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Commercialization and Legal Framework for Marine Biotechnology Products

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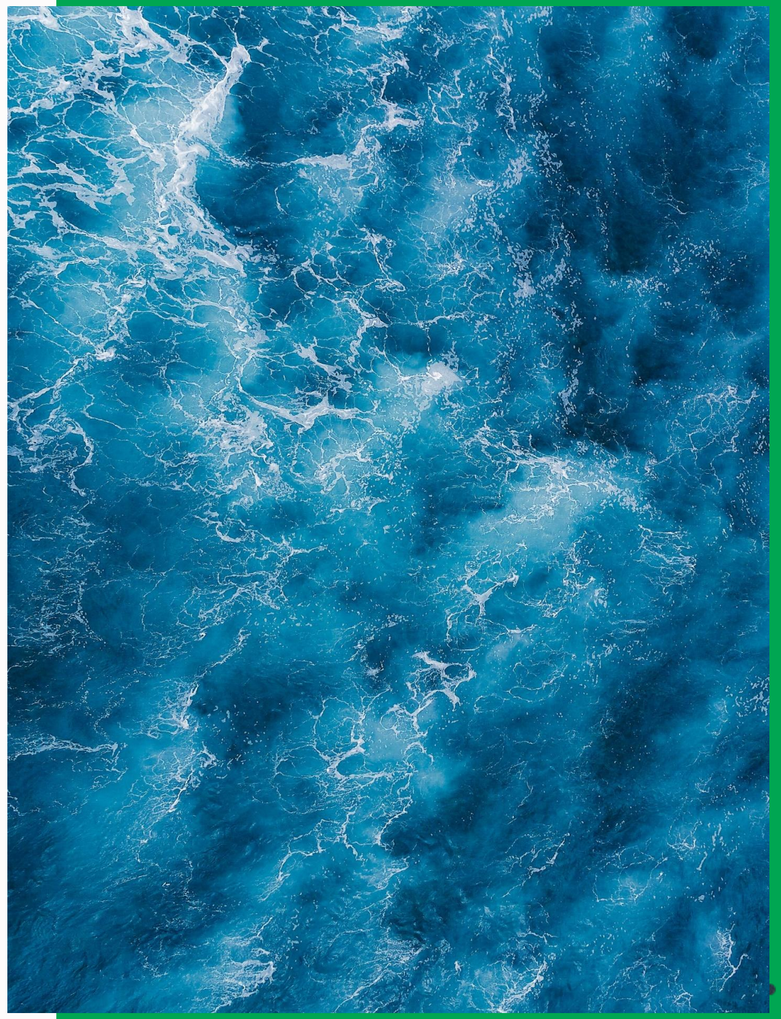
Content



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From Lab to Market

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How does a university create a robust entrepreneurial platform that can build value off of a huge pool of intellectual capital?

