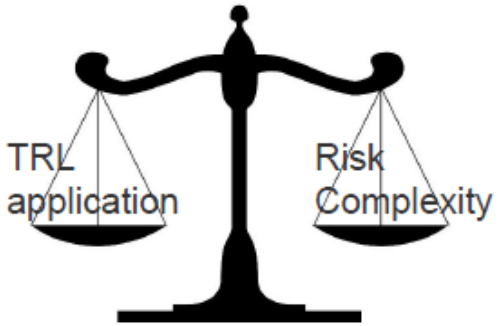
# Technology Readiness Level (TRL)
# Manufacturing Readiness Level (MRL)
# Investment Readiness Level (IRL)

# Technology Readiness Level (TRL)

- Technology readiness levels (TRLs) - Measurement of the maturity level of a particular technology
- TRLs are based on a scale from 1 to 9, with 9 being the most mature technology.
- Systematic addressing of TRLs is required, allowing a technology to evolve from conception through to research, development and deployment.
- Universities, along with government funding sources, focus on TRLs 1-4, while the private sector focuses on TRLs 7-9.
- The term 'Valley of Death' represents the often neglected addressing of TRLs 4 through to 7, where neither academia nor the private sector prioritize investment.

# Purpose of TRL

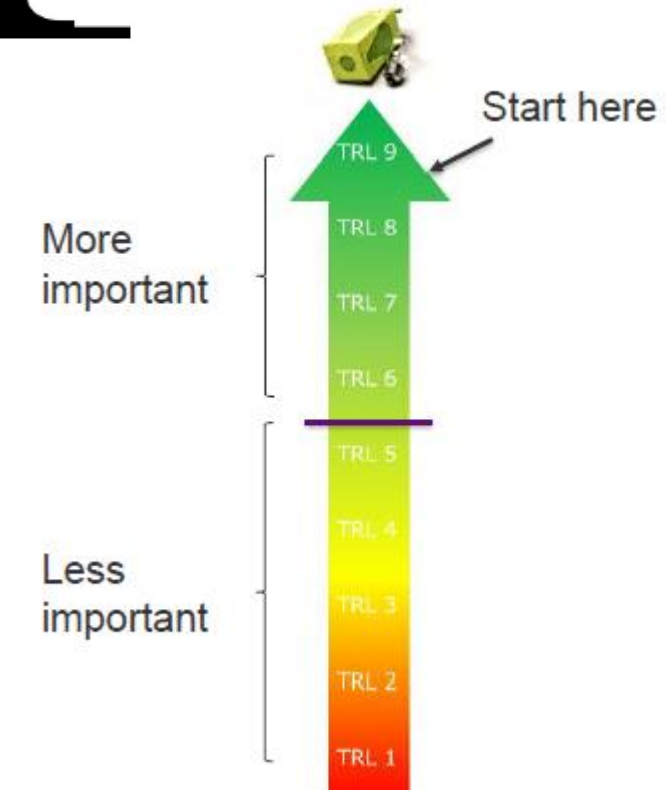



## Communication tool

More objective assessment of the development level between stakeholders


## Development roadmap

- Minimize risk in the development
- Develop products that are fit for purpose
- Encourage real-world testing and iteration
- Introduce "reality checks" in the development process




- Provides a common understanding of technology status
- Used to make decisions concerning technology funding
- Used to make decisions concerning transition of technology

# European Union (EU) Technology Readiness Levels

- European Union (EU) normalized the NASA readiness-level definitions, allowing for easier translation to multiple industry sectors – not just space exploration.
- TRL started using in EU-funded research and innovation projects in 2014.
- In 2013, the TRL scale was further canonized by the ISO 16290:2013 standard.

