

Services

Organization Engineering

- Establishing and support of quality management systems
- Analysis of company processes – from product development to disposal
- Coaching of Quality Managers
- Employee interviews, answer analysis and reporting of potential improvements
- etc.

Special Support for Medical Devices

- Moderation of risk analysis and support in risk management according to ISO 14971
- Development and support of technical documentations
- Development and review of quality assurance agreements for suppliers and distributors
- Analysis of product recalls and nonconformities based on supplier or customer complaints
- etc.

Auditing

- Internal quality audits and company analysis
- Supplier audits according to client specific requirements
- Quality Audits by order of Swiss TS Technical Services AG (Notified Body CE 1253)

Training

We prepare trainings according client specific requirements. For examples:

- Management systems according to ISO 13485
- Medical devices and their requirements in Europe
- Risk management on medical devices
- Motivation to quality
- etc.

In our service we pay attention that your company meets all applicable requirements of the standards ISO 9001 and ISO 13485, as well as Swiss Medical Devices Ordinance MepV, European Medical Device Directive 93/42/EEC and FDA 21 CFR part 820.

Company Profile

Organization

The company IMFELD Unternehmensberatung GmbH works in a network with cooperation partners with the aim to generate the optimized solutions.

Organization engineering and quality assurance in medical device affairs are our strengths.

As a small company we are very flexible and open for specific wishes of our clients.

We cultivate good contacts to authorities, notified bodies, consultants and medical device manufacturers.

Team

Christian Imfeld

Organizer eidg. FA, Mechanician eidg. FZ

Core competencies: quality management in medical field, quality audits, risk management, coaching, procurement and production processes, mechanic, electronic, plastic injection moulding, surgical instruments.

Christian Frei

Dr. Dipl. Machine Engineer ETH

Core competencies: product development, project management in medical and pharmaceutical field, clinical evaluations, biomaterials, class II and III implants, medical laser devices.

Michael Madjar

Dr. Dipl. Machine Engineer ETH

Core competencies: risk management, quality and safety management systems, quality audits, corporate governance, social accountability, conflict management, social institutions.

Markus Ramseyer

Dipl. Machine Engineer FH,
Dipl. Economic Engineer NDS

Core competencies: product development, technical documentation, clean room technology, process validation, quality management, product permission in EU-USA-Canada, quality audits, implants, medical laser devices.

Your profit

- Practical approaches and profit orientated solutions which were established on clients site
- Empathetic, reliable and credible attitude
- Economic, ecological and ethical method of operation
- Long-term considerate partnership

Visit our Website:

www.imfeld-beratung.ch