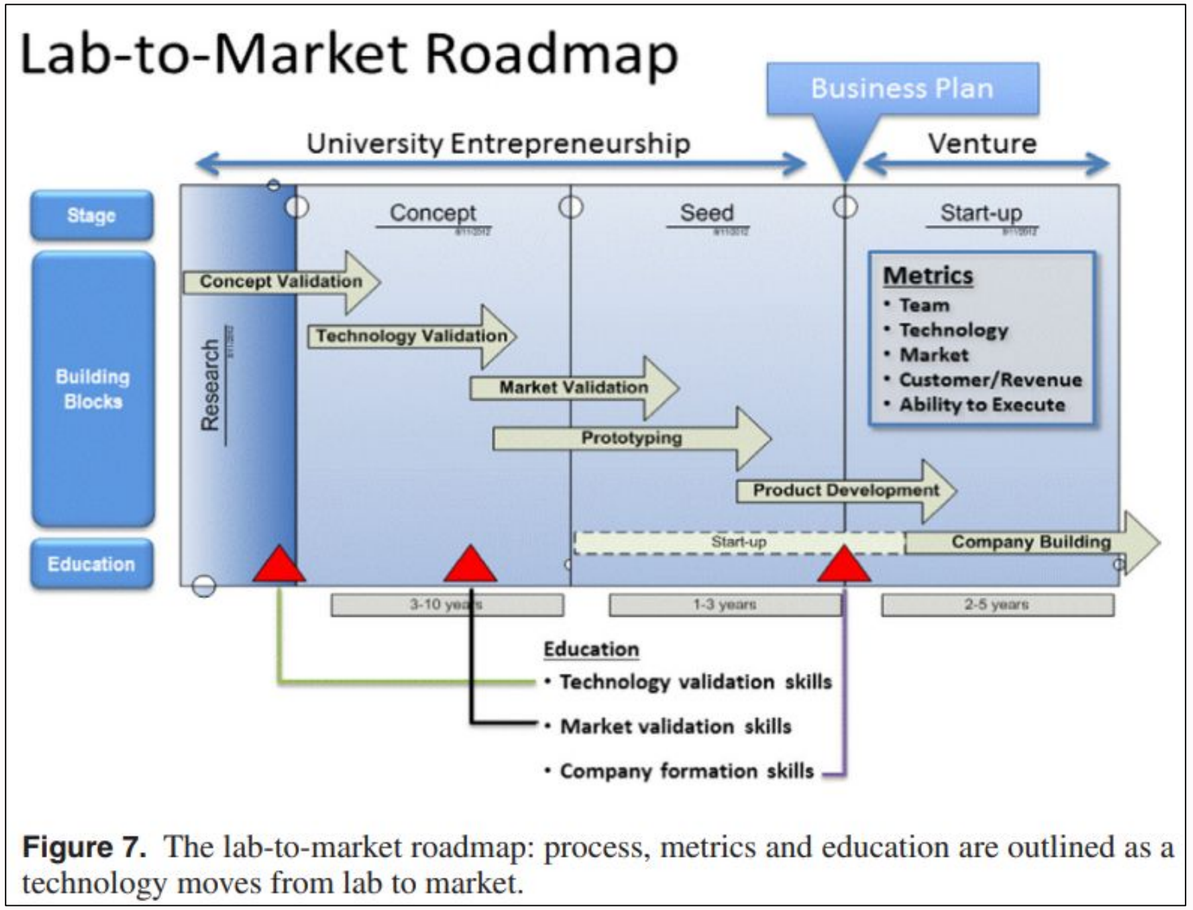

Figure 7. The lab-to-market roadmap: process, metrics and education are outlined as a technology moves from lab to market.

(Source: J Windheim and B Myers, 2014)

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From Lab To Market: Defining The Process

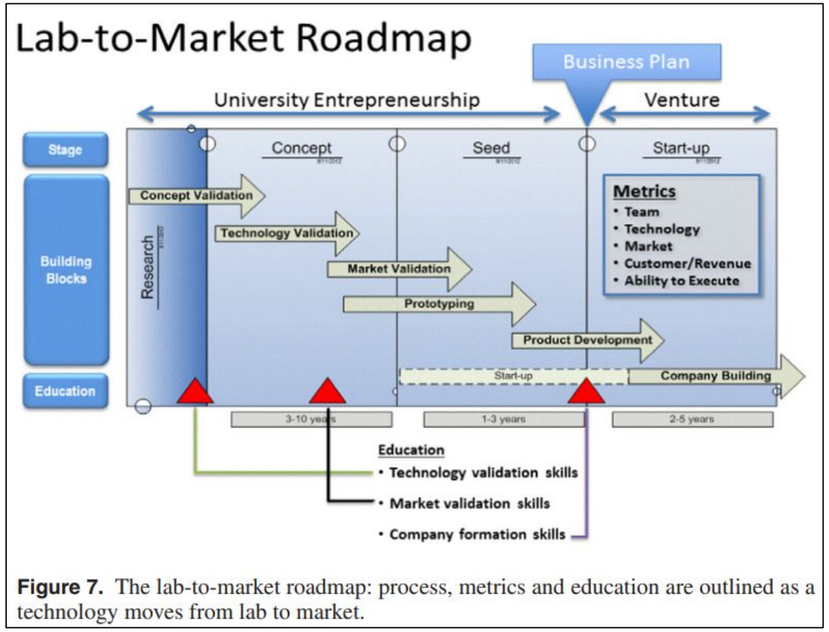

Figure 7. The lab-to-market roadmap: process, metrics and education are outlined as a technology moves from lab to market.

(Source: J Windheim and B Myers, 2014)

1. **Concept validation**
   Validate scientific data through peer review, ideally in the most prestigious journals.
2. **Technology validation**
   Create a technology demonstration vehicle within the lab that shows a physical demonstration of the science.
3. **Market validation**
   Validate technology demonstration with industry experts and customers who can speak to the value of the technology. Ideally, generate orders from customers.
4. **Prototyping**
   Validate working prototype with application thought leaders and customers who can confirm the value of the technology. Ideally, customers are paying for prototypes.
5. **Product development**
   Create robust, reproducible, functional product for customer testing and feedback.
6. **Company building**
   Start-up operations and growth with professional investors who can help maximize the potential of the company

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From Lab To Market: Defining The Process

