MedTech Business Consultant

Ing. Alina Draghici

Executive Profile

Strategic MedTech consultant with over 7 years of experience supporting leading medical device organizations across Central & Eastern Europe. Proven expertise in regulatory strategy, operational optimization, and market expansion. Track record includes successful projects with Philips, Zimmer Biomet, and Stryker. Combines technical proficiency, regional insight, and business acumen to deliver measurable, sustainable results in complex healthcare environments.

CONSULTING SERVICES

- Market & Business Strategy
- Quality Management
- Regulatory Affairs Management
- Operational Transformations
- Project & Program Management

Let’s Partner for Growth!

If you're scaling healthcare operations, navigating complex regulatory landscapes, or aiming to improve service delivery in across regions, I offer proven expertise, strategic execution, and measurable results.

BOOK A CONSULTATION

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Portfolio of detailed Services

A. Market & Business Strategy

- Identify high-value market opportunities, optimize product–market fit, and drive sustainable business growth
- Design innovative business models and perform comprehensive product portfolio analyses
- Implement strategic partner management initiatives for indirect channel expansion
- Build scalable commercial processes, align CRM workflows, and establish high-impact performance dashboards

B. Quality Management

- Develop and review QMS frameworks covering document control, change management, process validation, and risk mitigation
- Prepare for ISO 9001 and ISO 13485 audits with precision and compliance excellence
- Deliver targeted training programs to elevate organizational learning and development
- Conduct rigorous post-market surveillance and vigilance reporting to safeguard compliance
- Execute CAPA initiatives and manage non-conformities to uphold quality standards
- Champion continuous improvement practices for sustained operational excellence
- Facilitate impactful workshops and hands-on coaching to embed best practices

C. Regulatory Affairs Management

- Formulate and execute global regulatory strategies ensuring compliance with (EU) 2017/745 (MDR)
- Lead direct company launches in targeted CEE markets
- Support regulatory submissions and provide actionable RA intelligence
- Prepare markets for entry, ensuring smooth registration and inspection readiness
- Adapt to evolving regulatory changes and European legislative requirements proactively

D. Operational Transformations

- Optimize processes by standardizing and enhancing end-to-end service operations
- Unify direct and partner delivery models for maximum efficiency
- Enhance customer satisfaction by implementing advanced support metrics and service benchmarks

E. Project & Program Management

- Oversee complex cross-functional programs, including new product introductions (NPI), quality and compliance initiatives, and global process launches
- Establish PMO structures, KPIs, risk management protocols, and executive-level reporting systems
- Manage stakeholder engagement to ensure seamless team adoption during mergers, implementations, and transitions
- Optimize resources and timelines to maximize project delivery efficiency.

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