SUITABLE SOFTWARE SOLUTIONS

FUSE-AI develops individual and suitable solutions for your business.
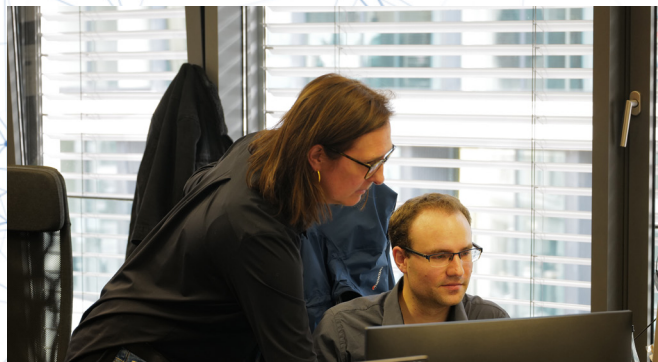
For this purpose, we work closely with you, analyze your requirements and develop a suitable solution for you.
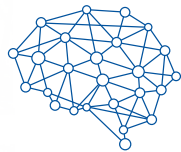
Contact us and let us be successful.

FUSE-AI

OUR NETWORK

KI BUNDESVERBAND

Westdeutscher Teleradiologieverbund

BiM BUNDESVERBAND INTERNETMEDIZIN

UNIVERSITÄTS KLINIKUM Jena

LIFE SCIENCE NORD

bitkom

Kantonsspital Aarau

KI·SIGS

Fabian Hielscher
Machine Learning Engineer

Juri Rohde
Head of Q&R, Operations

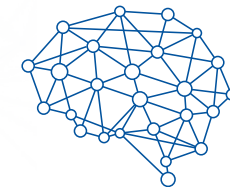*Anne Wesche*
Project manager & Medical Affairs

Leonard Wägele
Machine Learning Engineer
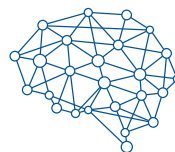
For even more impressions about FUSE-AI please have a look at our corporation film.

FUSE-AI

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juri.rohde@fuse-ai.de

FUSE-AI

YOUR SPECIALIST FOR ARTIFICIAL INTELLIGENCE AND SOFTWARE SOLUTIONS IN MEDICINE

App Development - DiGA

The European regulation for the approval of software as a medical device **(IEC 62304 and IEC 82304)** and especially for AI-supported software is associated with a particularly large amount of effort.

The companies, which are planning to launch their medical software products or their **medical digital solutions in the life science market in Europe**, often struggle to get an overview of the legal requirements for software as a medical device and the correct way to implement them. For application **("mobile Apps")** as a medical device (SAMD) which wants to register as a **DiGA ("Digital Gesundheitsanwendung")**, needs the approval from the BfArM.

In this specific **certification pathway** we can support and consult in the medical application development and **certification of a software as a medical device associated to a DiGA registration.**
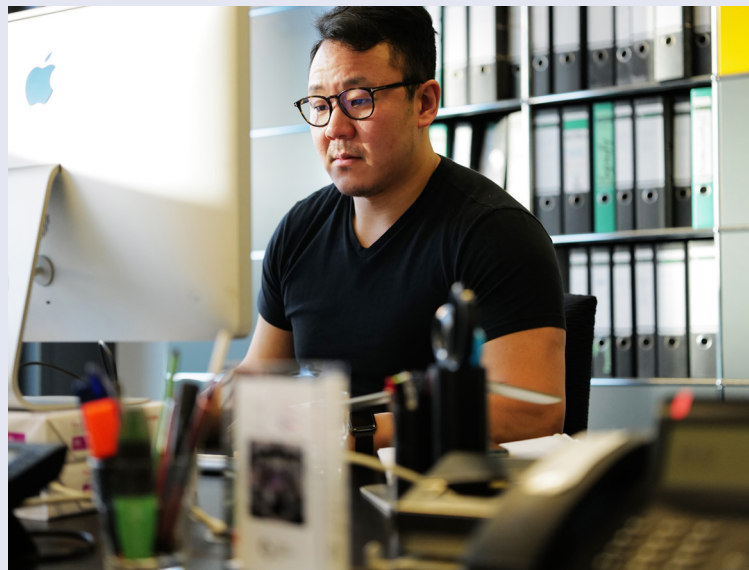
We are your partner!

Regulatory Affairs for Software as a Medical device

Companies with rudimentary experience in this area often struggle to get an overview of the legal requirements for **software as a medical device (SAMD)** and the correct way to implement them.

These challenges are faced by established companies that intend to launch their **medical software solutions** in the German or European market. In collaboration with our **regulatory affairs and quality professionals,** we advise you on the precise steps to be taken in order to design, to validate, to record and **register your SaMDs in compliance** with the required standards.

In addition, we also advise you on issues relating to **software development, validation, technical documentation and approval for software as a medical device.**

We are your partner!

Data Science Computer Vision

With increasing digitization, companies **have more and more information from different areas** of their own business at their disposal. This data can be analyzed in order to derive **added value for the company.** We offer consulting in the area of **Business Intelligence** / **Data Analysis** / **Data Science**, preparation of data for **further analyses, execution of data analyses for R&D, marketing and business intelligence.**

AI in Bioinformatics

Today, **intelligent algorithms in bioinformatics** are the basis for progress in applied biotechnological research, **drug development and personalized medicine.** Our interdisciplinary team of biochemists, machine learning researchers and biologists is ideally **suited to your bioinformatics questions.**

We develop develop convolutional and deep neural networks (CNN / DNN), **carry out exploratory data analyzes, develop intelligent algorithms and use visualizations and computer simulations** to uncover new, previously unknown relationships **in biomedical data.**

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