# Technology Readiness Levels

| Level | TRL 1 | TRL 2 | TRL 3 | TRL 4 | TRL 5 | TRL 6 | TRL 7 | TRL 8 | TRL 9 |
|---|---|---|---|---|---|---|---|---|---|
| Science & Engineering | Basic Idea | Concept Developed | Experimental Proof of Concept | Lab Demonstration | Lab scale validation (early prototype) | Prototype demonstration | Capability validated on economic runs | Capability validated over range of parts | Capability validated on full range of parts over long periods |
| | | | | | | | Pilot system demonstrated | System incorporated in commercial design | Proven system ready for full deployment |
| | | | | Component and/or system validation in laboratory environment | Laboratory scale, similar system validation in relevant environment | Engineering/pilot-scale, similar (prototypical) system validation in relevant environment | Full-scale, similar (prototypical) system demonstrated in relevant environment | Actual system completed and qualified through test and demonstration | Actual system operated over the full range of expected mission conditions |
| Software | | | Software to test and evaluate basic concepts on simple model problems representative of final need. | Escalate model to more realistic representation of industrial system. Confirm basic formulation. | Model contains all major elements of need. Solve industrial strength problems by code developers OR achieve functionality by expert users. Document performance. GUI. | No specialist intervention required from programmers/developers. This includes basic GUI interface. If required, programming to be according to ISO standards. | Install, run and evaluate software in actual goal environment (e.g. prospective client's computers). Demonstrate use by clients | Evaluation done by target representative clients on representative hardware platforms. Complete GUIs, users manuals, training, software support etc. Typical user driven "bug hunting" | Product proven ready through successful operations in operating environment. |
| Medical Science | Basic Research | | Preclinical Research | | Late Preclinical Research | Phase I Trials | Phase II Trials | Phase III Trials | Phase IV Trials |
| Phase | Research | | | Translation/Development | | | | Commercialisation | |

Image Source: Univ. of Cape Town R-2-M

# Complexity of System


- ***TRL 8-9 - System :*** **All technical elements** that comprise the project **operating as a single system** to **deliver a defined capacity**.
- **TRL 6-7 – Model :** A **physical or virtual model** used to evaluate the **technical or manufacturing feasibility or utility** of a particular **technology or process, concept, end item, or system**.
  - A **functional form of a system**, **generally reduced in scale, near or at operational specification**. Models will be sufficiently hardened to allow demonstration of the technical and operational capabilities required of the final system.
- **TRL 4-5 - Breadboard** : **Integrated components** that provide a **representation of a system/subsystem** and that can be used to determine concept feasibility and to develop technical data.
  - Typically **configured for laboratory use** to **demonstrate** the **technical principles** of immediate interest. May **resemble final system/subsystem in function only**.
- **TRL 3-4 - Component :** A **single element of technology**. The lowest sub-system that provides sufficient granularity to identify technical risks and opportunities.

# Environmental Description


- **TRL 8-9 – Actual operations :** Implementation of the final system by the **end-user** as they seem fit **in their day-to-day operations**
- **TRL 7 – Operational environment :** Environment that **addresses all** the **operational requirements** and specifications required of the final system
- **TRL 6 – Simulated operational environment :** Either (1) a real environment that can simulate all the operational requirements and specifications required of the final system or (2) a simulated environment that allows for testing of a virtual prototype
- **TRL 5-6 – Relevant environment :** Testing environment in a **lab or other controlled environment** that **simulates** both the most **important** and most **stressing** aspects of the **operational** environment.
- **TRL 3-4 – Laboratory :** The normal environment where the technology or product is developed, usually **not related** to the **environment where it will be used**
- **TRL 1-2 – Desk/Lab**

# Technology Readiness Level – Development Stages

| TRL | Description | Example |
|---|---|---|
| *1* | *Basic principles observed* | • *Scientific observations* made and reported. Examples could include paper-based studies of a technology's basic properties. |
| *2* | *Technology concept formulated* | • Envisioned applications are *speculative* at this stage. Examples are often limited to analytical studies. |
| *3* | *Experimental proof of concept* | • Effective research and development initiated. Examples include studies and laboratory measurements to validate *analytical predictions.* |
| *4* | *Technology validated in lab* | • Technology *validated through designed investigation*. Examples might include analysis of the technology parameter operating range. The results provide evidence that envisioned application performance requirements might be attainable. |