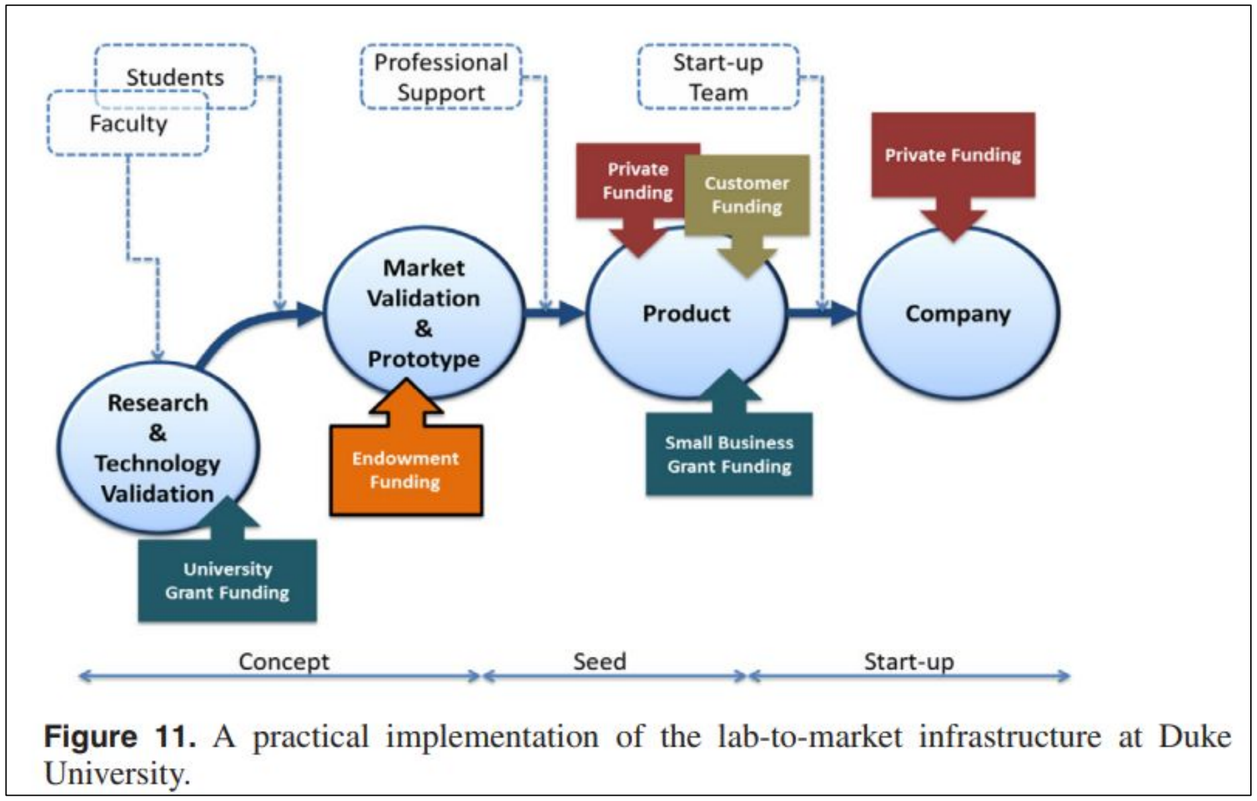

Figure 11. A practical implementation of the lab-to-market infrastructure at Duke University.

Implementation of Lab-to Market (Duke University)

- Align academic research with commercial needs
- Provide training in product development & customer engagement
- Secure internal or government seed funding
- Partner with licensing and venture offices

Overall, the approach demonstrated at Duke appears to offer a low-risk, high-reward pathway for technology valorization within universities.

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Challenges in Translating Lab Innovations

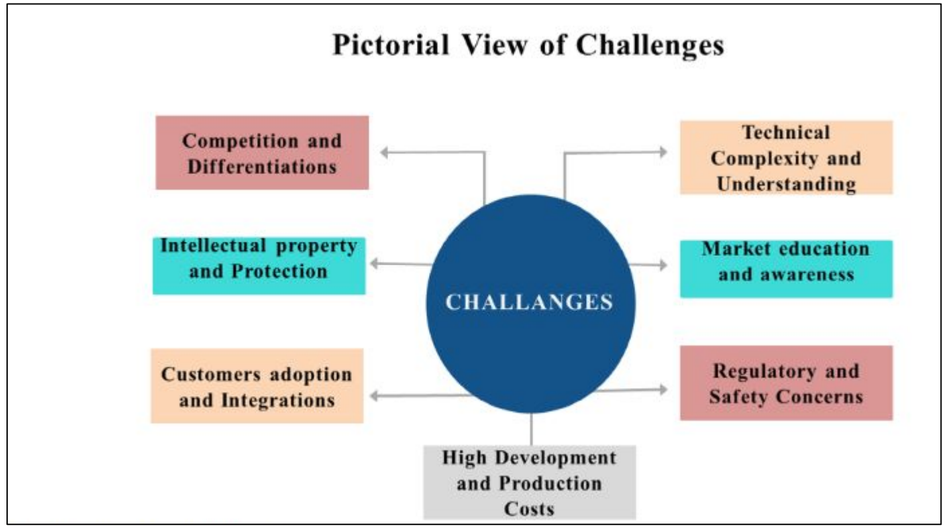
Challenges:

1. Slow timelines (often 10+ years)
2. High capital needs, limited early funding
3. Skill gaps: academic vs. commercial expertise
4. Cultural and organizational misalignment

Valley of Death in Innovation:

1. High failure rate in market testing stage
2. Often due to lack of commercial and customer focus

(Source: J Windheim and B Myers, 2014; Piccinno et al., 2020)



Challenges and Solutions (Source: Singh, et. al. 2025)

- **Scalability**: Addressed through green synthesis and controlled fabrication methods.
- **Cost & Accessibility**: Reduce via eco-friendly materials and simplified production techniques.
- **Market Entry Barriers**: Overcome by aligning R&D with commercial trends and real-life use cases.

