



# Roadmap for Nonmedical Hardware Startups



## 01 - Problem and Need Identification

### Purpose

The goal of this step is to validate that you are solving a meaningful operational or technical problem in a real customer environment. Before building hardware, you need to understand who experiences the problem, how costly it is, and what standards or barriers may shape adoption.

### Activities

- **Identify the operational or technical problem in detail.** This may involve challenges related to efficiency, throughput, quality, safety, cost, or workflow in labs, hospitals, production, or logistics environments.
- **Observe users in their working environment.** Visit relevant sites and speak with technicians, engineers, lab staff, operators, or buyers to understand how work is actually performed and where the problem matters most.
- **Segment the market and identify promising customer groups.** Clarify whether the best first market is research labs, clinical labs, manufacturing environments, logistics providers, or another customer type.
- **Estimate market opportunity and business potential.** Build an early view of TAM, SAM, and SOM, taking into account hardware sales, services, consumables, or other recurring revenue streams.
- **Map the standards and compliance landscape.** Understand which product standards, safety requirements, import rules, or technical regulations may apply to the solution.
- **Assess existing alternatives and switching barriers.** Analyze how the problem is currently solved and what practical, technical, or financial barriers could slow customer adoption.

### Milestones and Outputs

- A documented problem and prioritized use cases
  - An initial value proposition with quantified benefits
  - Early understanding of standards and regulatory context
  - A stronger basis for product and market selection
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### Materials from LSA Training Camps

#### Business model design 1

Business Model Design Level 1 helps early-stage startups build a strong business model through practical work with the Value Proposition Canvas and Business Model Canvas. The training camp helps founders clarify customers, value creation, and commercial logic across segments, relationships, channels, revenue, activities, resources, partners, and costs, while making assumptions visible and testable.

#### Master Your Market

Master Your Market will help you learn how to understand the healthcare landscape, identify and prioritize customers, sharpen your value proposition, and communicate your story across presentations and digital channels.

## 02 - Business Model Preparation & Early Investment

### Purpose

This step is about shaping a viable hardware business and making the opportunity investable. The company needs to show not only that the product is useful, but also that the economics and go-to-market approach can work.

### Activities

- **Define the core hardware business model.** Consider whether value is created through equipment sales, leasing, consumables, service contracts, data services, or a combination of these.
- **Estimate the cost structure early.** Build a first view of bill of materials, assembly, logistics, installation, quality control, service, and support costs so the business model is grounded in reality.
- **Develop pricing and commercial assumptions.** Explore how customers may buy the product, how often, through which channels, and what long-term revenue potential each customer could represent.
- **Outline the sales and distribution strategy.** Consider whether the product should be sold directly, via distributors, through OEM relationships, or in collaboration with industry partners.
- **Prepare an early funding strategy.** Hardware often requires more capital earlier, so map relevant funding sources such as grants, angels, pre-seed investors, leasing partners, or asset-based financing.
- **Create a milestone roadmap for development and market entry.** Include the most important prototype, testing, certification, and customer milestones that will reduce risk and support fundraising.

### Milestones and Outputs

- An investment-ready pitch with business model and go-to-market logic
- Clear target customer segments and pilot pipeline
- Early pricing and unit economics assumptions
- A milestone roadmap aligning product, sales, and compliance

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### Materials from LSA Training Camps

#### Basics of Investment & Capital for Life Science Startups

Basics of Investment & Capital helps early-stage Life Science and health tech startups understand investor expectations and prepare for funding. The training camp covers investor readiness, how investors evaluate Life Science opportunities (due diligence), strategic networking, and the role of ESG, EU taxonomy and non-dilutive funding.

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### **Business model design 2**

Business Model Design Level 2 builds on the work from Level 1 and helps startups turn business model assumptions into structured learning. Through practical exercises, founders identify key hypotheses, design experiments, and use evidence to refine their strategy and business model. The training camp introduces experimentation as a way to test desirability, feasibility, and viability, and includes work on validation methods, business strategy, and different commercialization paths such as direct sales and licensing.

### **How venture capital works & the key elements of raising capital**

How Venture Capital Works & the Key Elements of Raising Capital gives a practical introduction to venture capital, what makes a company investable, and how to prepare for fundraising. The training camp covers financing options across stages, how investors assess risk and return, and how to communicate a credible equity story.

### **Master Your Market**

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### **Winning the deal – Selling to public sector**

Winning the deal – Selling to public sector helps life science startups understand how public healthcare systems buy, decide and implement new solutions. The training camp introduces procurement logic, key decision-makers, value propositions, business cases, partnerships and market entry strategies. Participants work hands-on with where their solution fits, who to approach, and how to communicate value in a way that resonates with public buyers.