# Technology Readiness Level Examples

| TRL | Description | Example |
|---|---|---|
| *5* | *Technology validated in relevant environment* | • Reliability of technology significantly increases. Examples could involve validation of a *semi-integrated system/model* of technological and supporting elements in a simulated environment. |
| *6* | *Technology demonstrated in relevant environment* | • *Prototype system verified*. Examples might include a prototype system/model being produced and demonstrated in a simulated environment. |
| *7* | *System model or prototype demonstration in operational environment* | • A major step increase in technological maturity. Examples could include a prototype model/system being verified in an operational environment. |

# Technology Readiness Level Examples

| TRL | Description | Example |
|---|---|---|
| *8* | *System complete and qualified* | *System/model produced and qualified*. An example might include the knowledge generated from TRL 7 being used to manufacture an actual system/model, which is subsequently qualified in an *operational environment*. In most cases, this TRL represents the end of development. |
| *9* | *Actual system proven in operational environment* | System/model proven and ready for full *commercial deployment*. An example includes the actual system/model being successfully deployed for multiple missions by end users. |

## Technology Readiness Level (TRL) Process

NASA's quest to make jet engines quieter led to the development of chevrons, which moved relatively quickly through the TRL process to be deployed into the commercial marketplace.

### TRL 8-9 (2005-now)

- Certification by the Federal Aviation Administration
- Deployed into market

### TRL 7 (2001-2005)

- Validation of concept in flight
- Flight tests, final design

### TRL 6 (1998-2000)

- Full scale tests for acoustics and aerodynamics
- Static engine tests

### TRL 4-5 (1995-1997)

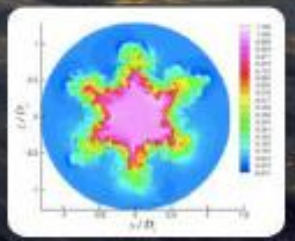
- Model tests for acoustics and aerodynamics
- Sub-scale model tests

### TRL 3 (Early 1990s)

- Applications to small nozzles and airfoils
- Lab tests, concept on paper


### TRL 1-2 (1980s)

- Fundamental investigations of air-mixing devices (tabs, chevrons, etc.)
- No specific application, basic research in fluid physics



# Generic TRL → Specific TRL

The TRL is generic → the stages and definitions have to be adapted to the specific project

"Technology validated in relevant environment"

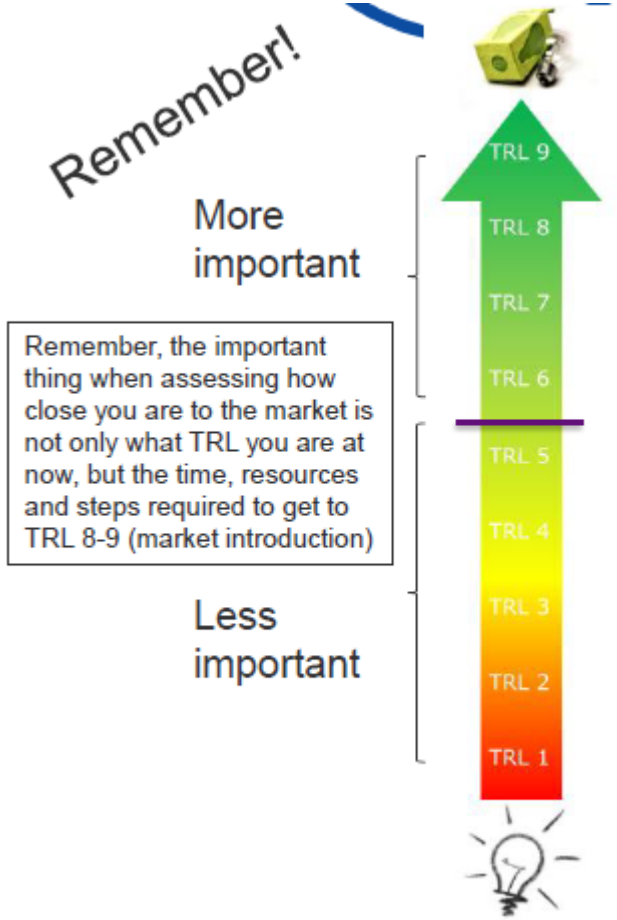
Technology development stage

Proof-of-Concept?
Validation?
Demonstration?
System?
Technology?
Component?

