Supporting your compliance and effectiveness

KAN Consulting MON. I.K.E.

Brochure 2021

Kamila A. Novak

MISSION

KAN Consulting
Pharma & Biotech

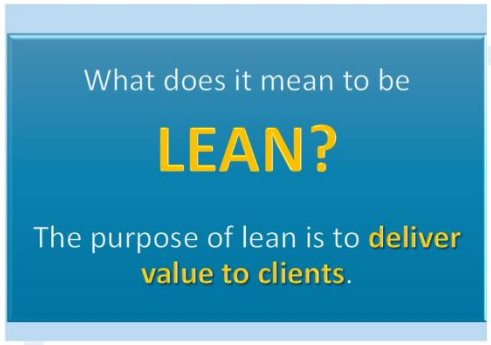
Incorporated in 2019 as an organic step forward from a freelance consultancy founded in 2011 by Kamila A. Novak, MSc, KAN Consulting MON. I.K.E. collaborates with and provides expert solutions to biotechnology and pharmaceutical companies to facilitate their medicinal product development, consult research projects, identify and manage risks, develop documents for clinical studies, train personnel, audit vendors and sites, thus, facilitate meeting their targets on time, with the desired quality, and within budget.

Apart from biotech and pharma, our client portfolio includes other key players in the R&D field, namely, institutions, individual researchers – investigators, IRB/IECs, and CROs.

Our goal is to optimise processes related to planning, execution and reporting in clinical studies for patients to benefit from new therapies as soon as possible.

ADVANTAGES

We are lean, networking, standardised, and risk-management oriented.



Scaling your project

Scaling your project to support future growth.

Network of peers

Networking with peers in the fields of computer system validation, data analytics, certifications for various ISO standards to meet your targets.

Support to follow ISO standards

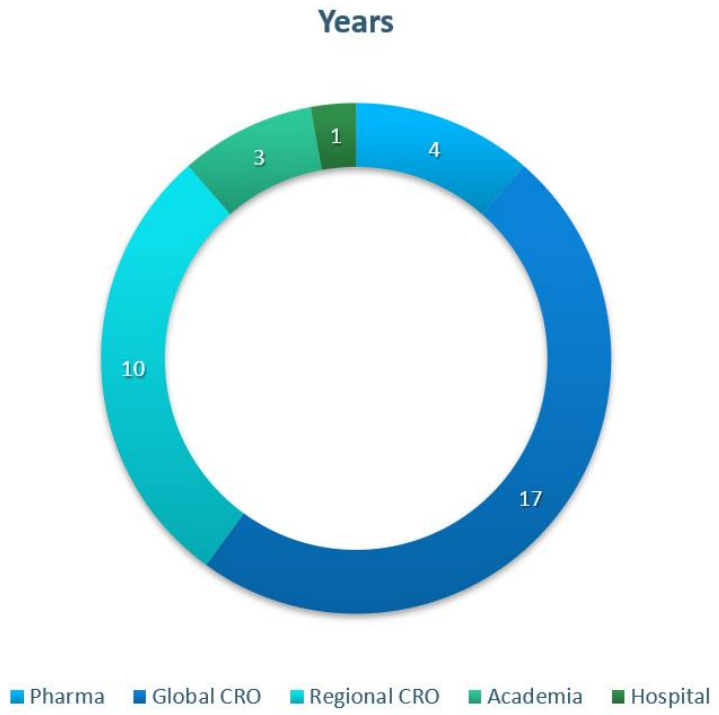
ISO 9001:2015
ISO 31000:2018
ISO 14155:2020
ISO 21500:2012

