

# Steps in Microbial Entrepreneurship

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IDEATION

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VALIDATION

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PROTOTYPING

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MARKETING

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DEVELOPMENT

6

LAUNCH

7

IMPROVEMENT

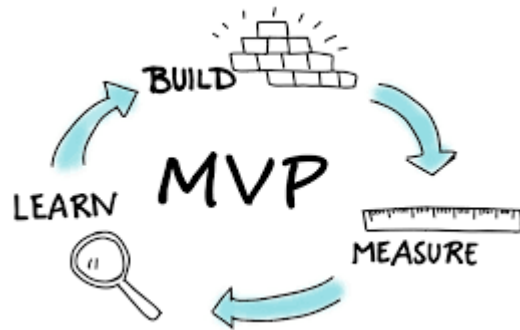
# Identifying a Market Opportunity

- Define Problem-Ideation Stage
- Develop Prototype: A prototype is **an early sample, model, or release of a product** built to test a concept or process.
- Conducting market research to identify industry gaps.
- Analyzing competitors and potential customers.
- Defining a **unique value proposition** for the microbial product.
  - A company developing a rapid diagnostic test for foodborne illnesses might frame its value proposition as follows:
    - *"Eliminate foodborne outbreaks faster with our rapid diagnostic test. Our technology delivers accurate results within minutes, minimizing contamination risks and reducing costly recalls, protecting both public health and your brand reputation."*
    - This value proposition clearly identifies the problem (foodborne outbreaks), highlights the solution (rapid diagnostic test), and quantifies the benefits (faster results, minimized risks, reduced costs).
- The first step in market research is defining the overall market size and potential.
  - Total Addressable Market (TAM): represents the total potential market for your product or service, encompassing all potential customers worldwide
  - Serviceable Available Market (SAM): more refined estimate, considering geographical limitations, specific customer segments, and other factors that might restrict access to the entire TAM
  - Serviceable Obtainable Market (SOM) represents the realistic portion of the SAM that your startup can realistically capture, given its resources and competitive landscape.

For example, a startup developing a rapid diagnostic test for a specific bacterial pathogen might initially target a regional market (SAM) rather than attempting to address the global market (TAM) immediately. Their SOM would be a further refined subset based on their production capacity and marketing reach.

# Developing the Minimum Viable Product (MVP)

- Conducting laboratory proof-of-concept studies.
- Iterative process



- A minimum viable product, or MVP, is a **product with enough features to attract early-adopter customers** and validate a product idea.
- Optimizing strain development, fermentation processes, or bioengineering.
- Testing small-scale production before scaling up.

# Protecting Intellectual Property

- Filing for patents on microbial strains, bioactive compounds, and processes.
- Ensuring compliance with biotechnology patent laws.
- Exploring technology transfer and licensing options.
- Explore in Unit 5-IPR

# Navigating Regulatory Approvals

- Understanding FDA, EPA, EMA, FSSAI, and USDA regulations for microbial products.
- Conducting necessary toxicology and safety tests.
- Preparing regulatory documentation for approvals.

