

YOUR MEDTECH PRODUCT. READY FOR GERMANY.

Regulatory expertise meets technical implementation.

Dr. Jörg Caumanns
Partner _fbeta
joerg.caumanns@fbeta.de
+49 171 2717358

_fbeta

Understanding the German Healthcare Market **3**
What international MedTech companies need to address

_fbeta Services **4**
Our modular portfolio for the German healthcare market

Regulatory & Market Access 4
Understanding requirements, pathways and implications for your product

Digital Health & Telematics 5
Connecting your product to the German healthcare ecosystem

Software, Interoperability & Security 5
Adapting technology to German requirements

Spotlight: HDDT **6**
What manufacturers need to know now

From Requirements to Production **7**
One partner across regulation and technology

Further Informations

Services for HDDT

Services for TI Integration

Upcoming _fbeta Event for MedTech



UNDERSTANDING THE GERMAN HEALTHCARE MARKET

What international MedTech companies need to address

Entering and navigating the German healthcare market can be complex. Specific legislation, evolving technical specifications, interoperability requirements, national security and privacy standards and approval processes all need to work together.

_fbeta helps MedTech and Digital Health companies understand the evolving regulatory framework, make informed decisions and adapt existing solutions to German national requirements.

A REGULATORY DEVELOPMENT MEDTECH MANUFACTURERS SHOULD WATCH

Is your medical device already on the German market?

Then you should understand the emerging requirements around interoperability and health data exchange.

The proposed “Law for Data and Digital Innovation in Healthcare” (GeDiG) includes planned changes relevant to the exchange of health data between certain medical devices and Digital Health applications.

A key element is the further development of § 374a SGB V and the technical requirements associated with Health Device Data Transfer (HDDT).
But the potential impact on existing products and infrastructure is worth understanding now.



Depending on your product, the requirements could affect:

DATA · INTERFACES · ARCHITECTURE · SECURITY · DEVELOPMENT · COMPLIANCE

Understanding the potential impact early gives you more time to assess your options and integrate the topic into your product roadmap.



_FBETA SERVICES

From understanding German requirements to implementing them in your product

Entering the German healthcare market often means bringing several perspectives together: Regulation needs to fit the market; Market requirements need to fit the product; Technical specifications need to fit the existing architecture.

_fbeta combines these perspectives. We support international MedTech and Digital Health companies in understanding the German healthcare environment, assessing what it means for their products and translating requirements into practical solutions.
Our portfolio covers three closely connected areas:

REGULATORY & MARKET ACCESS
DIGITAL HEALTH & TELEMATICS
SOFTWARE, INTEROPERABILITY & SECURITY

Regulatory & Market Access

Understand where your product fits into German healthcare.

- REGULATORY ASSESSMENT
  Understand which German healthcare requirements are relevant to your product and how regulatory developments may affect your existing solution.
- MARKET ACCESS & REIMBURSEMENT
  Assess suitable access and reimbursement pathways depending on the product, target group and intended role in care.
- PRODUCT & MARKET STRATEGY
  Translate regulatory and market requirements into implications for your product strategy, roadmap and market approach.
- STAKEHOLDER LANDSCAPE
  Understand the relevant institutions, payers, healthcare providers and other stakeholders within the German healthcare system.
- REGULATORY & STAKEHOLDER DIALOGUE
  We support discussions with relevant institutions and authorities where requirements, specifications or implementation approaches need to be clarified.

The goal: understand what applies to your product - before turning requirements into concrete technical and market decisions.





DIGITAL HEALTH & TELEMATICS

Connect your product to the German healthcare ecosystem.

We support MedTech and Digital Health companies with the integration into the **German Telematics Infrastructure** (TI) and its applications.

- Electronic Health Record (ePA)
- E-Prescription
- AuthN via Health ID
- Billing Service
- German National Terminology Server (ZTS)
- KIM
- TI-Messenger
- 116117 appointment API

We guide you from regulatory and technical requirements to architecture, implementation, testing and approval support.
We also provide **ready-to-use software components** for selected TI use cases.

SOFTWARE, INTEROPERABILITY & SECURITY

Build technology that works in the German healthcare environment.

We help companies adapt their existing products to the specific requirements of the German healthcare market.

Our expertise includes:

- SOFTWARE DEVELOPMENT
  Development and integration of healthcare applications, interfaces and backend components.
- INTEROPERABILITY
  Adaption to international standards (HL7v2, HL7 FHIR, OIDC etc.), mapping to Germany specific APIs and integration with national healthcare infrastructures and existing systems.
- DATA PROTECTION & IT SECURITY
  GDPR, Technical Requirements of Federal Office for Information Security, Social Code Book, Security-by-Design, secure architectures, identity and access management, risk analysis and regulatory security requirements.
- REGULATORY IMPLEMENTATION
  We translate German healthcare requirements into concrete technical and product decisions.

The goal: understand what applies to your product - before turning requirements into concrete technical and market decisions.



SPOTLIGHT

HDDT

What does it mean for your medical device?

Health Device Data Transfer (HDDT) is the technical framework, which will be a new legal requirement, for interoperable exchange of relevant health data between suitable medical devices and Digital Health applications.

For manufacturers, HDDT is more than an API.
The key questions are:

- AM I AFFECTED?
  Does § 374a SGB V and the emerging regulatory framework apply to my product?
- WHAT DO I NEED TO BUILD?
  What does HDDT mean for my existing data, architecture, interfaces, and processes? What can stay, what have to change?
- HOW DO I IMPLEMENT IT?
  What needs to be developed, integrated, tested and validated?

From regulatory assessment to technical implementation.

_fbeta supports manufacturers across the entire HDDT journey:

- REGULATORY & PRODUCT ASSESSMENT
  Understand the current regulatory situation and what the proposed requirements could mean for your product.
- ARCHITECTURE & INTEROPERABILITY
  Assess your existing infrastructure and define the right approach for interoperable health data exchange.
- TECHNICAL IMPLEMENTATION
  Develop or integrate the required interfaces and technical components — including our HDDT Gateway.
- TESTING & CONFORMITY
  Prepare and support relevant testing, documentation and conformity processes.
- STAKEHOLDER DIALOGUE
  We support technical and regulatory discussions with relevant institutions and authorities, including where requirements or specifications need to be clarified or further developed.

The regulatory framework is evolving. Your product strategy can start today.

FROM REQUIREMENTS TO PRODUCTION

One partner across regulation and technology.

German healthcare requirements rarely affect only one part of a product.
A regulatory change can create new interoperability requirements. These can affect architecture, interfaces, security and development — and ultimately need to be tested, documented and maintained in operation.
_fbeta connects these perspectives throughout the entire implementation process.



UNDERSTAND	DESIGN	IMPLEMENT	VALIDATE	OPERATE
▪ Regulation	▪ Strategy	▪ Software	▪ Security	▪ Support
▪ Requirements	▪ Architecture	▪ Interfaces	▪ Compliance	▪ Governance
▪ Market	▪ Interoperability	▪ Integration	▪ Testing	▪ Evolution

READY FOR GERMANY?

Whether you are already active in Germany or planning to enter the market, _fbeta helps you navigate the regulatory and technical challenges of the German healthcare system — and turn requirements into practical solutions.

Let's talk.



Dr. Jörg Caumanns
email: joerg.caumanns@fbeta.de



Jie Wu
email: jie.wu@fbeta.de

Wechat of Jie Wu

_fbeta GmbH
Akazienstr. 31
10823 Berlin

www.fbeta.de
+49 (0) 30 610 769 16
info@fbeta.de

Grafiken: _fbeta Media Studio | canva