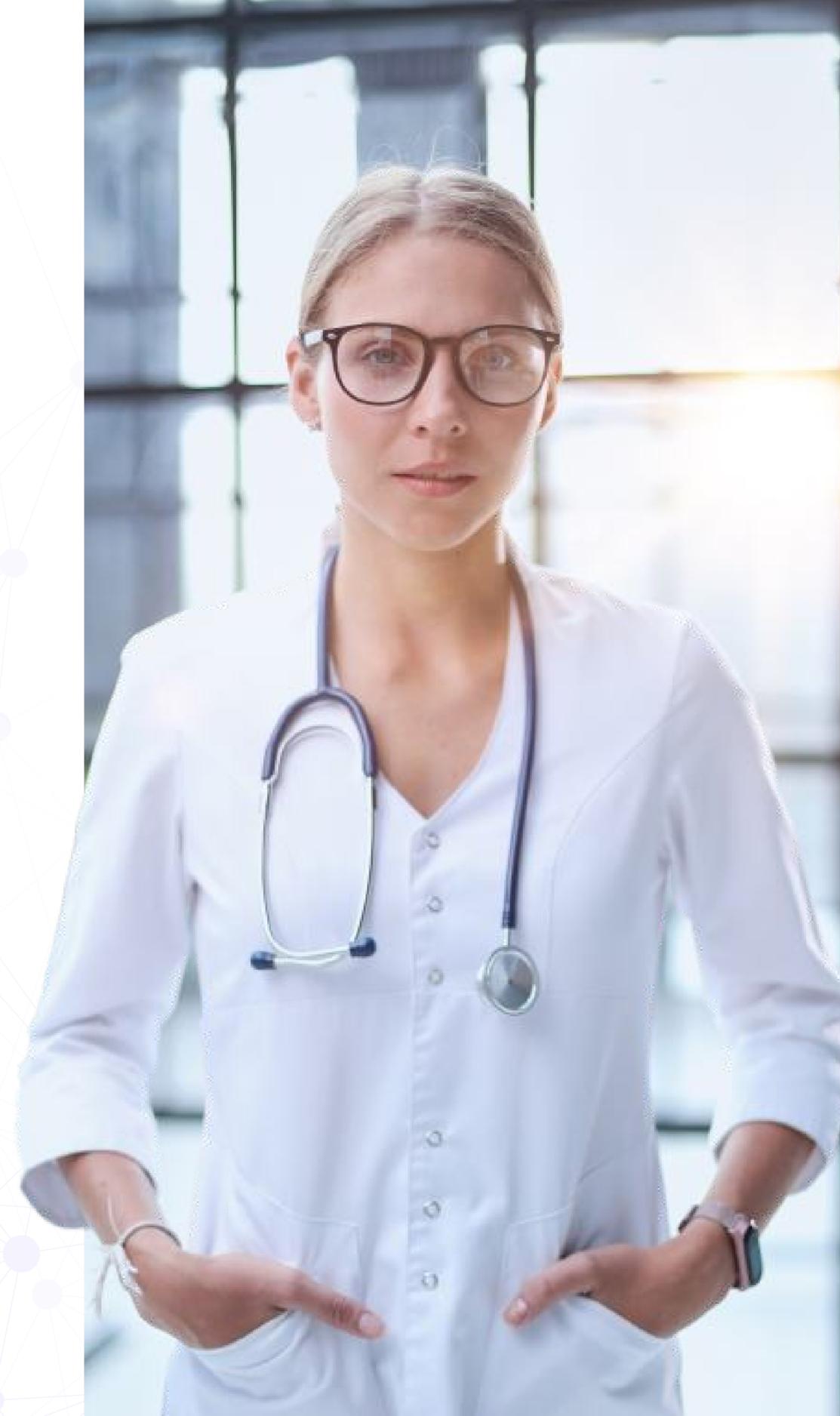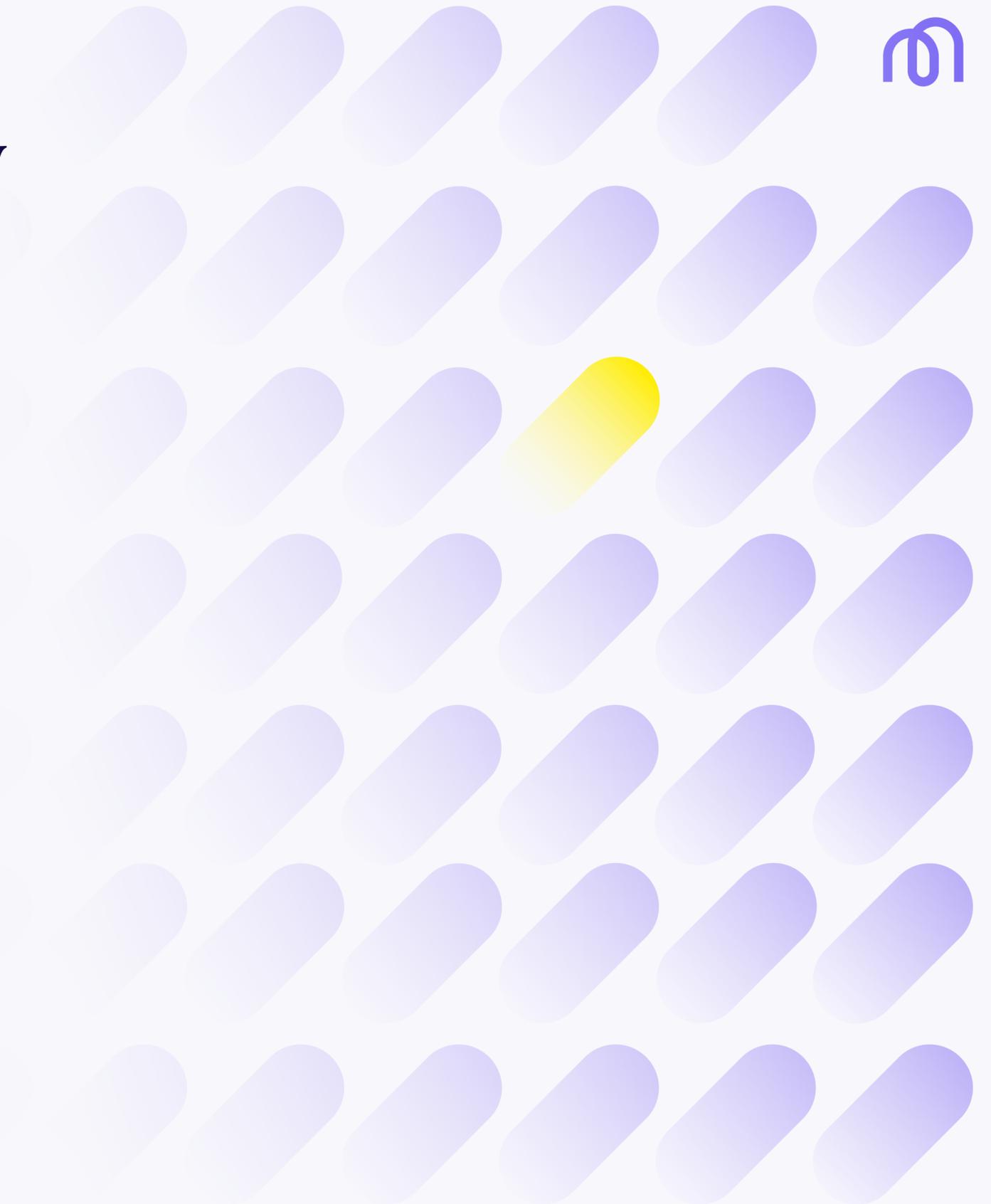# brighthills