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Scaling Up Production

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Laboratory Scale (Discovery & Feasibility)
- Identify strains or bioactive compounds
- Characterize biological activity
- Develop lab protocols and assays
- Conduct early environmental screening (LCA)

Scale-Up Design Framework (Piccinno et al., 2020)
- Collect complete lab protocols
- Design plant process flow diagram
- Scale unit operations (heating, stirring, filtering)
- Perform mass and energy balance
- Conduct LCA and technoeconomic analysis

Pre-Commercial Legal and Business Setup
- Legal and business administrarion
- Prepare Technology Transfer Package (TTP)
- Secure seed funding and partnerships
- Align lab-to-market timeline early

Industrial Scale Manufacturing
- Scale up to 1000+ L production
- Automate production and QA/QC systems
- Downstream: filtration, drying, packaging
- Follow GMP and QMS standards

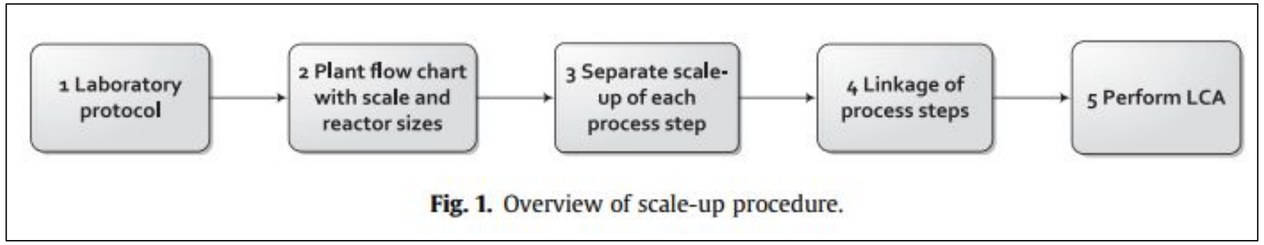

Fig. 1. Overview of scale-up procedure.

Table 1
Translation of laboratory to large-scale processes according to the presented framework.

Laboratory scale process	Scaled-up process according to framework
Reaction under heating	Heated liquid batch reaction in an insulated batch reactor with an in-tank stirrer
Mixing (magnetic stirrer) Dispersing	In-tank stirring
Blending Mixing (viscous solution) Homogenizing (all types) Dispersing	Rotor-stator type homogenizer
Pestling in mortar Grinding/milling Other particle size reduction	Grinding
Filtration (e.g. membrane, reverse osmosis, dialysis) Sieving Centrifugation/cyclonic separation Other solid–liquid separation	Filtration/centrifugation
Distillation (Rotary evaporation)	Distillation
Vacuum drying Drying Rotary evaporation	(Oven) drying/vaporization
(Manual) Transferring of liquids	Pumping
Waste disposal	Pre-treatment (case specific) Solvent recycling – distillation Solvent recycling – filtration Co- and by-product isolation
Normally not included in laboratory process	Heat recovery through heat exchangers