## 03 - Company Formation

### Purpose

The purpose of this step is to build the legal and organizational foundation required for a hardware startup. This includes ownership of designs and IP, clarity on founder roles, and early access to the right partners.

### Activities

- **Incorporate the company and define founder ownership.** The legal setup should support fundraising, contracts, and future operational scale.
- **Agree on founder roles based on the needs of a hardware business.** This often includes engineering, operations, manufacturing, and commercial responsibilities, which should be clearly allocated early.
- **Secure IP across hardware and software elements.** Make sure the company controls relevant rights related to mechanics, electronics, firmware, software, and technical know-how.
- **Put key contracts in place with external partners.** If design, prototyping, or manufacturing is outsourced, establish agreements that protect the company and clarify responsibilities.
- **Build an advisory structure with industry relevance.** Hardware startups benefit from experienced support in manufacturing, certification, supply chain, and commercialization.
- **Start building an initial partner and supplier network.** Early relationships with prototyping partners, component suppliers, and manufacturing contacts can become strategically valuable later.

### Milestones and Outputs

- A legal entity with ownership of core designs and IP
- Founder and governance structure in place
- Initial supplier and development partner network established
- A company setup ready to support prototype development

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### Materials from LSA Training Camps

#### Dynamic Leadership & Team Excellence for Life Science Startups

Dynamic Leadership & Team Excellence will help you understand and develop your leadership and communication skills so you can lead clearly and confidently. You learn how to create a strong, healthy team with clear roles and responsibilities, and how to build a supportive structure. Throughout, the workshop connects sustainable leadership and culture to building a long-term, resilient business.

## 04 - Prototype and Technical Feasibility

### Purpose

This step is about proving that the hardware solution works technically. The company builds a functional prototype and begins validating performance, usability, and fit with real-world workflows.

### Activities

- **Develop the first functional prototype.** This may include mechanical components, electronics, firmware, control systems, and software needed to demonstrate the core concept.
- **Test the core technical performance.** Assess whether the product delivers the expected functionality, precision, reliability, and safety at a level that justifies further development.
- **Consider manufacturability from the start.** Even in early prototypes, begin thinking about design-for-manufacturing and design-for-assembly to avoid costly redesign later.
- **Put key contracts in place with external partners.** If design, prototyping, or manufacturing is outsourced, establish agreements that protect the company and clarify responsibilities.
- **Get user feedback in relevant environments.** Bring the prototype into labs, hospitals, or industrial settings where real users can interact with it and comment on ergonomics, usability, and workflow fit.
- **Use testing to improve the design.** The goal is not only to prove that it works, but also to identify what must change before the design can become production-ready.

### Milestones and Outputs

- A working prototype that demonstrates core functionality
- Initial user feedback on usability and workflow fit
- Refined product requirements and technical specifications
- Early evidence that the concept can work in practice

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## 05 - Product Engineering & Pre-Compliance Testing

### Purpose

The purpose of this step is to move from prototype toward a robust and production-ready product design. The company focuses on engineering improvements, pre-compliance testing, and reducing technical risk.

### Activities

- **Refine the design through engineering iterations.** Improve robustness, safety, cost, reliability, and ease of use based on prototype testing and user feedback.
- **Run pre-compliance testing early.** Assess electrical safety, EMC, environmental tolerance, mechanical stress, and other relevant conditions before formal certification begins.
- **Improve manufacturability and assembly planning.** Strengthen DFM and DFA so the product can move into pilot batches or small-series production more efficiently.
- **Select and qualify key suppliers and partners.** Identify reliable suppliers for critical components and assess manufacturing partners that can support the next stages.
- **Define essential quality elements.** Start building incoming inspection routines, test procedures, traceability practices, and documentation standards.
- **Plan the path to formal compliance.** Clarify which certifications, declarations, standards, and test reports will be needed for commercialization.

### Milestones and Outputs

- A nearly final product design ready for pilot production
  - Pre-compliance results or a clear mitigation plan
  - Defined quality and test strategy
  - Reduced technical and regulatory risk before formal certification
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## 06 - Pilot Production and Field Pilots

### Purpose

This step is where the company starts proving real-world value. The focus is to test the product with actual customers, demonstrate useful outcomes, and learn what is needed for adoption and commercialization.

### Activities

- **Conduct formal certification and compliance testing.** Complete the required testing and conformity work for relevant standards such as CE, EMC, electrical safety, machinery rules, UL, or similar requirements.
- **Finalize the product documentation package.** Prepare manuals, labels, safety instructions, technical files, declarations, and other materials required for market entry.
- **Define service and support conditions.** Establish warranty terms, service level agreements, spare-parts policies, and support models that can be offered consistently to customers.
- **Prepare for country-specific market access needs.** If relevant, adapt for import rules, local safety requirements, language needs, and distribution conditions across geographies.
- **Refine pricing, channel, and service models.** Make sure the commercial setup reflects the realities of installation, support, maintenance, and long-term customer ownership.
- **Coordinate compliance and launch planning.** Certification should lead directly into commercial readiness rather than being treated as a separate final task.