Definition of the environment in which the technology has been tested

# Improvements of Existing Products

- New Product Development
  - TRL is most clear cut when dealing with genuine New Product Development with high inherent risk and insecurity (that's what it was designed for)
  - Requires more thought when applied to product or process improvements
- Improvement of Existing Product
  - Substantial improvement of a TRL 8-9 system = starting again at TRL 2
  - The road from a low TRL to a high TRL may be very short and fast.



# TRL - Software Development


| | |
|---|---|
| **TRL 9** | v1.x, v2.x, etc. – continuous development and improvement |
| **TRL 8** | v1.0 - Final stable release to the end-users |
| **TRL 7** | Open beta testing - open for anyone who signs up ("Black-box") |
| **TRL 6** | Beta testing for invited end-users ("Black-box") |
| **TRL 5** | "Black-box" alpha testing for selected external end-users or in-hose users/testeers not associated with the development |
| **TRL 4** | Alpha testing of the software by one or a few in-house developers or testers ("White-box") |
| **TRL 1- 3** | 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 |

**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 features working, may be some bugs that may not have shown up in alpha testing

**White-box:** tests internal structures or workings 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.

# TRL - Pharmaceutical Development


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

Source: US Army Medical Department

# Medical device development


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

# TRL - BIRAC, DBT, GoI

- Keeping NASA TRLs as a reference, BIRAC has come up with detailed definitions of levels in the TRL scale for each of these thematic areas.
- These TRL definitions intend to guide the innovators, evaluators and investors in identifying the stage of technology under development more objectively.
- The definitions also include some of the regulatory approvals and quality certifications which may be relevant for progression of TRLs and commercialization of the technology/products in India.

https://www.birac.nic.in/desc_new.php?id=443

1.) *Drugs (including Drug Delivery)*

2.) *Vaccines*

3.) *Biosimilars*

4.) *Regenerative Medicine*

5.) *Medical Devices and Diagnosis*

6.) *Artificial intelligence, Big Data Analysis, IoT's, software development & Bioinformatics*