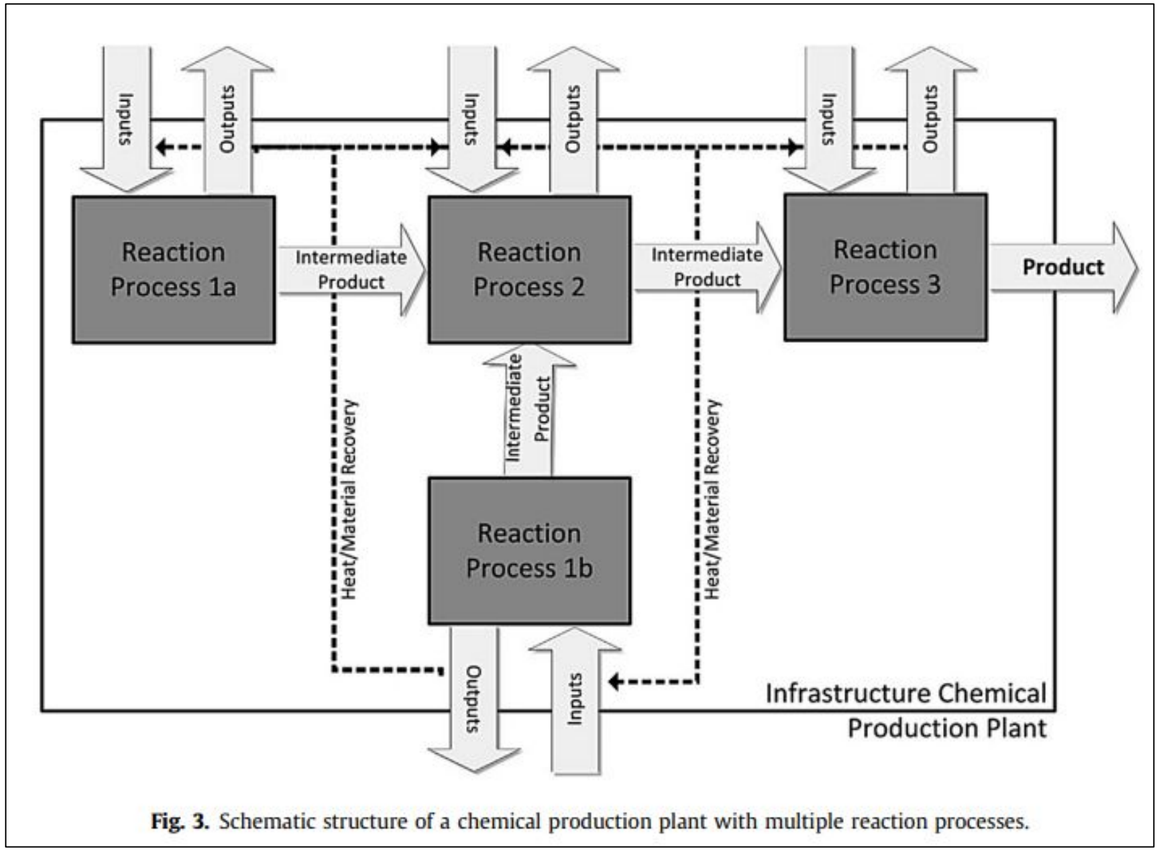

Fig. 3. Schematic structure of a chemical production plant with multiple reaction processes.

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(Source: Piccinno et al., 2020)

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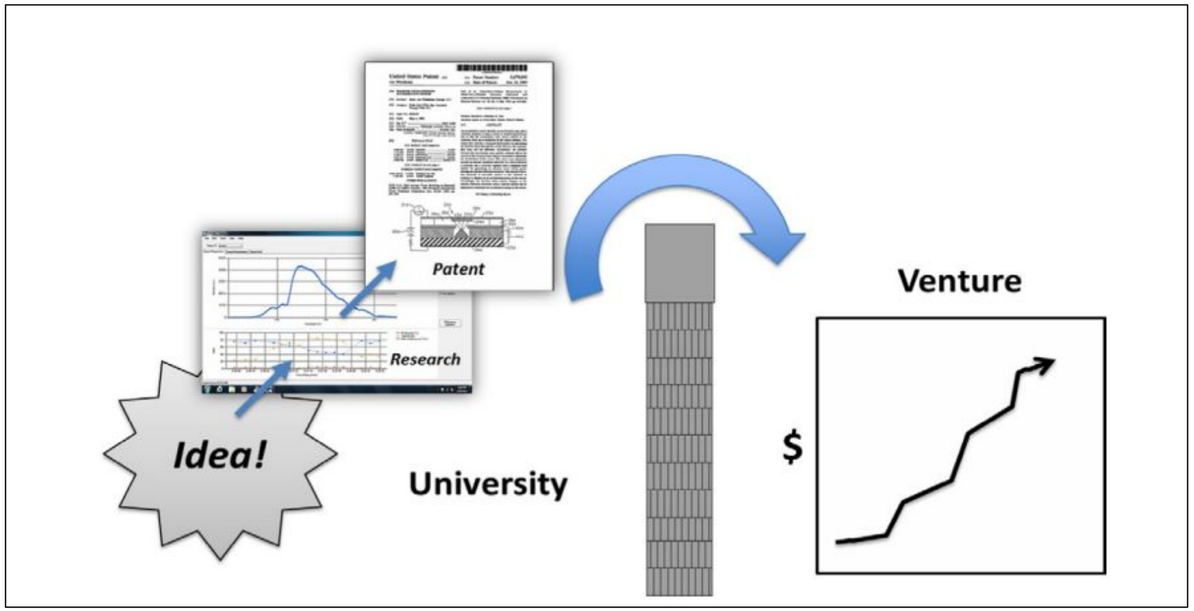
Industrial Production Strategy

Market Launch and Feedback Loop:

- Launch legally certified product
- Collect customer feedback
- Monitor safety and performance
- Improve future formulations

Cross-Cutting Enablers:

- Education: train scientists in business and law
- Key Metrics: team, tech, market, execution
- Integrate LCA and risk management tools
- Encourage university-industry collaboration



(Source: J Windheim and B Myers, 2014)

