Service brochure

KAHLITY, your strategic partner in pharmaceutical excellence

At KAHLITY, we enable the growth of your drug-device combination product business by designing, implementing and enhancing products and processes through a deep understanding of product development and our key offerings.

We offer a bespoke approach for each client based on individual needs through a comprehensive two-tier service that blends strategic advisory with hands-on operational support whilst navigating the evolving global regulatory landscape.

"We tailor our services to meet our customers' specific needs, exceeding expectations through dynamic and adaptable solutions."

Our key offerings for our customers

1. Strategic support in drug-device combinations (DDC)

We define and operationalize development roadmaps, ensuring alignment between regulatory objectives, operational goals, and business growth plans.

Our support includes, for example:

- **Device-development strategies:** develop tailored approaches aligned with organizational goals, supported by deep technical expertise,
- **Third party (supplier) selection, qualification and evaluation:** offer support in managing stakeholders and manufacturing partners to meet compliance requirements.

2. Leveraging Artificial Intelligence (AI) in DDC

Building on the strategic foundation, we help our customers leverage AI responsibly across the DDC lifecycle:

- **AI use-case development**: define and implement AI-driven use cases (e.g., complaint trend analysis, PMS automation, risk prediction) tailored to your DDC product and business strategy,
- **Integrated implementation:** embed proposed strategies seamlessly into Quality Management System (QMS) processes and technical documentation,
- **Regulatory-aligned validation**: establish iterative validation pathways in compliance with the new AI regulatory evolving framework (e.g., ISO/IEC 42001, EU AI Act and FDA PCCP expectations).

3. Regulatory affairs and compliance

- **Regulatory strategy, submissions and Health Authority interactions**: offer expert guidance on compliance with global regulatory frameworks, including EU MDR (e.g., Article 117) and FDA 21 CFR Part 4, along with strategic support in engaging with Health Authorities (HAs) to facilitate regulatory approvals,
- **Technical documentation**: develop and remediate technical files to meet regulatory standards,
- **Platform documentation**: have DDC platforms available for clinical studies, streamline submissions, and minimize redundancies across technical documentation.

4. Audit readiness and strategic compliance

- **Audit readiness**: lead internal audits, supplier audits, and gap assessments to train teams towards "all-time audit readiness" and comply with applicable global requirements,
- **Strategic compliance**: throughout the entire product lifecycle, support the design, implementation, and continuous improvement of the entire QMS, including documentation control, training, post-market surveillance, and more.

5. Training and knowledge transfer

- **Customized training programs**: deliver trainings focused on regulatory compliance, risk management, DDC product lifecycle, and QMS optimization,
- **Hands-on workshops**: empower teams with practical, scenario-based sessions that build confidence in preparing for audits, managing documentation, and sustaining compliance.

6. Project and Portfolio Management (PPM)

- **PMO setup and optimization:** establish and refine Project Management Office (PMO) frameworks for seamless execution.
- **Program management**: oversee and coordinate interconnected projects and initiatives to achieve broader strategic outcomes and long-term business value.

7. Why KAHLITY?

☑ **Development, Quality and Regulatory Excellence**: KAHLITY offers an expert team of consultants delivering specialized knowledge for each project. Our ability to scale and adapt allows us to assign the right consultants to each project, ensuring optimal outcomes. Our team consists of senior regulatory experts, quality assurance specialists, and project managers, all dedicated to driving success.

☑ **Flexible, Tailored Solutions**: We offer dynamic and adaptable solutions, tailoring our processes to meet the specific and unique needs of each client's DDC. This unmatched flexibility ensures that we exceed expectations through customized regulatory strategies and quality management approaches.

☑ **Global compliance solutions**: KAHLITY is ISO 13485 certified and ensures that clients stay aligned with applicable requirements, fostering excellence.

☑ **Proven track record**: We are uniquely positioned with decades of pharmaceutical experience in the development, approval and commercialisation of cutting-edge packaging solutions, drug-device combinations, and platform technologies.

Partner with KAHLITY to drive compliant and efficient DDC product development.

Connect with our experts to explore how KAHLITY can streamline your business strategies.

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