# MedWay Consult

Your guide to operational excellence and compliance of your medical devices

MedWay Consult offers Consulting, Audit and Training services to MedTech industries

# Our solutions

## Consulting

- Quality
- Regulatory affairs
- Design control
- Industrialization
- Improvement of processes

## Audit

- Internal audit
- Audit of suppliers / subcontractors
- Identification of areas for improvement

## Training

- MDR 2017/745 regulation
- Technical documentation
- MDSAP audit
- Process validation
- Design/Change control

# Expertise

## Regulatory Affairs & Quality

We are experts in the development of regulatory strategies and the creation of technical documentation, controlling perfectly the requirements of CE marking (2017/745) and international registration, regardless of the class of the medical device.

We also support you in quality management according to ISO 13485 / 21 CFR Part 820, ensuring the effectiveness of your QMS and also managing audits, supplier and operational quality as well as management of non-conformities, CAPA, complaints.

## Design & Industrialization

We master design and change control of medical devices, from the concept phase to production transfer, including verification and validation of the device, as well as the implementation of risk management.
We also establish effective industrial strategies, and conduct validation of manufacturing processes, software and test methods.

We also complete design and production documentation (DHF/DMR/DHR/VMP).

## Process optimization

We excel in setting up and implementing innovative solutions to improve your productivity and efficacy in placing compliant medical devices on the market.

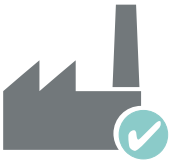
# Full Support

## Tailoring our support throughout the lifecycle of the medical device

Design
Development

Verification Validation
Industrialization

Homologation



Manufacturing

Product launch

Post–market
surveillance

# Why choose

MedWay Consult

**DEEP EXPERTISE**
Combined experience of over 37 years in medical devices

**PERSONALIZED SUPPORT**
Solutions adapted to the specific needs of each client

**DIVERSE SKILLS**
Wide and complementary range of skills (R&D, quality, regulatory affairs, industrialization)

**INNOVATION & DEVELOPMENT**
Innovative, technical and practical approach to new product and process development

**EFFICIENT PRODUCT LAUNCH**
Tailored regulatory strategies and proven good collaboration with notified bodies

# Contact us

## Natacha Lafitte

**CEO / CO-FOUNDER**

- Regulatory affairs
- Quality management
- Design control
- Project management
- Company strategy

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## Mathieu Lafitte

**CEO/ CO-FOUNDER**

- Research & Development
- Quality in operations
- Industrialization
- Project management
- Optimization of operational processus

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