Navigating MedTech Regulations with Expert Software Solutions

Turning MedTech Complexity into Your Competitive Advantage

We simplify the development process, helping you overcome regulatory hurdles and **deliver cutting-edge medical software** that meet the highest standards of quality and compliance.

Our Company in Numbers: A Snapshot of Success

With relationships spanning nearly two decades, most of our **customers view us as a long-term strategic partner**. Our **employees demonstrate this mindset through their loyalty;** our average turnover rate is 5.8 years.

+5.8
years – our employee turnover rate

Loyalty to our company helps us retain crucial domain knowledge for our clients.

+20
years of MedTech experience

has positioned us as leaders in the industry, delivering innovative solutions that meet evolving healthcare needs.

+150
colleagues

work tirelessly to ensure our clients are satisfied and achieve their business goals.

+400
projects

successfully completed, each crafted to maximize value and effectiveness for our clients.

Why BrightHills ?

A Trusted Partner in Innovation

We run the full marathon with you. We provide continuous support, helping MedTech innovators bring their products to market swiftly and with confidence. Our **longstanding collaborations** prove that clients can always rely on us for successful project outcomes.

Comprehensive Software Services for Market Success

Whether to address a short-term development need or build a complete solution, our comprehensive service offering helps clients standout among their competitors. Our MedTech experts offer a **one-stop-shop** with a proven, high-quality development model that helps clients **go to market faster.**

Streamlined Development combined with Extensive QA Expertise

Whether U.S. FDA or EU MDR, we **simplify the complexities** of navigating **regulatory compliance** so clients have the peace of mind to focus on coming up with innovative solutions. Our QA team meticulously oversees **process control, risk management, and continuous improvement, enabling smooth regulatory approvals** and market success.

