Congenius

Shaping the impact of Agentic AI on your MedTech business

Maximise your understanding of Agentic AI and anticipate practical action with Congenius.

Read on to find out how our MedTech experts can help you formulate and execute a sustainable AI strategy.

While traditional digitalisation primarily focused on process automation, Agentic AI affects decision-making, product development, quality management, compliance, and cross-functional collaboration.

We combine deep sector expertise, regulatory understanding, and practical transformation experience to turn emerging AI developments into insightful action across five key areas:

1 AI strategy for MedTech companies

2 Regulatory & Reimbursement support for AI in MedTech products

3 Quality support for AI in MedTech products

4 AI-enabled process support

5 AI solution selection

1 AI strategy for MedTech companies

Proactively shape the future of leadership, innovation, and compliance.

Early understanding of how Agentic AI will reshape leadership, functional operating models, and regulated innovation is crucial to staying ahead of the curve.

We can support you with:

- Identifying relevant developments early
- Creating a shared understanding of Agentic AI amongst leadership
- Preparing key functions for new ways of working
- Assessing opportunities & risks in regulated environments
- Building internal & external thought leadership
- Translating insights into concrete transformation initiatives

2 Regulatory & Reimbursement support for AI in MedTech products

Successfully navigate the evolving regulatory landscape for AI-enabled medical devices.

Distilling complex AI regulations into practical product, development, and market-access decisions saves time and cost, and mitigates compliance risk.

We can help you to:

- Identify whether AI functionality is regulated as a medical device
- Clarify what's allowed, restricted, or high-risk in target markets
- Define a compliant intended use & claims strategy
- Prepare for notified body or health authority interactions throughout the product life cycle
- Assess reimbursement pathways
- Align regulatory, clinical, & reimbursement strategies
- Reduce regulatory & market-access risk whilst maintaining innovation momentum

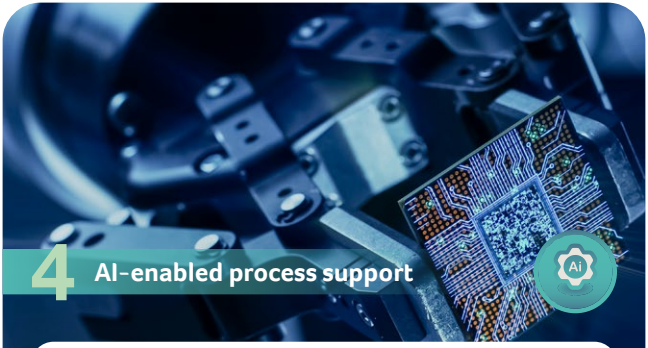
3 Quality support for AI in MedTech products

Fulfil AI requirements efficiently and effectively.

Developing and maintaining safe, compliant AI-enabled medical devices while integrating AI-specific regulatory requirements into efficient QMS and product life cycle processes facilitates smooth, consistent product delivery.

Our support includes:

- Defining a manageable intended purpose
- Identifying an adequate AI model & learning algorithm
- Meeting AI-specific challenges in non-engineering functions & tasks
- Building AI-specific evidence & documentation packages
- Managing AI updates & model changes throughout the product life cycle
- Integrating AI governance into QMS & product development
- Reducing compliance & operative risks without compromising innovation



4 AI-enabled process support

Implement quality-compliant, validated, and audit-ready AI-supported processes.

Evolving from informal AI experimentation to controlled, validated, and scalable AI-enabled ways of working can accelerate productivity across quality, regulatory, engineering, clinical, manufacturing, and business functions.

We can help with:

- Identifying quality-relevant AI use cases
- Defining what's allowed, restricted, or unacceptable in regulated processes
- Assessing AI process risks & validation needs
- Establishing audit-ready AI governance
- Validating AI-supported workflows using a risk-based approach
- Updating SOPs, work instructions, & QMS documentation
- Defining human oversight & approval models
- Controlling AI-generated outputs & regulated records
- Preparing for audits, inspections, & notified body questions
- Scaling adoption whilst maintaining process control

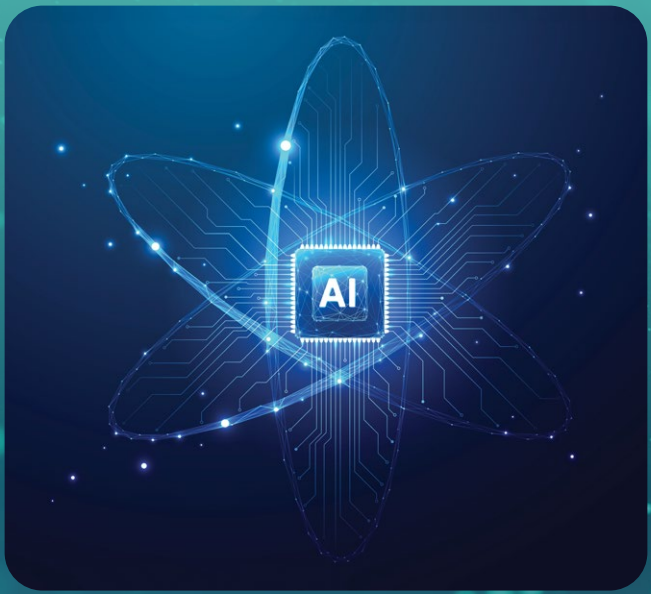
5 AI solution selection

Select, evaluate, and implement the right AI-enabled platforms for your organisation.

Identifying appropriate, compliant, and scalable AI tools for your regulatory, quality, clinical, and operational needs is an investment in sustainable success.

Through a risk-based approach, we can support you with:

- Identifying the most relevant AI use cases
- Understanding the available market solutions
- Avoiding unsuitable or non-compliant tools
- Objective vendor comparison
- Aligning tool selection with QMS & regulatory expectations
- Defining validation & supplier qualification needs
- Designing controlled pilots before scaling
- Reducing technology, compliance, & implementation risk
- Building a practical roadmap for cross-functional AI adoption



Let's shape the impact of Agentic AI on your business.

From strategic leadership guidance and cross-functional insight to practical advice and hands-on support, our smart approach to AI integration enables improved productivity - ultimately fuelling innovation to deliver enhanced medical solutions.

Get in touch to find out how we could help with your AI journey.

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