Regulatory Roadmap to market – Medical Device

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Training camp description

Regulatory Roadmap to Market – Medical Device gives startup founders a practical introduction to bringing a medical device to market under EU rules. It covers the path from intended purpose and classification to quality management, clinical evidence, CE marking and post-market surveillance, helping early-stage companies make stronger development and regulatory decisions from the start.

Key takeaways from the workshop

Start with intended purpose and regulatory route - A clear intended purpose is the foundation for the entire roadmap. Founders need to define what the product does, who it is for, where it is used and what claims are being made. These decisions determine whether the product qualifies as a medical device, how it is classified and which regulatory path, standards and evidence requirements will apply.

Build compliance into development from day one - Regulatory work should not sit outside product development. Quality management, risk management, design controls, supplier oversight and documentation need to be built into the way the company works from an early stage. This creates structure, reduces rework and makes it easier to prepare for technical documentation, conformity assessment and CE marking.

Think beyond approval to long-term market readiness - Clinical evidence, compliance and product safety are built step by step and must continue after launch. Startups should treat evidence generation, post-market surveillance and continuous improvement as part of the full market journey. CE marking is an important milestone, but not the end of the manufacturer's responsibilities.

Best practices

Turn strategy into clear working documents - Write and maintain short core documents for intended purpose, product claims, regulatory route and evidence needs. These should be practical tools used across product, clinical and commercial discussions, helping the team stay aligned and avoid unclear or unsupported claims.

Create lean systems that support execution - Set up a simple but effective quality structure early, with clear processes for document control, design and development, risk management, supplier control and change handling. Use milestone-based reviews to check progress, confirm requirements and identify gaps before they become expensive problems.

Build the right support around the company - Bring in regulatory, quality and clinical expertise early enough to shape key decisions, not only to review them later. Combine internal ownership with external guidance where needed, so the company can move faster while building a realistic and compliant path to market.