What BrightHills brings to the table?
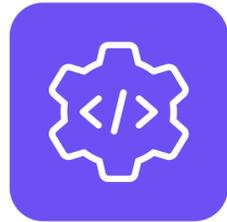
Software as a Medical Device (SaMD)

You can count on our expertise for your innovative project, whether it's a full journey from idea to end-user or just specific steps.

Standard Operating Procedures (SOPs)

From writing to streamlining, we offer customized SOPs that enhance every stage of your Software Development Life Cycle.

Premium team extension

We tailor our scalable teams to your needs, so you can be sure that the team size and expertise will always align with your constantly changing business needs.

Our Services

Services to help you with streamlined innovation.

1. Design
2. Software Development
3. Testing
4. QA/RA
5. Support
6. Consultation

Product Design

Let's design a product people love!
We build a **digital experience** to help you
achieve your **business goals**.

UI Design

+ High-fidelity Proto
+ Look and Feel
+ Visual Design
+ App Design
+ Design System
+ Icon System
+ Typography
+ Interaction Design

Product Design, Business Analysis

+ Product Strategy
+ Business Needs
+ Product Ownership
+ Technical Analysis
+ User Story Writing

UX Design

+ User Research
+ User Journey
+ User Persona
+ Low-fidelity
+ Proto Usability Test
+ UX Copy
+ Information
+ Architecture

Software Development

Our full stack development team delivers **high-quality, scalable solutions** using agile project management methodologies.

MedTech relevancies

+ HL7, FHIR
+ Mirth Connect, Iguana
+ DICOM
+ HIPAA
+ Physical device integration

Cloud and Scalability

+ Microsoft Azure
+ Amazon Web Services
+ Cloud migration
+ Lift and Shift
+ Cloud Native solutions

Backend and Integration

+ Java, .NET, C/C++, Node.js, Python
+ API implementation
+ Microservices
+ Event-drive architectures
+ Serverless architectures

Frontend development

+ Angular, Vue.JS, React
+ State managament
+ Progressive Web Apps
+ Responsive applications

Mobile application development

+ Java, Kotlin, Swift
+ React Native, Flutter
+ Hardware integration
+ In-app purchase integration
+ Offline application development

HelloAI professional

Microsoft CERTIFIED AZURE DEVELOPER ASSOCIATE

aws certified Cloud Practitioner FOUNDATIONAL

Software Development

Our full stack development team delivers **high-quality, scalable solutions** using agile project management methodologies.

Data

+ SQL (Oracle, SQL Server, PgSQL, MySQL)
+ NoSQL (Cassandra, MongoDB)
+ Data Pipelines
+ Data visualization (PowerBI, Qlik)
+ Apache Kafka, Snowflake

DevOps and Automation

+ Infrastructure as a Code
+ Docker, Kubernetes
+ CI/CD (GitLab, Jenkins, GitHub Actions)
+ Monitoring
+ Security and Compliance

AI & ML

+ Gen AI
+ ML integration (TensorFlow, PyTorch)
+ Flowise
+ LangChain
+ ChainLit
+ LangFlow
+ PyTorch
+ Python
+ Pinecone
+ PostgreSQL – pgvector

Testing

We fully test MedTech products in order to catch and fix issues early and ensure solutions are market-ready. Our rigorous approach guarantees that our clients' solutions will meet all **regulatory and quality standards** while also ensuring **customer satisfaction.**

AI-driven Testing

Our AI-powered testing tool streamlines the generation of precise test cases linked to specific requirements and hazards. AI-driven testing ensures regulatory compliance and optimizes your testing process, freeing up resources to focus on core business operations and innovation.

Automated Testing

Our automation solutions, including regression, performance, and API testing, can save you time and reduce human error. With expertise in tools like Selenium and Playwright, we ensure reliable and reusable tests that enhance accuracy and speed up your development process.

Manual Testing

By incorporating manual testing, we add a layer of human insight that complements automated processes, providing comprehensive validation to ensure our medical software performs accurately in real-world scenarios.

ISTQB® Gold Partner
International Software
Testing Qualifications Board

Support

We proactively engage with teams and users to ensure expectations are met. The Support services we offer you not only aim to solve problems, but also form the foundation for strong, long-term relationships.

Inside Sales Support

✦ Outsourced sales activity
✦ Administrative work
✦ Contract creation
✦ Contract modification
✦ Warranty requests

Technical Support Levels

✦ Tier 1
✦ Tier 2
✦ Tier 3

Technical Support Languages

✦ English
✦ German
✦ French
✦ Italian

Quality & Regulatory Assurance

Our processes and current project portfolio are firmly grounded in **extensive market research** and past **experience**.

