



QUALITY ASSURANCE

# Navigating MedTech Regulations with Expert Software Solutions



**Do the complexities of MDR and FDA regulations in MedTech feel overwhelming?**

**Let's simplify them together.**

BrightHills' expertise in quality assurance (QA) ensures your software complies with global standards, enhancing market trust.

With BrightHills, MedTech innovators receive comprehensive support in software development, **regulatory documentation**, and **audit preparation**, to meet legal requirements and international standards. Our QA practices involve meticulous **process control**, **risk management**, and continuous improvement, fostering high-quality outcomes and robust compliance.





# How can brighthills back you up?



## FDA/MDR Guidance

Expert guidance on FDA and MDR regulations, ensuring smooth regulatory navigation.



## Team Scaling

Empowers SMEs to scale their teams effectively with the aid of our experienced Quality Assurance team, optimizing project alignment and saving valuable time.



## Gap Analysis

Identifies and addresses gaps in documentation and processes for regulatory compliance.

## Deliverable Compliance Assurance

Ensures all project deliverables comply with applicable regulations, enhancing project success and regulatory acceptance.

## Applicable Procedures Assurance

Verifies that procedures align with industry standards, ensuring seamless regulatory compliance.

## Process Improvement Consulting

Provides expert consulting to enhance processes, boosting efficiency and ensuring compliance in MedTech software development.

## Ongoing Production Records Review

Regular review of production records to maintain continuous compliance and quality.

## Documentation Refinement Consulting

Consults on refining documentation to meet regulatory standards, reducing bulk and improving clarity.

## Documentation and Regulatory Compliance Updates

Ensures that both your documentation and processes are up-to-date with the latest product changes and regulatory requirements, facilitating seamless regulatory re-submissions and ongoing compliance.



**PARTNERS**

MITGLIED IM





# Results



## Regulatory Strategy

Smooth market entry with comprehensive regulatory strategy and support.



## Audit Readiness

Prepare seamlessly for both internal and external audits.



## Stress-Free Documentation Management

Rely on our experienced QA team to handle compliance documentation seamlessly, guaranteeing accuracy and up-to-date submissions.

# Enhance MedTech Innovation with Expert Regulatory Support



Get in Touch!



**Stevie Farkas**

☎ +43 677 6299 0045

✉ [sfarkas@brighthills.com](mailto:sfarkas@brighthills.com)

🌐 [www.brighthills.com](http://www.brighthills.com)