MEDICAL SOFTWARE CONSULTING

WWW.TRUE-NORTH.IO

TRUE NORTH

"Unlocking medical software innovation."

We are passionate

about supporting healthcare digitalization to enhance the quality of life for many.

With our practical approach, we simplify the process of achieving regulatory compliance, freeing our clients to prioritize the delivery of exceptional medical software

EU MDR and FDA Expertise

Our **team of international regulatory and quality experts** are specialised in obtaining approvals for software classified as a medical device. Whether you are introducing medical software into a new market or maintaining regulatory compliance in an existing market, we **will help you drive the effort to overcome the regulatory challenges.**

We offer comprehensive solutions with a full suite of services to guide our clients through **every step of the process from device classification to compiling regulatory submissions**.

We work hands on with you and your team to drive the process within your organisation. **Our services are tailored to the specific needs of your organization.**

"Securing market access for medical software"

OUR SERVICES

GAP ANALYSIS

WE OFFER

a comprehensive approach to compliance analysis that ensures our clients implement the correct standards for their business and products. With our help, they meet all the necessary requirements and comply with all the applicable guidances, regulations and international standards.

WE HELP

our clients navigate the complex landscape of regulatory compliance, and implement a QMS that meets all necessary requirements for their specific market and device type in accordance with ISO 13485. With our help, clients are able to implement a QMS that is lightweight and optimised for designing and developing medical software.

QUALITY MANAGEMENT SYSTEM

SOFTWARE DEVELOPMENT LIFE CYCLE

WE ASSIST

our clients in selecting the right combination of software development tools and methodologies to ensure consistent delivery of high-quality software products. We implement software development life cycles and its supporting tools in accordance with the latest industry standards using both Agile and Waterfall methodologies.

WE WORK

closely with the teams of our clients to understand their specific needs and develop SOPs that are tailored to their business objectives to maximise their productivity and efficiency. We help develop SOPs that are compliant with widely recognised international standards e.g. ISO 13485, ISO 14971, IEC 62304, IEC 82304 etc.

STANDARD OPERATING PROCEDURES

REGULATORY SUBMISSION

WE GUIDE

our clients through the entire regulatory submission process, compile 510(k) and/or technical documentation and help them submit their application. During the approval process, we support our clients communicating and answering all the questions from the notified body or FDA.

OUR REFERENCES

>>> RE-DESIGN SDLC FOR U.S. MANUFACTURER

In partnership with a leading American medical device manufacturer, our team successfully spearheaded a transformative project, revolutionizing the Software Development Life Cycle (SDLC) for medical software. The primary focus was transitioning from a traditional waterfall approach to an agile mindset while ensuring strict adherence to EU and US regulations. Our responsibilities included overseeing the project, evaluating current SDLC processes, and reviewing Standard Operating Procedures (SOPs). We identified procedural shortcomings and crafted a comprehensive plan for redesign, streamlining outdated processes and harmonizing methodologies to meet regulatory requirements and stakeholder expectations. Our role also involved facilitating a seamless transition to the revamped SDLC and implementing simplified, tool-agnostic SOPs.

>>> 510(K) SUBMISSON FOR BECS

Led the regulatory submission project for a blood establishment software system, ensuring thorough documentation compilation for the 510(k) submission. Facilitated stakeholder understanding of regulatory requirements, enhanced collaboration, and managed documentation creation for the submission process.

>>> REGULATORY SUBMISSIONS FOR EU AND US MARKETS

Our team took on a pivotal role for a medical device manufacturer, leading efforts to secure CE mark and FDA clearance for an AI-supported ECG analysis system. The main focus was a meticulous review and preparation of both the quality management system and product documentation to ensure regulatory submission readiness. Our tasks encompassed a comprehensive gap analysis aligned with EU and US medical device regulations, updating the QMS and SOPs to adhere to international standards (e.g., ISO 13485, ISO 14971, EN 62304, EN 82304, ISO 20417, ISO 15223), reviewing and revising product documentation, creating technical documentation, compiling the 510(k) submission, coordinating with the notified body and FDA, and overseeing the ISO 13485 audit.