Project Support

- Deliverables compliance assurance
- Applicable procedures assurance
- Process optimization consulting
- Ongoing production records review

Consultation

- Team scaling for startups
- FDA/MDR guidance

Project Review

- Deliverables assessment
- Gap analysis
- Documentation refinement consulting

Re-submission

- Documentation preparation
- Regulatory compliance updates

MedTech Consulting

Our experts and mentors are committed to strengthening business through innovation management, design thinking, and technical training.

Design Thinking

The Design Thinking methodology allows for creative problem solving in cases where no obvious solutions are apparent or new perspectives from clients or colleagues should be considered.

Startup and innovation

Our startup mentors are highly experienced with the entire life cycle of product and service development, so they understand idea validation, prototyping, investment opportunities, and business planning.

Technology

We have experts versed in a broad range of technologies, so if you have questions about development or planning processes, standards, or quality assurance, we've got you covered.
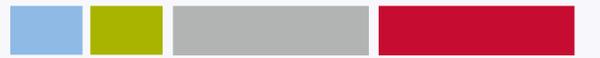
Key-Client Portfolio

SMART RESPIRATORY

SINCE 2017
Respiratory and Inhaler
Digital Therapeutics

MEKYSKA
Management Consultants GmbH

SINCE 2007
IT financial
management and
controlling

HAEMONETICS®
THE Blood Management Company™

Global Med Technologies®

SINCE 2005

GPi

USA
SINCE 2020
International
Healthcare Group

GPi

Italy
SINCE 2021
International
Healthcare Group

OMIXON

SINCE 2017
Molecular Diagnostics
Company

During a partnership that spans two decades, BrightHills has played a key role in the **development of six devices and 14 software solutions** from Haemonetics which play an essential role in **global blood management**. **Millions worldwide benefit** from Haemonetics' solutions, underscoring BrightHills' influence in **driving healthcare innovations through cutting-edge software development.**

This collaboration exemplifies our global impact and leadership in MedTech.

It was a pleasure working with you and your team. The partnership has been a model for success and we have always been very proud to tell the story of how it started and where it has evolved to today.

Rob Weyer
former VP R&D

GPI

In partnership with GPI, BrightHills has contributed to the evolution of their Global Suite of Medical Device Software, covering diagnostics, blood management, critical care, and telemedicine. By leveraging our software expertise, BrightHills has helped GPI revolutionize these key healthcare segments, ensuring **that cutting-edge technology drives better outcomes and more effective care worldwide.**

I have been working with BrightHills since 2005. I have been lucky enough to work with them with multiple companies. BrightHills is a professional organization. They have very good hiring practices, since they find the right people for the specific job. BrightHills can work either on a project basis or extend an already existing team. They can provide resources for the full development cycle, project managers, business analysts, developers, testers, and DevOps people. They are open with the communication and ready to make adjustments if needed.

All around, I highly recommend this organization for your next development project.

Miklós Csőre
Director of GPi4Med.BLOOD

SMART RESPIRATORY

We work closely with smaller businesses as well to guide them through the complexities of MedTech innovation. Our collaboration with SMART Respiratory, for example, shows how we help SMEs overcome economical and technical barriers to bring impactful products to market. We **provide the support and resources** necessary for **smaller firms to thrive in the competitive healthcare landscape.**

Check out our SMART Respiratory success story video!

I have been working with the BrightHills UI/UX team for two years and am very satisfied with their work. They took the time to understand the project both on a high level and down to the details of user interactions. They developed alternatives, engaged in discussion, did user testing and have stayed engaged with product evolution and upgrades ever since. A rare team that has confidence in their work as well as the humility to not get opinionated when a customer has questions or ideas. The result is a thoughtful and great looking user interface.

Thomas Antalffy
CEO

Alliances & Certifications

ISTQB Gold Partner
International Software
Testing Qualifications Board

MITGLIED IM

MEDICAL VALLEY
Europäische Metropolregion Nürnberg

Medical Mountains

Microsoft®
GOLD CERTIFIED
Partner

ISO 9001
TÜV SÜD
ÉMI-TÜV

Quality Management System
ISO 9001
Certified

Information Security Management
ISO 27001
Certified *

MEDICAL DEVICES
ISO 13485:2016
QUALITY MANAGEMENT *

*In progress

Our excellent **customer relationships**, **wide range of software services**, **expertise** and **quality assurance practices** make us the right choice for success.

Paul Andor Farkas

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brighthills

MASTERING MEDTECH SOFTWARE DEVELOPMENT AND REGULATORY CHALLENGES