



« Our Mission is to assist our global customers to overcome the challenge of navigating through the fast changing Medical Device Environment.

With our expert knowledge, efficient problem solving skills and extensive audit experience, we provide tailored solutions to support our customers in achieving their specific goals. »

Angelina Hakim
Founder & CEO



Our services:

- MDSAP, MDR, IVDR, ISO 13485:2016
 - Mock Audit / Audit preparation
 - Compliance projects
 - Training (public & in-house)
 - Gap Assessments
 - Compilation & Review of Technical Documentation
- Setting up Quality Management Systems according to ISO 13485:2016 & ISO 9001:2015
- Regulatory Affairs (market authorisation in EU, US and other markets)

Who we are:

- Certified ISO 13485:2016 and MDSAP Lead Auditors
- A Team of Professional Experts in RA and QM
- Extensive experience in the Medical Device Industry
- A Bridge between different Stakeholders

Our customers:

- Medical Device Manufacturers
- Medical Device Suppliers
- Economic Operators
- Notified Bodies
- Training Institutions
- Hospitals
- Universities
- Consulting Companies