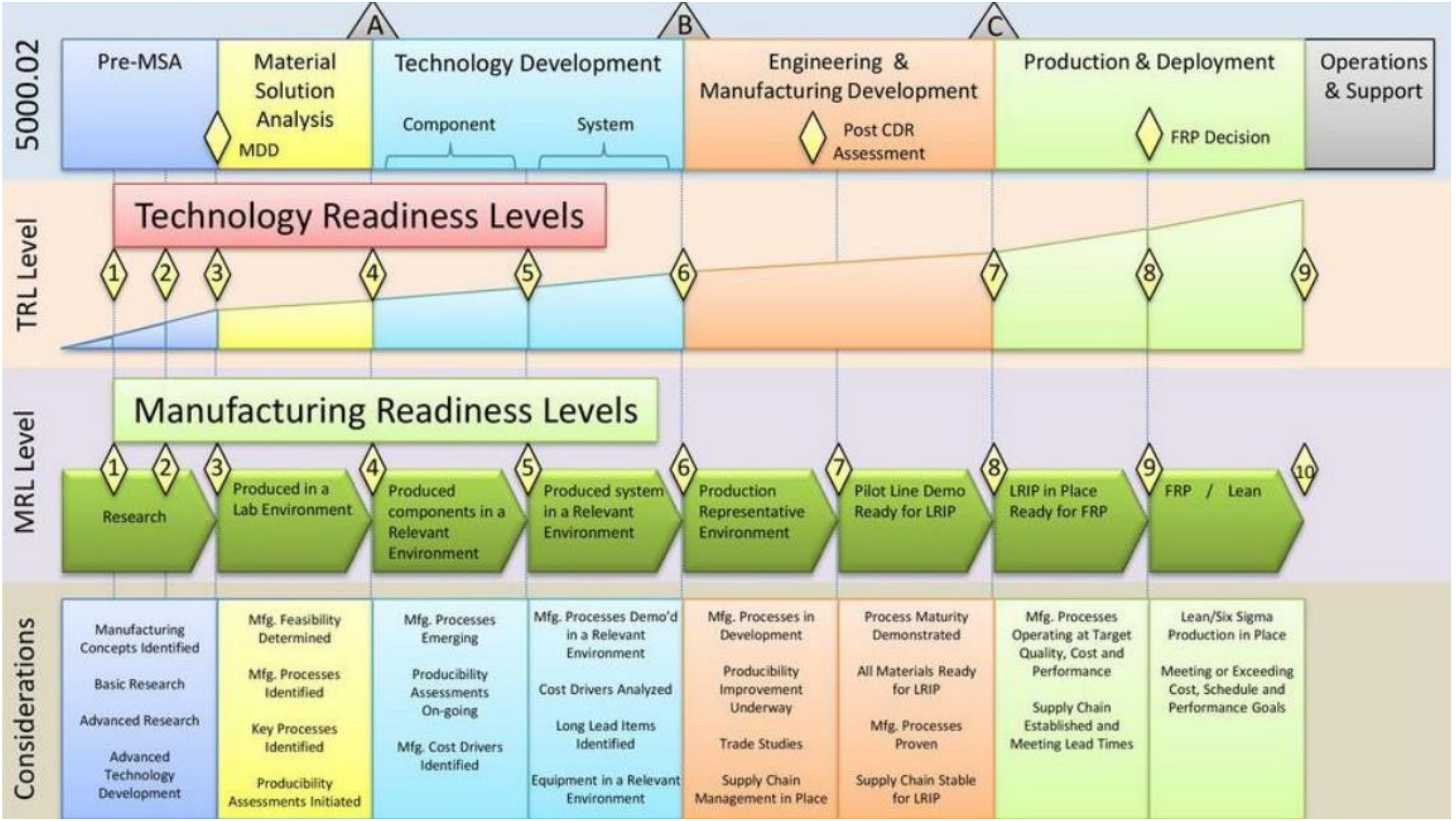
7.) Industrial Biotechnology (including secondary agriculture) 8.) *Agriculture*

9.) *Aqua Culture and Fisheries*

10.) Veterinary

# Manufacturing Readiness Level (MRL)

- MRLs are a method for understanding the maturity of a manufacturing process readiness, similar to how Technology Readiness Levels (TRLs) are used to understand technology maturity.
- MRLs allow innovators to have a consistent datum of reference for understanding manufacturing maturity evolution.
- The MRL concept was developed by the United States Department of Defence (DoD) to assess the maturity of a manufacturing process throughout its conception, development, deployment and support progression phases.
- MRLs are based on a scale from 1 - 10, with 10 being the most mature.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A
B
C
Pre-MSA
Material Solution Analysis
MDD
Technology Development
Component
System
Engineering & Manufacturing Development
Post CDR Assessment
Production & Deployment
FRP Decision
Operations & Support
TRL Level
Technology Readiness Levels
1
2
3
4
5
6
7
8
9
MRL Level
Manufacturing Readiness Levels
1 Research
2
3 Produced in a Lab Environment
4 Produced components in a Relevant Environment
5 Produced system in a Relevant Environment
6 Production Representative Environment
7 Pilot Line Demo Ready for LRIP
8 LRIP in Place Ready for FRP
9 FRP / Lean
10
Considerations
Manufacturing Concepts Identified
Basic Research
Advanced Research
Advanced Technology Development
Mfg. Feasibility Determined
Mfg. Processes Identified
Key Processes Identified
Producibility Assessments Initiated
Mfg. Processes Emerging
Producibility Assessments On-going
Mfg. Cost Drivers Identified
Mfg. Processes Demo'd in a Relevant Environment
Cost Drivers Analyzed
Long Lead Items Identified
Equipment in a Relevant Environment
Mfg. Processes in Development
Producibility Improvement Underway
Trade Studies
Supply Chain Management in Place
Process Maturity Demonstrated
All Materials Ready for LRIP
Mfg. Processes Proven
Supply Chain Stable for LRIP
Mfg. Processes Operating at Target Quality, Cost and Performance
Supply Chain Established and Meeting Lead Times
Lean/Six Sigma Production in Place
Meeting or Exceeding Cost, Schedule and Performance Goals

