

# Consulting, Coaching, Auditing and Training in Medical Device Affairs

www.imfeld-beratung.ch

## Organization

Since company establishment in 2001, the Imfeld Unternehmensberatung GmbH has operated with a network of cooperating partners with the goal to offer the best service for clients. Because we are a small company, we are very flexible and able to fulfill specific needs. We have good contacts to authorities, certification bodies, other consultants and medical device companies.

#### **Team**







Christian Frei



Michael Madjar



Franz Geissmann



Markus Ramseyer



Suzana Bosanac

## **Services**

In providing our services, we ensure that your company meets all applicable requirements of the standards ISO 9001 and ISO 13485, as well as the Swiss Medical Device Ordinance MepV, the European Medical Device Directive 93/42/EEC, European Medical Device Regulation 2017/745 and FDA 21 CFR part 820.

#### Consulting

Our wide range of consulting services are processoriented, effective and result in easy solutions.

Examples of services we have done our customers:

- Analysis of company/business processes from product development to disposal
- Establishing, support and improvement of quality management systems
- Conducting due diligence before company acquisitions/ investments
- Accompaniment in the development and certification of medical devices

#### Coaching

We offer individual, team and executive coaching. Our coaching sessions are based on trust, respect and process expertise.

We have the following understanding of coaching:

- The coachee is the expert for his problems and the respective solutions
- The coachee activates its resources and is developing alternatives to its previous behavior, or his previous views
- Our work is systematic and constructive coaching, resource- and solution-oriented

### **Auditing**

Whether internal or supplier quality audits or system audits for a certification body: We are the auditors with specialized and social competence.

We have the following audit-understanding:

- We audit thoroughly and according to standards and in compliance with the law
- How we deal with the auditee is based on facts and respectful

## Training

We offer customer specific developed training sessions: practice oriented, interesting and easy to understand.

Customized training conducted at your company have the following advantages:

- The attendees get specifically prepared information
- There is a high practical component due to inclusion of samples from your company
- Study group sessions increase the learning benefit
- The attendees require neither travel time nor expens-
- The work absence is limited to training participation