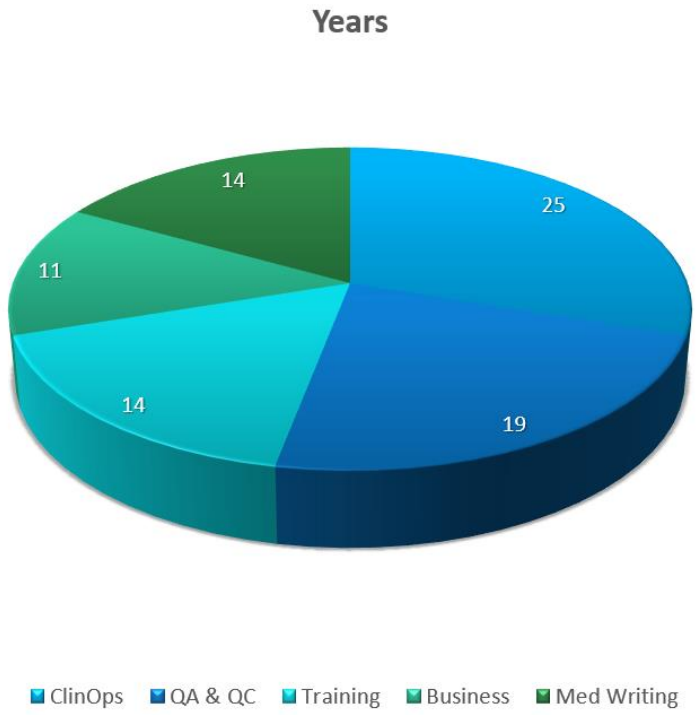
Risk management

In compliance with ISO 31000:2018, FDA & EMA guidelines & regulations as well as TransCelerate recommendations, we help you implementing risk-based approach in vendor management and clinical operations.

EXPERIENCE & EXPERTISE

Having worked in different environment settings, we understand you well no matter if you are a drug developer, institution or contract research organisation.





MEET YOUR CONSULTANT

Kamila A. Novak, MSc.

Kamila A. Novak holds a master's degree in molecular genetics. She has been involved in clinical research since 1995, having worked in various positions in pharma and CROs. Since 2010, she has been working as an independent consultant.

Her business activities include **medical writing, auditing, quality management risk management system implementation, and training**.

Kamila Novak is a certified Lead Auditor for ISO 9001:2015 and ISO 31000:2018, Certified ISO 14155:2020 Medical Devices auditor, and cGMP – QMS auditor. She is a member of the Society of Quality Assurance (SQA), the Association for GXP Excellence (AGXPE), the Drug Information Association (DIA), the European Medical Writers' Association (EMWA), the Continuing Professional Development (CPD) UK, and other professional societies.

In the DIA, Kamila Novak serves as a Co-Chair of the Clinical Research Community, a Core Team Member of the GCP & QA Community, leads Working Groups on Computer System Validation and on Data Interoperability, and is a member of Working Groups on Clinically Meaningful Outcomes, and Project Management.

SERVICES

CONSULTING

- Implementing a robust **Quality Management System with a risk-based approach** is key to your compliance and success. Whether you wish to *build your QMS* from scratch up upgrade the existing one, we offer expert support to achieve your objectives as well as *independent audits* of your processes.
- Working with the right **vendors** is vital to ensure they perform to the quality standards you need them to maintain. We offer *vendor qualification and re-qualification audits* as well as support in developing *risk-based vendor oversight plans*.
- Following fitting **Standard Operating Procedures** helps teams to comply with regulatory requirements, work effectively and efficiently. We offer *SOP gap analysis* and support in *developing or revising your SOPs* to meet required standards.

QUALITY ASSURANCE AND QUALITY CONTROL

Acceptance of study results by the Regulatory Authorities is the prerequisite of your asset further development. Whether you plan to out-license your molecule or bring it to the market yourself, regulatory compliance is mandatory all along the way.

We offer

- ✓ Quality oversight visits to study sites,
- ✓ Site staff training in GCP and study management for investigators,
- ✓ In-house and site preparation for inspections,
- ✓ Study site audits,
- ✓ TMF audits,
- ✓ CRO audits,
- ✓ CAPA Plan development and implementation support.

