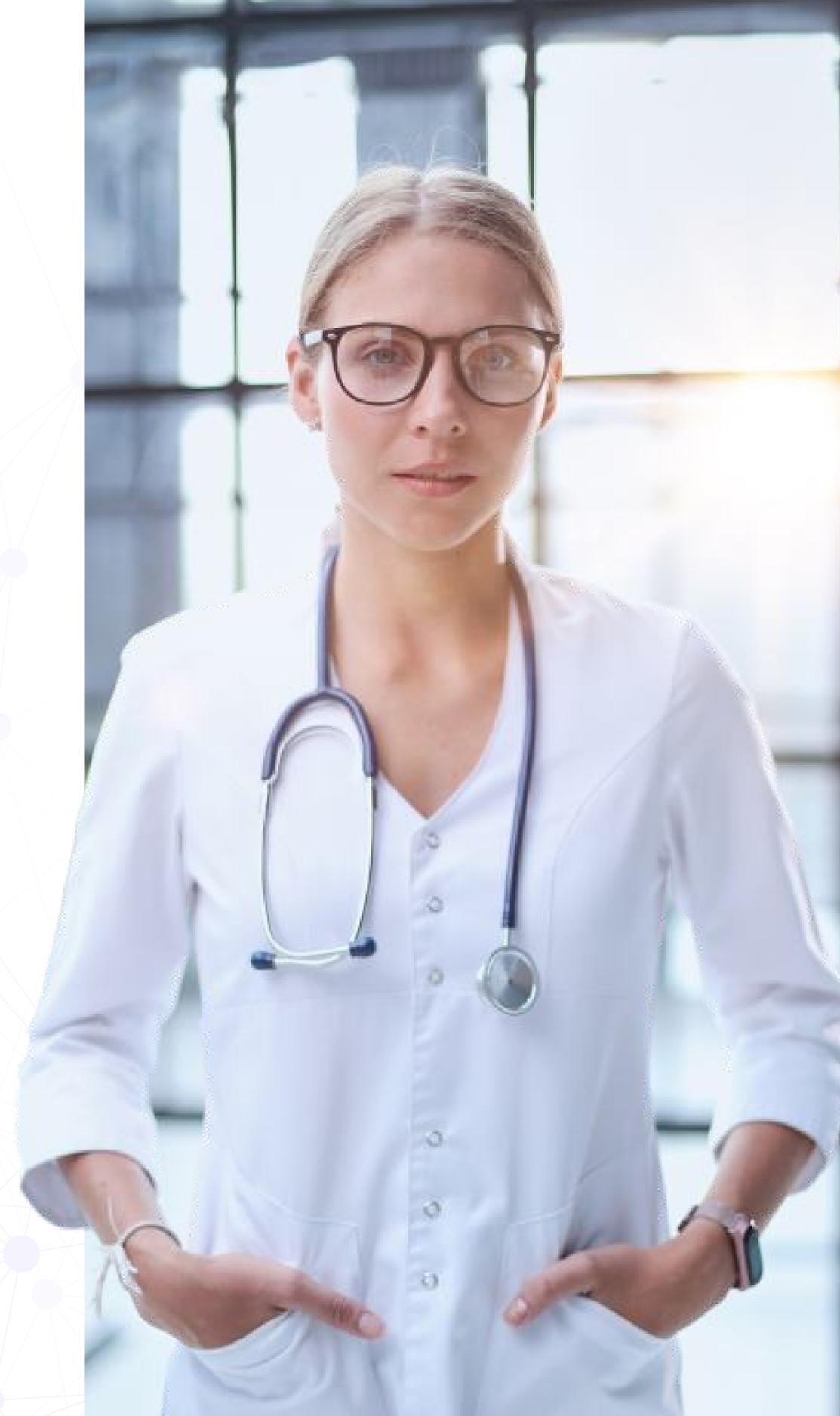




# Innovate with Confidence in MedTech



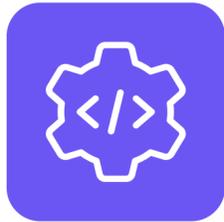


# Struggling to develop medical software that meets regulatory and quality standards?

Leverage our 20 years of MedTech experience in software development to create robust solutions that navigate regulatory complexities and accelerate your innovation.



# How can brightHills back you up?



## 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.



## Flexible and scalable teams

We tailor our scalable, flexible teams to your needs, so you pay only for the exact number of FTEs required for your project.



# WE ARE PROUD OF OUR...

**400+**  
PROJECTS

**150+**  
MEDTECH  
EXPERTS

**20**  
YEARS OF  
EXPERIENCE

**3**  
LOCATIONS  
EU AND US





## Product design

Your product's design will meet all necessary regulatory requirements, giving you a solid foundation for development and compliance.

## Testing

Improve your product quality with our state-of-the-art testing methodology, including automated testing and AI-driven tools. We help you ensure your product is ready for market.

## MedTech Consultation

Adhering to U.S. FDA and EU MDR regulations is crucial. We guide you through compliance, securing 510(k) clearances and CE marking leveraging our expertise in regulatory strategy, post-market surveillance and ISO certifications. This guidance facilitates successful market entry and ongoing compliance in the rapidly evolving regulatory landscape.

## Software Development

Whether you're looking for a full software development solution or need additional support for specific aspects of your project, we offer flexible services to meet your needs.

## Support

Your team and your end-users will benefit from our support services. We're here to keep your operations running smoothly and promptly address any issues that arise.

## Team Augmentation

Enhance your capabilities with our skilled professionals who seamlessly integrate with your team to provide additional expertise and capacity.

### PARTNERS

MITGLIED IM





# Results



## Time-to-market

Product launch with our streamlined processes and expert guidance, reducing development cycles and ensuring timely market entry.



## Reduce cost

Cost savings through efficient project management, optimized development workflows, and our flexible, scalable solutions.



## Quality

Our comprehensive testing and validation processes ensure high reliability and compliance with industry standards.

# We will help you achieve faster, more efficient, and error-free releases



Get in Touch!



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