# Manufacturing Readiness Level

| Phase | Leading to | MRL | Definition | Description |
|---|---|---|---|---|
| Material solutions analysis | Material development decision review | 1 | Basic manufacturing implications identified | • Basic research expands scientific principles that may have manufacturing implications. The focus is on a high-level assessment of manufacturing opportunities. The research is unfettered. |
| | | 2 | Manufacturing concepts identified | • Invention begins. Manufacturing science and/or concept described in application context. Identification of material and process approaches are limited to paper studies and analysis. Initial manufacturing feasibility and issues are emerging. |
| | | 3 | Manufacturing proof of concept developed | • Conduct analytical or laboratory experiments to validate paper studies. Experimental hardware or processes have been created, but are not yet integrated or representative. Materials and/or processes have been characterized for manufacturability and availability but further evaluation and demonstration is required. |
| | A: Milestone decision | 4 | Capability to produce the technology in a laboratory environment | • Required investments, such as manufacturing technology development identified. Processes to ensure manufacturability, producibility and quality are in place and are sufficient to produce technology demonstrators. Manufacturing risks identified for prototype build. Manufacturing cost drivers identified. Producibility assessments of design concepts have been completed. Key design performance parameters identified. Special needs identified for tooling, facilities, material handling and skills. |

# Manufacturing Readiness Level

| Phase | Leading to | MRL | Definition | Description |
|---|---|---|---|---|
| Technology maturation and risk reduction | B: Milestone decision | 5 | Capability to produce prototype components in a production relevant environment | • Manufacturing strategy refined and integrated with Risk Management Plan. Identification of enabling/critical technologies and components is complete. Prototype materials, tooling and test equipment, as well as personnel skills, have been demonstrated on components in a production relevant environment, but many manufacturing processes and procedures are still in development. Manufacturing technology development efforts initiated or ongoing. Producibility assessments of key technologies and components ongoing. Cost model based upon detailed end-to-end value stream map. |
| | | 6 | Capability to produce a prototype system or subsystem in a production relevant environment | • Initial manufacturing approach developed. Majority of manufacturing processes have been defined and characterized, but there are still significant engineering/design changes. Preliminary design of critical components completed. Producibility assessments of key technologies complete. Prototype materials, tooling and test equipment, as well as personnel skills have been demonstrated on subsystems/ systems in a production relevant environment. Detailed cost analysis include design trades. Cost targets allocated. Producibility considerations shape system development plans. Long lead and key supply chain elements identified. Industrial Capabilities Assessment for Milestone B completed. |

# Manufacturing Readiness Level

| Phase | Leading to | MRL | Definition | Description |
|---|---|---|---|---|
| Engineering and manufacturing development | Post-CDR (Critical Design Review) Assessment | 7 | Capability to produce systems, subsystems or components in a production representative environment. | • Detailed design is underway. Material specifications are approved. Materials available to meet planned pilot line build schedule. Manufacturing processes and procedures demonstrated in a production representative environment. Detailed producibility trade studies and risk assessments underway. Cost models updated with detailed designs, rolled up to system level and tracked against targets. Unit cost reduction efforts underway. Supply chain and supplier Quality Assurance assessed. Long lead procurement plans in place. Production tooling and test equipment design and development initiated. |
| | C: Milestone Decision | 8 | Pilot line capability demonstrated. Ready to begin low rate production. | • Detailed system design essentially complete and sufficiently stable to enter low rate production. All materials are available to meet planned low rate production schedule. Manufacturing and quality processes and procedures proven in a pilot line environment, under control and ready for low rate production. Known producibility risks pose no significant risk for low rate production. Engineering cost model driven by detailed design and validated. Supply chain established and stable. Industrial Capabilities Assessment for Milestone C. |