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Case Example: Zenalux Biomedical

zenalux BIOMEDICAL

Date	Event
2000	• Optical tissue spectroscopy technology invented University of Wisconsin-Madison
2004	• Inventors move to Duke University to gain access to clinical collaborators
2005	• Initiate formal translational process at Duke University (Innovation to Application program) • Seed funding ($120K)
2006	• Form Company • Apply for small business grant funding
2008	• Begin product development • $160K small business grant funding
2009	• Develop engineering prototype • $1.6M small business grant fuding
2012	• Product development complete (Zenascope™)
2013	• Initiate product seeding strategy with industry and technology thought leaders • Product placement with Duke University, Tulane University, Roswell Park Cancer Institute

University Infrastructure
- Research
- Application identification
- Market assessment
- Prototyping
- Testing

Company Platform
- Product development
- Business development
- Customer acquisition
- Venture/customer funding

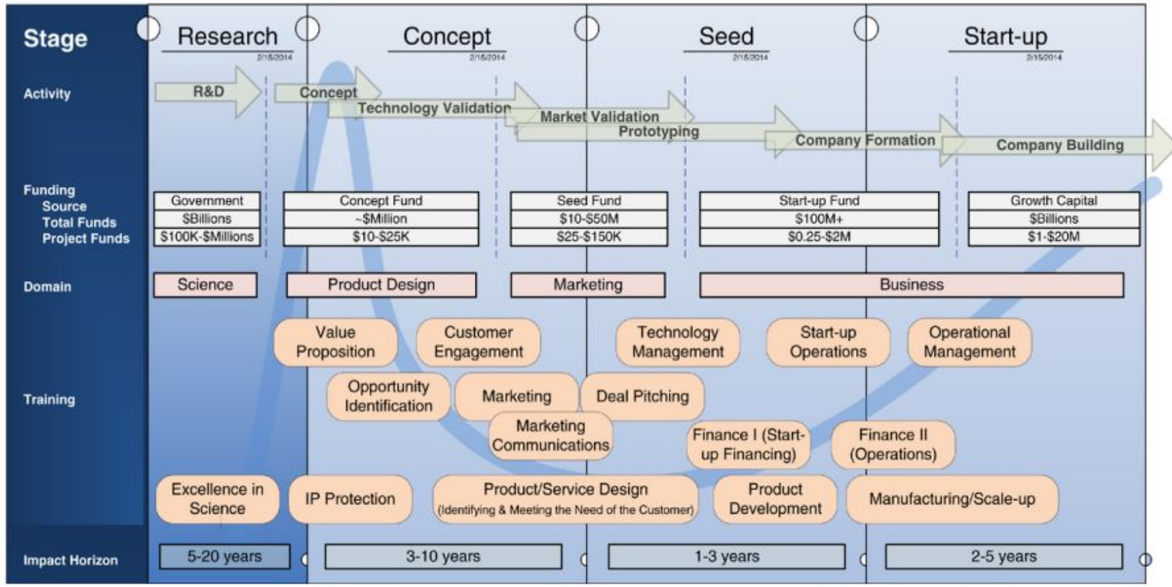

Figure 10. An example of an operational infrastructure that helps guide an entrepreneurial process without impeding creativity in the early stages. The product lifecycle (figure 1) and lab-to-market roadmap (figure 7) are shown as overlays.

- University spin-out for cancer diagnostics
- Took 12 years from invention to first product
- Example of long cycle and high capital demand

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(Source: J Windheim and B Myers, 2014)

