

**Evnia's Lifecycle Management
Services for HealthTech Startups**

**Holistic Consulting Services for
MedTech & BioTech**



www.evnia.dk

The secret to MedTech/BioTech's full potential? Remembering it's never just about the Tech!

Evnia introduces a paradigm shift in the MedTech/BioTech consulting services for start-ups by offering expert lifecycle management services.

We support manufacturers throughout the medical products development roadmap. From the early concept and design stages to verification and validation, until market access and post-market adulthood, **Evnia enables compliance and ensures audit and inspection readiness.**

We serve MedTech/BioTech Startups by remaining flexible and proactive.

From building long-term partnerships to developing regulatory and clinical strategies, Evnia recognises each medical product's unique needs and offers customised services adding clinical and commercial value to innovative ideas. We shorten the time until market access and we support day-to-day business pre- and post- market.

Using industry knowledge, proprietary tools, and streamlined processes, we help you turn challenges into opportunities.

Not sure how to turn the sketch on that napkin into a successful medical product?

Contact Evnia today and take your idea to the international markets faster, with less risk, and make patient impact.



**A start-up does not only need compliant solutions to thrive in a rapidly evolving Medtech/BioTech industry.
It mostly needs customised and pragmatic answers to the correct questions!**

It is often challenging to navigate the regulatory decision-making process, which eventually results in a significant burden for start-ups.

Evnia's mission is to debunk the misconception that regulatory compliance kills innovation. We enable start-ups to identify and address regulatory requirements to achieve agility, resilience, market differentiation, and sustainable business growth!

Technology we support



Medical Devices



SaMD



AI-assisted medical products



Digital Health



Wearables



In-Vitro Diagnostics



Companion Diagnostics



Drug Delivery Systems



Evnia recently opened an office in London, we currently serve our clients with two offices in Denmark (Copenhagen, Aarhus), UK and Greece.



The Evnia way

An ecosystem of in-house and ad-hoc experts that combine field expertise with “big picture” strategic mindset accompany our start-up clients during their product development and certification journey to create value at every step of the process.

Our mission:

A one-stop shop to cover the life-long needs of your portfolio!
We assess, develop and implement growth readiness roadmaps by analysing market unmet needs, identifying key growth drivers and prioritising regulatory tasks that align with your go-to-market strategy.



Strategic market analysis



- Competitive analysis and product positioning
- Due diligence
- Value proposition
- Identification of “optimal” first market
- Opportunity Evaluation
- Support with funding opportunities
- In- and Out- Licencing
- Market Access

Regulatory Journey



- Device Classification
- Benchmarking
- State of the Art
- Regulatory framework analysis
- Verification and Validation requirements
- Clinical data requirements
- Post-Market requirements
- Conformity assessment and approval processes
- Communication with Authorities

Quality Management System



- ISO 13485
- International QMS requirements
- Establishment of processes and templates
- Internal Audits

Technical Journey



- Support with V&V testing
- Technical Files
- Technological Scouting

(Risk Management, Usability, Electrical Safety, Cybersecurity, Sterilisation, Packaging, Biological Safety etc.)

Clinical Journey



- Clinical Strategy
- Development and conduct of clinical activities
- Evnia Clinical Network
- Patient Journey

Training Journey



- Workshops (regulatory, technical, clinical)
- Personalised Learning expeditions
- On-site educational missions
- Operational Excellence
- Corporate Mindfulness



Evnia's Thessaloniki (Greece) office.



Contact Evnia today to turn your idea to a successful medical product!



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