

Enabling the growth of your medical device and drug-device combination product business

We provide processes and solutions that transform complexity into efficiency, quality, and compliance

ISO 13485 Certified

Consulting & Strategic advisory

Authorised Representative

Importer

Who we are

We are a team of dynamic consultants specialising in medical devices and drug-device combination, with a proven track record of delivering result across a broad range of services.

Why choose us

- ✓ Strengthen your global regulatory foundation - ensure consistency, compliance, and readiness across all markets
- ✓ Identify the correct pathway to navigate your way through global regulatory and product development challenges
- ✓ Understand how to unlock the business value of well-designed Drug Device Combination Products
- ✓ Unblock Artificial Intelligence solution implementation – understand return on investment and achieve internal alignment on governance and strategy implementation

Our approach

EFFICIENT · AGILE · FLEXIBLE

Our consulting blends strategic advisory with hands-on operational delivery, ensuring efficiency, compliance, and sustainable growth. Irrespective of the service we provide, the KAHLITY way of working is efficient, agile and flexible and our core objective in everything we do is to deliver solutions which are fit for purpose and contribute to the efficiency of your business.

ASSESS



We analyse and understand the problem

DESIGN



We design a solution, in partnership with our client

CREATE



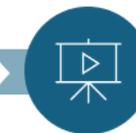
We create the solution, either building bespoke, or utilising an existing product

VALIDATE



We test and validate the Solution to be sure it addresses the Problem in a compliant and efficient manner

IMPLEMENT



We implement the solution and provide on-going support if needed

Our Services



Medical Device & Drug-Device combination advisory support



Quality Assurance & Regulatory Affairs Compliance



Artificial Intelligence Integration & Governance



Audit & Inspection Readiness



Training



Authorised Representation & Importer

Our Results

- 8+ years partnership with Bureau Veritas
- Proven efficiency improvements across Quality Assurance / Regulatory Affairs functions
- Conducted over 500 audits
- +800 individuals trained
- Designed and deployed 10+ Quality Management Systems globally
- Development of 20+ products into clinical trials, Health Authority approval & launch in several industries (Pharma, Biotech, Medical Device, Digital Health, Consumer Health)

Schedule your Medical Device / Drug-Device Strategy Assessment

<https://bit.ly/3XzFxoV>
Melodie.Kahl@Kahlity.com