Case Example: Nanomaterials for Sensor Applications in India

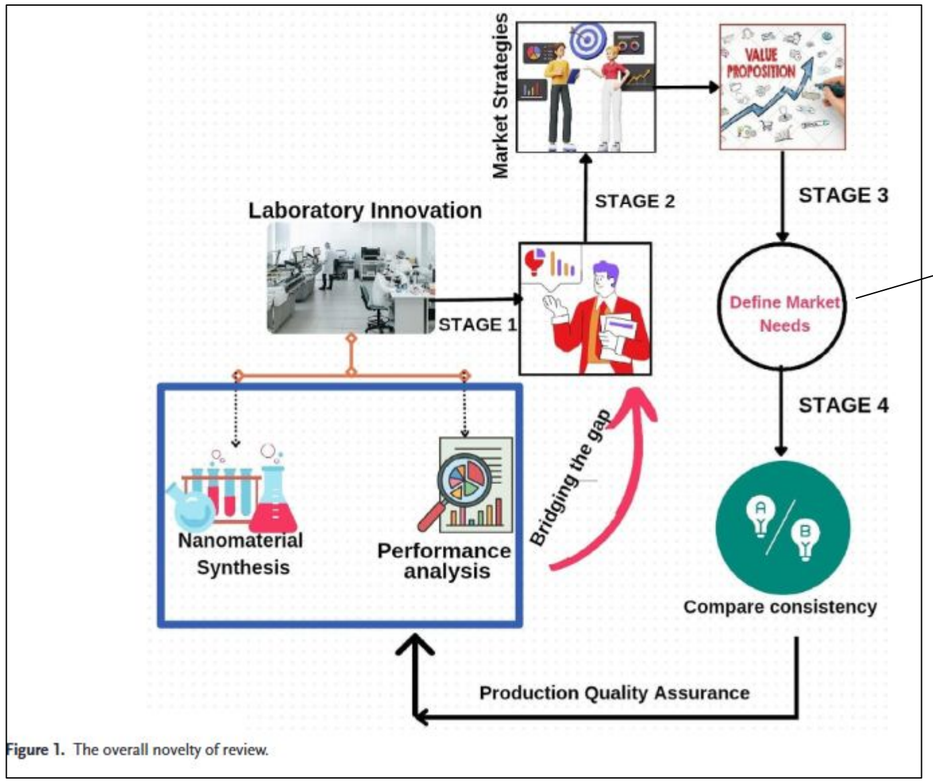
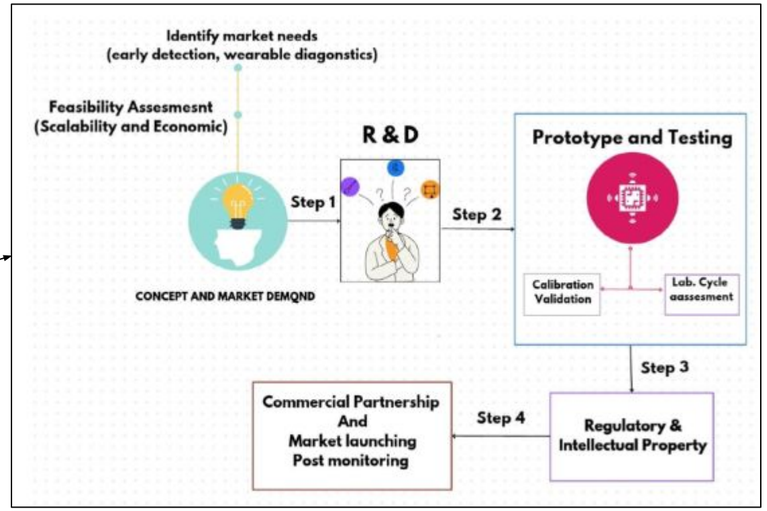


Figure 1. The overall novelty of review.



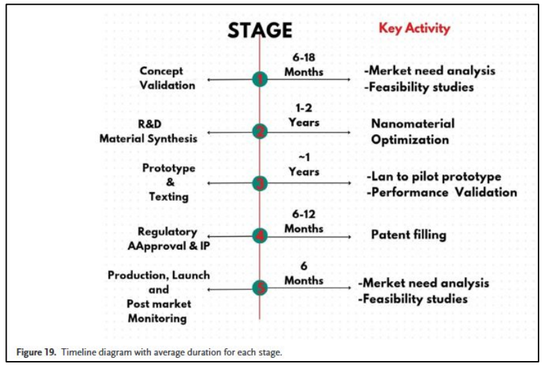


Figure 19. Timeline diagram with average duration for each stage.

Commerzialitation Strategy:

- **Understand Market Needs**: Identify real-world problems nanomaterials can solve better than traditional solutions.
- **Regulatory Compliance**: Meet safety, performance, and material use standards.
- **IP Management**: Secure patents and trade secrets to protect innovations.
- **Strategic Partnerships**: Collaborate with industry, academia, and government for R&D, funding, and distribution.
- **Customer Education**: Promote the advantages of nanomaterial-based sensors to end-users and stakeholders.

Types of Nanomaterials Used in Sensors

- **Carbon-Based**: Excellent for electrochemical sensing (e.g., ascorbic acid, uric acid, metal ions) due to high conductivity and biocompatibility.
- **Noble Metal Nanoparticles (e.g., AuNPs, AgNPs)**: Used for colorimetric sensing and biosensors; green synthesis enhances eco-friendliness.
- **Metal Oxide Nanomaterials (MONMs)**: Used for catalytic and optical sensors; tunable by pH and functional groups.
- **Quantum Dots**: Fluorescence-based detection with high sensitivity; useful in biomedical diagnostics and environmental monitoring.
- **Polymer-Based and Other Hybrids**: Versatile and tunable for mechanical flexibility, wearable applications, and enhanced performance.

