Accelerate Development and Delivery of Your Modern Medicines

Get More Done.

Kymanox

Kymanox is a premier professional services organization with the goal of accelerating the development and delivery of modern medicines — from bench to patient. We are your life science solutions partner who ensures you have the right end-to-end solutions to address challenges in early development, commercialization, and post-market for your combination products, biologics, pharmaceuticals, and medical devices. With our diverse team of experts, we differentiate ourselves by offering a broad range of services backed by our Project Management Office. We serve clients globally from our headquarters in Research Triangle Park (RTP), North Carolina and from our branch office hubs across the United States.

Be More Effective.

STRATEGY, PLANNING, & EXECUTION

Be More Strategic.

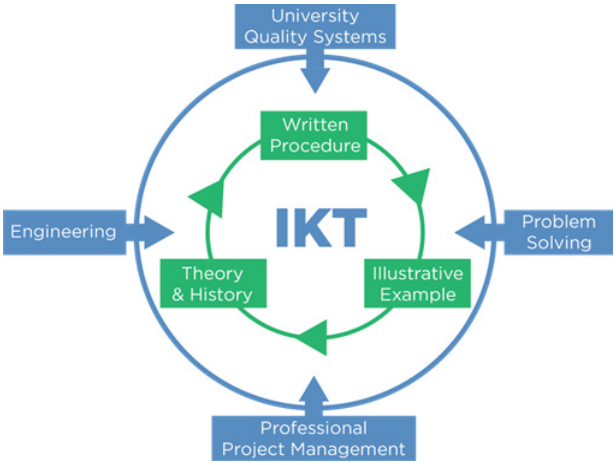
QUALITY, REGULATORY, & COMPLIANCE

Be More Innovative.

DEVELOPMENT & OPERATIONS

Be More Accurate.

COMMISSIONING, QUALIFICATION, & VALIDATION



Throughout the growth of the company, **Ideal Knowledge Transfer™** (IKT™) has remained the focus for our teams. When know-how, expertise, or technology moves from one place or person to another, knowledge transfer is taking place. Our teams utilize this process in each of our projects, guaranteeing you best-in-class service and facilitating the development and delivery of products with optimized safety, quality, efficacy, accessibility, and efficiency.

From Bench To Patient,
Your Life Science Solutions Partner

Kymanox

Your Life Science Solutions Partner

Bio | Pharma | Device | Combo

www.kymanox.com

STRATEGY, PLANNING, & EXECUTION

- Proven Project Management tools that drive projects to the highest level of performance
- Honed CGxP documentation-based approach to technology transfer
- Innovative strategic capabilities to help you get your product to market effectively, efficiently, and in a compliant manner
- International provider of ERP optimization, implementation, and compliance solutions
- Ready-now resources that cover a broad range of scientific, engineering, software, and compliance disciplines
- Due diligence support with strategic insight, experience, and a fact-based approach

QUALITY, REGULATORY, & COMPLIANCE

- Certified auditors with extensive expertise in preparing clients for audits, regulatory body inspections, and other evaluations.
- End-to-end engineering and compliance solutions for all life cycle stages
- Ensure facilities and personnel operate in a state of control — ultimately ensuring patient safety
- Industry-leading scientific and medical expertise to ensure efficient and compliant clinical activities and best-in-class solutions for medical affairs
- Experienced in the interpretation of applicable FDA and EMA regulations to ensure compliance
- PAI readiness gap assessments to ensure you're aligned with regulatory guidelines and expectations

DEVELOPMENT & OPERATIONS

- Quality by Design (QbD)-guided principles for establishing and improving manufacturing processes
- Combine expert product and process knowledge with a quality-first mindset to ensure Right First Time submissions across the globe
- CGMP compliant design, implementation, operation, and maintenance of your processes and process equipment
- Support for all product development phases, from early clinical to post-commercial life cycle management
- Comprehensive human factors (HF) solutions and strategies
- Packaging system design and testing

COMMISSIONING, QUALIFICATION, & VALIDATION

- CGMP Commissioning, Qualification, and Validation (CQV) leveraging requirements documentation and risk management
- Proven past performance includes facilities, utilities, equipment, Computer System Validation (CSV)/Part 11, methods, processes, and cleaning
- Best-in-class documents stand as monuments for compliance and your business
- Extensive design experience means we understand what we are validating
- Specialty CSV and Part 11 compliance for Enterprise Resource Planning (ERP) systems (e.g., SAP)