# Manufacturing Readiness Level

| Phase | Leading to | MRL | Definition | Description |
|---|---|---|---|---|
| Production and deployment | Full rate production decision | 9 | Low rate production demonstrated. Capability in place to begin Full Rate Production. | • Major system design features are stable and proven in test and evaluation. Materials are available to meet planned rate production schedules. Manufacturing processes and procedures are established and controlled to three-sigma or some other appropriate quality level to meet design key characteristic tolerances in a low rate production environment. Production risk monitoring ongoing. Low Rate Initial Production (LRIP) cost goals met, learning curve validated. Actual cost model developed for Full Rate Production environment, with impact of Continuous improvement. |
| Operations and support | N/A | 10 | Full rate production demonstrated and lean production practices in place. | • This is the highest level of production readiness. Engineering/design changes are few and generally limited to quality and cost improvements. System, components or items are in rate production and meet all engineering, performance, quality and reliability requirements. All materials, manufacturing processes and procedures, inspection and test equipment are in production and controlled to six-sigma or some other appropriate quality level. Full rate production unit cost meets goal, and funding is sufficient for production at required rates. Lean practices well-established and continuous process improvements ongoing. |

# Investment Readiness Level (IRL)
# Idea-to-Start-up-to-VC

- **IRL 9:** Full Commercial Development – A full time process engineering staff continuously verifies that operations are meeting cost, yield and productivity targets.
- **IRL 8:** Pre-Commercial Demonstration – Operating Conditions and quality stabilized
- **IRL 7:** Prototype High Fidelity MVP: Integrated Pilot Continuous Operation
- **IRL 6:** Validate Business/Revenue Model: Integrated Pilot Development– understanding operational nuances
- **IRL 5:** Validate Product-Market Fit (Integrated Validation of the Minimum Viable Process and Process Engineering). "High-fidelity" - A high-fidelity laboratory environment would involve testing with equipment that can simulate and validate all system specifications within a laboratory setting.
- **IRL 4:** Prototype Low-Fidelity Minimum Viable Product (MVP): "Low-fidelity" - A representative of the component or system that has limited ability to provide anything but initial information about the end product.
- **IRL 3:** Validate Problem - Solution Fit (Confirmed Value Proposition & Techno-Economic Analysis) & Minimum Product Cost (Maturity of Core Technology)
- **IRL 2**: Applied Research (Market Size and Competitive Analysis) & Business Plan – Value Proposition & IP Identification
- **IRL 1:** Basic Research (Need Identification & Peer Review Publications) & Completed First-Pass Business Model Canvas (BMC)

| IRL 1<br>Complete First-Pass BMC | IRL 2<br>Market Size/ Competitive Analysis | IRL 3<br>Problem/ Solution Validation | IRL 4<br>Prototype Low-Fidelity MVP | IRL 5<br>Validate Product/Market Fit | IRL 6<br>Validate Revenue Model | IRL 7<br>Prototype High-Fidelity MVP | IRL 8<br>Validate Value Delivery | IRL 9<br>Identify and Validate Metrics that Matter |
|---|---|---|---|---|---|---|---|---|
| BMC filled in | Detailed map of total addressable market | At least one potential market segment invalidated | Market hypotheses and tests developed to guide learning from MVP | Map of customer ecosystem and flow | Map money flow | Market hypotheses and tests developed to guide learning from MVP | Partnership ecosystem mapped | Key growth metrics identified |
| Describe assumptions that must be true for each entry into the BMC | Sub-sections of the market | First target segment identified (60-100 interviews) | MVP is built (sample data, financial model etc) | Get-Keep-Grow loop outlined | Revenue model validated **(20+ interviews)** | Actual market-based prototype is built | Funding and growth model built | Measurement system in place |
| Outline how each assumption will be tested & measured, and how success will be identified (Test Card) | First niche we will address (in terms of $ we can earn, not total value of each segment) | Customer problem validated (60-100 interviews) | Prototype solution validated **(20+ interviews)** | Market channels and customer relationships validated **(20+ interviews)** | | Prototype solution validated **(20+ interviews)** | IP requirements identified and secured | Some customer acquired (may happen in IRL 6) |
| | Competitor map (Petal Diagram) | Solution validated **(60-100 interviews to do this)** | | | | | Assumptions in the left four blocks are tested/validated **(30+ interviews)** | Idea ready for launch/sale/ license etc |

# Thank You


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