# Scaling Up Production

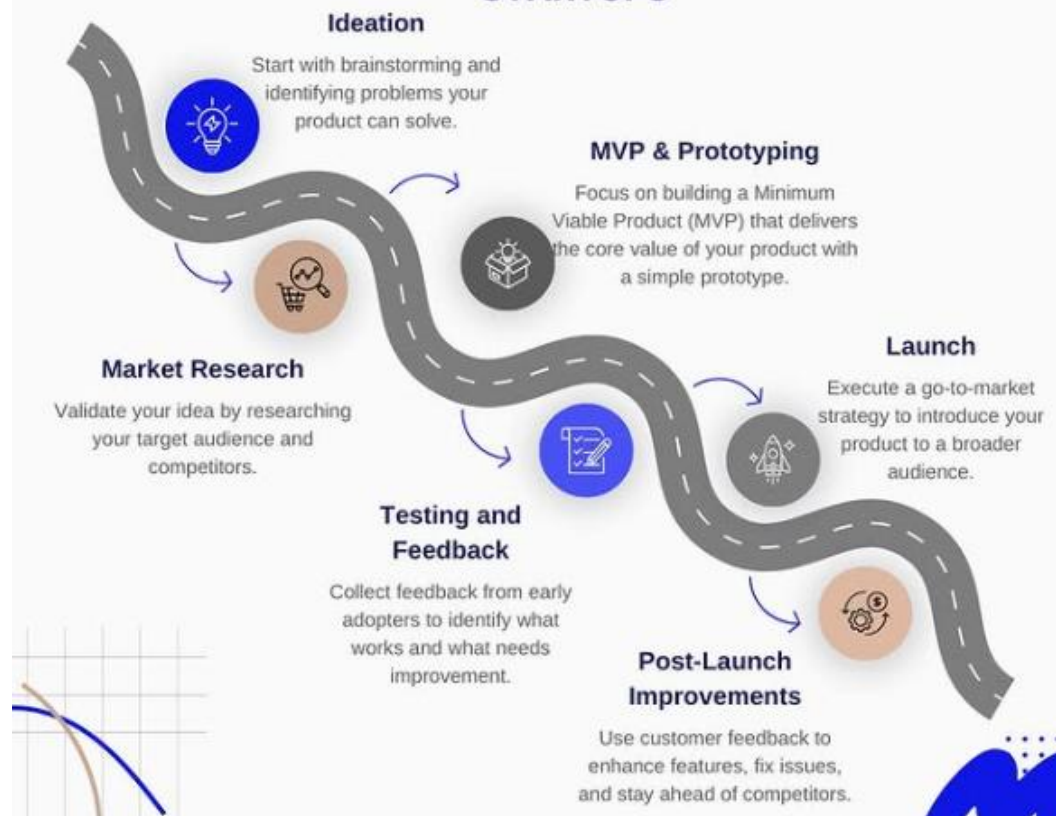
- Moving from lab-scale to pilot-scale fermentation.
- Optimizing bioreactors, media formulation, and purification processes.
- Partnering with contract manufacturing organizations (CMOs) if needed.

# Commercial Launch and Market Entry

- Developing a branding and marketing strategy.
- Establishing distribution channels (e-commerce, B2B partnerships, retail).
- Conducting customer education and outreach programs.



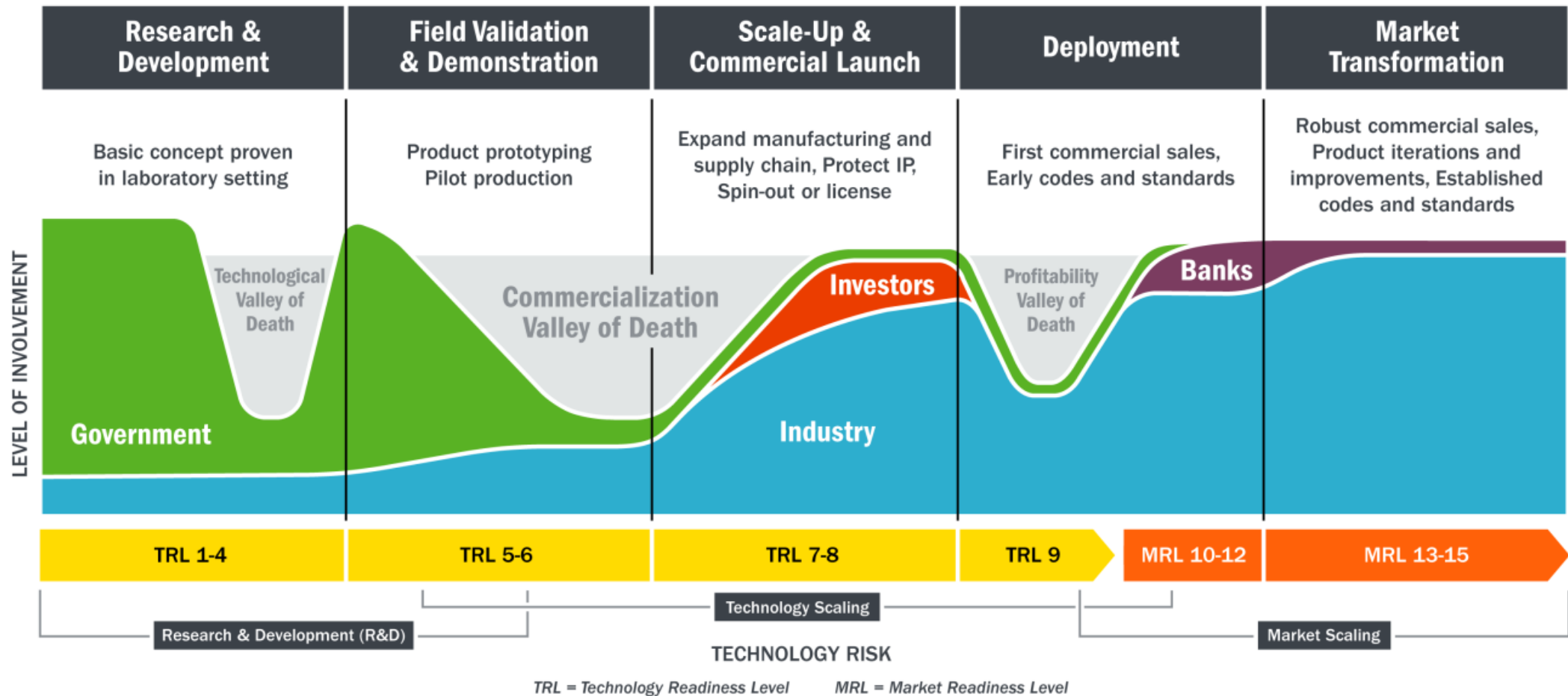
## PRODUCT DEVELOPMENT ROADMAP FOR STARTUPS