### Milestones and Outputs

- Required certifications and declarations of conformity obtained
  - Complete documentation package ready for market
  - Market access and launch plan defined
  - Product and organization prepared for broader rollout
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## 07 - Advanced Clinical Development / Market Access Preparation

### Purpose

The goal of this step is to obtain the certifications and market-readiness needed for broader commercialization. The company finalizes product documentation, completes compliance work, and prepares its launch model.

### Activities

- **Conduct formal certification and compliance testing.** Complete the required testing and conformity work for relevant standards such as CE, EMC, electrical safety, machinery rules, UL, or similar requirements.
- **Finalize the product documentation package.** Prepare manuals, labels, safety instructions, technical files, declarations, and other materials required for market entry.
- **Define service and support conditions.** Establish warranty terms, service level agreements, spare-parts policies, and support models that can be offered consistently to customers.
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  - Complete documentation package ready for market
  - Market access and launch plan defined
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## 08 - Commercialization

### Purpose

This step is about turning validated hardware into a growing business. The company ramps up production, builds its customer base, and creates the commercial and service capabilities needed for growth.

### Activities

- **Ramp up production and supply chain operations.** Improve forecasting, inventory planning, logistics, and delivery performance so the company can meet customer demand reliably.
- **Build or expand sales and service channels.** This may include direct sales teams, distributors, installation partners, and field service structures.
- **Launch targeted sales and marketing activities.** Engage relevant industries, labs, hospitals, manufacturers, or operations teams with messaging that reflects the product's practical value.
- **Provide customer training and onboarding.** Successful hardware adoption often depends on users understanding setup, operation, maintenance, and performance expectations.
- **Establish strong support channels.** Build systems for remote support, service response, maintenance, and issue handling to create customer trust and retention.
- **Improve the offer through market feedback.** Real customer use will reveal how the company can refine features, service models, and positioning.

### Milestones and Outputs

- Growing revenue from equipment, services, or consumables
  - A growing installed base of customers
  - Stronger recurring service or maintenance revenue
  - Positive customer references and market traction
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## 09 - Organizational Build-Up and Scaling

### Purpose

The purpose of this step is to build a hardware organization that can scale sustainably. Growth now depends on strong operations, service quality, and leadership across multiple functions.

### Activities

- **Hire the key roles needed for scale.** Expand the team with leaders in operations, supply chain, service, quality, sales, and other functions required for a larger installed base.
- **Implement operational KPIs and reporting.** Track metrics such as delivery performance, failure rates, service response time, customer satisfaction, and quality outcomes.
- **Standardize the way the company operates.** Build repeatable processes across production, quality assurance, installation, service, and commercial execution.
- **Expand internationally through the right model.** Use distributors, subsidiaries, or joint ventures depending on market size, complexity, and strategic fit.
- **Secure financing to support scaling.** Hardware scale often requires a mix of equity, debt, leasing facilities, or asset-backed arrangements.
- **Improve operations continuously based on data.** Scaling well requires tight feedback loops between production, service, and customer experience.

### Milestones and Outputs

- A robust operations and service organization
- Stable supply chain and delivery performance
- Repeatable operational processes across markets
- A stronger platform for growth and expansion

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## 10 - Strategic Maturity and Exit / Expansion

### Purpose

This final step is about long-term strategic development and value creation. The company strengthens its market position while preparing for expansion, acquisition, or another strategic outcome.

### Activities

- **Prepare the company for strategic options.** This may include IPO preparation, strategic sale, stronger governance, and more mature financial and operational reporting.
- **Expand the product portfolio over time.** Consider additional hardware lines, complementary software, service offerings, or adjacent applications that deepen the company's market presence.
- **Strengthen the global commercial structure.** Mature hardware companies often need stronger distributor networks, key account capabilities, and international operating models.
- **Optimize the capital structure.** Review how equity, debt, project financing, leasing, or other instruments can best support long-term growth and flexibility.
- **Build a stronger strategic position in the market.** Increase the company's attractiveness to partners, acquirers, customers, and investors through installed base, recurring revenue, and brand strength.
- **Keep adjusting strategy as the market evolves.** Geography, partnerships, product priorities, and business model choices should continue to evolve with competitive and customer dynamics.

### Milestones and Outputs

- A mature hardware company with a strong installed base
- Growing service and recurring revenue streams
- Attractive strategic positioning for partners or acquirers
- Readiness for exit, expansion, or long-term independent growth

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