MEDICAL WRITING

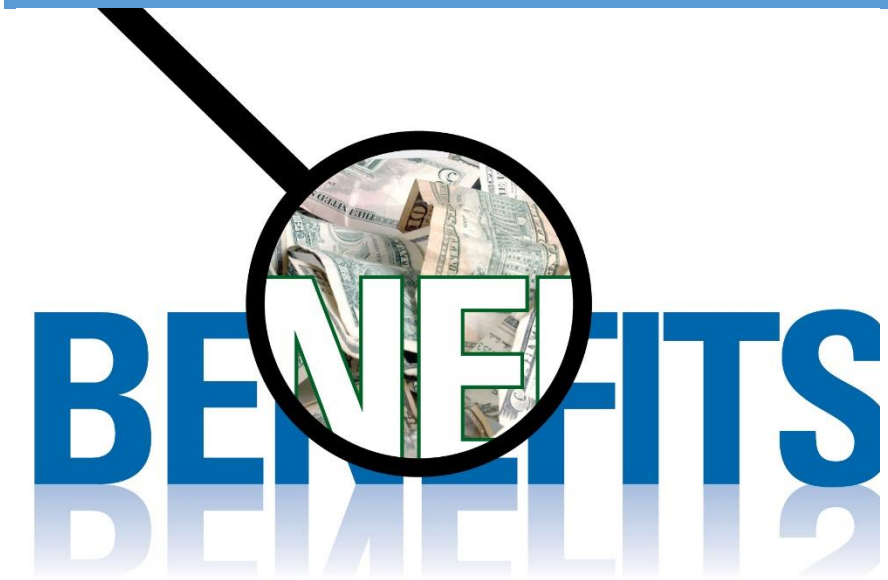
A clear, well-written, easy-to-read study **protocol** helps to get your studies approved without delays and study sites to conduct your studies with less deviations. For submissions to Regulatory Authorities, your **Clinical Study Reports** should be accurate, readable, with clear presentation of study results. And if you wish to publish the results, your **manuscript** must follow the Journal's Guide for Authors and capture the audience. We offer medical writing expertise to save your time.

TRAINING

As the drug / device development and clinical trial landscape keeps evolving, continuing professional development is a must to stay competitive. We offer numerous courses tailored to our clients' needs. Courses on high demand include:

- ✓ Clinical Project Management
- ✓ Clinical Risk Management
- ✓ GCP for Study Sites
- ✓ GCP for Sponsor's Clinical Operations teams
- ✓ Quality Management in Clinical Trials

YOUR BENEFITS



Everyone could do with a bit of extra time and money and KAN Consulting can help save you both. Whether you are a biotechnology or pharmaceutical company, an institution representative, an investigator, or a CRO, you may find something in our offer you can benefit from.

INSTITUTIONS

Institutions engaged in research, whether conducting its own or industry-sponsored projects, are more successful with functional research offices or centres taking care of organisational and technical aspects of studies. It relieves investigators and their teams from the administrative burden allowing them to focus on the science and patient care.

KAN Consulting supports institutions wishing to enhance their research potential with

- Establishment or optimisation of research office operations,
- Training of personnel, including but not limited to GCP, regulations, study management for investigational sites, contract negotiation, protocol development.

INVESTIGATORS

Whether you are just starting your research career or run your own studies routinely, a strong project plan including budget calculations will help you to present your research idea to the grant committee or find a sponsor in the industry. Pharmaceutical and biotechnology companies do offer funding, however, each investigator-driven project undergoes a thorough scrutiny in order to get selected for funding.

KAN Consulting offers support in

- Project plan development and its presentation to increase your winning score.
- Protocol development.
- Study report and manuscript writing.

SPONSORS AND CROs

Our industry clients are particularly interested in

- Specialised training courses and workshops on project management, risk management, negotiation skills, presentation skills and business development;
- Support in implementing advanced project management and risk management approaches to keep pace in the rapidly changing drug development environment.

CONTACT US

Thank you for reading out brochure. Hope you have found the information you sought. Thanks to technology, physical distances are less and less important. Please do not hesitate to contact us with inquiries, we will respond within 24 - 48 hours.

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ZOOM meetings will be scheduled upon request.