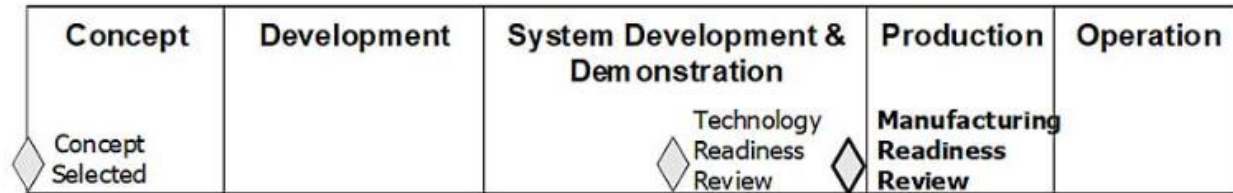
# Technology Readiness Levels

- TRL 0: Idea.** Unproven concept, no testing has been performed.
- TRL 1: Basic research.** Principles postulated and observed but no experimental proof available.
- TRL 2: Technology formulation.** Concept and application have been formulated.
- TRL 3: Applied research.** First laboratory tests completed; proof of concept.
- TRL 4: Small scale prototype** built in a laboratory environment ("ugly" prototype).
- TRL 5: Large scale prototype** tested in intended environment.
- TRL 6: Prototype system** tested in intended environment close to expected performance.
- TRL 7: Demonstration system** operating in operational environment at pre-commercial scale.
- TRL 8: First of a kind commercial system.** Manufacturing issues solved.
- TRL 9: Full commercial application,** technology available for consumers.



*Tech-to-Market Process: Technology readiness is commonly measured on a nine-point scale referred to as Technology Readiness Level (TRL). TRLs are used to consistently identify technology development stages across technology types. Market Readiness Levels (MRLs) refer to the readiness of a market to accept and adopt a new technology.*

# Manufacturing Readiness Level



Manufacturing Readiness Level (MRL)		
Phase	MRL	State of Development
Phase 3: Production Implementation	9	Full production process qualified for full range of parts and full metrics achieved
	8	Full production process qualified for full range of parts
	7	Capability and rate confirmed
Phase 2: Pre production	6	Process optimised for production rate on production equipment
	5	Basic capability demonstrated
Phase 1: Technology assessment and proving	4	Production validated in lab environment
	3	Experimental proof of concept completed
	2	Application and validity of concept validated or demonstrated
	1	Concept proposed with scientific validation

The manufacturing readiness level (MRL) is a measure to assess the maturity of manufacturing readiness

It was developed by the United States Department of Defense (DOD), who adopted the usage of MRLs in 2005.

MRLs are assessed to:

- define the current level of manufacturing maturity

- identify maturity shortfalls and associated costs and risks

- provide the basis for manufacturing maturation and risk management