(Source: Singh, et. al. 2025)

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Case Example: The Blue Iodine II

The Blue Iodine II project, funded in 2016 as part of the SME instrument, is developing new economic algae-based products rich in iodine to combat iodine deficiency in three main target groups for which no dedicated products are yet on the market: infants/7- to 14-year-olds, pregnant and breastfeeding women and the elderly. By developing the best cultivation conditions, propagules can be grown in ground tanks and obtained on a large scale. The proximity of the installations to the sea can make sea water available throughout the year, at minimal pumping costs. Seaweed production near seafood farms in the open sea also makes it possible to exploit the waste from sea bream, rich in nutrients, as food for the algae, which helps avoid discarding waste into the marine environment. The project includes the development of a biorefinery process to exploit algal biomass using cold extraction and filtration techniques to obtain purified extracts. The product obtained (IODOBEM) is a natural extract rich in iodine and other nutrients such as proteins, vitamins, and minerals, with numerous advantages over products already on the market. Firstly, it has a higher concentration of iodine (30%), and vitamin C (300%). The proteins extracted also contain essential amino acids and stabilize iodine during assimilation. IODOBEM also avoids sodium chloride overdose, a problem often found in synthetic products. Instead, it is rich in iron, which works in synergy with iodine to support thyroid function, and copper, another essential mineral for the body. The specific production mechanism also enables a 10–30% reduction in price of these products compared with their competitors.

More About Blue Iodine II: https://cordis.europa.eu/article/id/247461-novel-seaweed-products-to-combat-iodine-deficiency-disorders

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The Others Case Example

1. **CryoPlankton2**: This Norwegian project developed proprietary technology for the cryopreservation of crustacean nauplii to be used as live feed for fish aquaculture. This innovative feed significantly **improves the survival rate, growth rate, and health of juvenile fish**, while reducing deformities, addressing a major obstacle in aquaculture production. The technology matured to TRL 9, reaching industrial production volumes.
2. **INMARE (Industrial Application of Marine Enzymes)**: This project aimed to accelerate and enhance the discovery of new industrial enzymes from marine sources using innovative screening and expression platforms. By targeted sampling and generating one of the largest genomic and metagenomic enzyme collections, it successfully developed 15 ready-to-use industrial enzymes, leading to publications, patent applications, and a start-up, demonstrating the potential of omics technologies combined with high-throughput screening for new compound discovery.
3. **LIFEOMEGA**: This project focused on the industrial development and commercialization of a highly concentrated omega-3 nutritional product (EPA) for cancer patients undergoing chemotherapy. Its innovation lies in a patented emulsion formulation that is easily administered and absorbed, showing potent anti-inflammatory effects and improving patient well-being during treatment.
4. **SMILE (Slimming and Memory-Booster MIcroaLgae Extract)**: This project developed a nutraceutical product from microalgae, targeting weight control and cognitive function. It uses innovative, patented 5000-litre tubular photobioreactors for controlled microalgae cultivation, ensuring purity and sustainability. The active ingredients, fucoxanthin and omega-3 fatty acids, are delivered in a natural coconut oil matrix, and the project secured patents for cultivation methods and product use.
5. **VOPSA 2.0 (Value Omega 3 and Astaxanthin Products from SeaAlgae)**: This project developed a sustainable system for producing omega-3 and astaxanthin from microalgae. It uses a cultivation system with columnar photobioreactors and controlled raceways, combined with a **supercritical CO2 extraction method** to avoid toxic solvents, resulting in highly pure, pollutant-free, competitively priced products suitable for vegans. These products have been commercialized in a line of cosmetic items and food supplements.

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Legal Business Administration in Indonesia

1. Company Name Approval
2. Deed of Incorporation
3. Legal Entity Approval
4. Tax Number Registration
5. Domicile Letter (Except Jakarta)
6. Business Identification Number
7. Other Licenses Application

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Legal Business Administration in Indonesia

1. BPOM (Badan Pengawas Obat dan Makanan)

Definition:
BPOM is the **Indonesian Food and Drug Authority**, a government agency responsible for **supervising the safety, quality, and efficacy** of drugs, food, cosmetics, and health supplements before and after they are marketed.

Main Functions:
- Conduct pre-market evaluation (registration, testing).
- Monitor post-market products (surveillance, recalls).
- Enforce regulations to protect public health.

Example: A snack product must be registered and approved by BPOM to ensure it is safe for public consumption.

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2. NIB (Nomor Induk Berusaha)

Definition:
NIB stands for **Business Identification Number**, a **unique registration number** issued through the **OSS (Online Single Submission)** system. It legally identifies a business in Indonesia and functions as:
- Business license
- Company registration certificate (TDP)
- Import identification number (if needed)

Purpose:
Simplifies and unifies business licensing across all sectors and regions.

Example: A small business selling packaged food must obtain an NIB to operate legally and gain access to permits like BPOM or halal certification.

3. Halal Certification

Definition:
A **formal certification issued by the Halal Product Assurance Organizing Body (BPJPH)** of the Indonesian Ministry of Religious Affairs, confirming that a product or service complies with **Islamic dietary laws** and is safe for Muslim consumption or use.

Certification Process:
- Material and ingredient audit
- Production and storage process inspection
- Issuance of halal certificate and logo

Example: A cosmetics company must apply for halal certification to assure Muslim consumers that its products are free from forbidden (haram) substances.

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