Kymanox DONE

Get projects done.

Kymanox Quality, Compliance, and Regulatory Services

Quality by Design

Kymanox's overall approach to providing services is aligned with the principles of Quality by Design (QbD). QbD is a **universal quality system** that incorporates sound science, knowledge transfer, risk management, Process Analytical Technology (PAT), Six-Sigma, LEAN, and other valid technical and quality tools that have been adopted by the **Biotechnology**, **Pharmaceutical**, and **Medical Device** industries. When fully embraced, QbD returns higher product quality while saving time, money, and regulatory scrutiny. Unlike other quality-based initiatives of the past, the FDA has worked diligently with other governing bodies around the globe to promote QbD as being the new standard to which regulated healthcare products will be evaluated.

Improved FDA Interactions

Kymanox helps **eliminate the ambiguity** surrounding regulations and published guidance to make end-requirements clear. Once this clarity is established, interactions with the FDA can be **efficient and productive**. Kymanox operates effectively in both proactive and reactive situations. We have expertise in organizing data for **FDA review** and assembling logical and thorough explanations on complex and involved issues. Both the guidance we provide and work we get done is based on a strong foundation of previous experience with the FDA:

- IND, NDA, BLA, PMA and 510k **Submissions**
- Inspections and **Audits** including Pre-Approval Inspections (PAIs)
- **Responses** to Deficiency, Observation (i.e., 483), and Warning Letters
- DQ/IQ/OQ/PQ **Validation**

Whole Enterprise Quality

With access to **world-class expertise** in every aspect of GMP, Kymanox can help design your internal processes so that they all work together supporting product quality. **Every system** – documentation control, materials management, QC, validation, etc. – should be part of the overall solution, not part of the problem.

Minimize Setbacks

With Kymanox involved early on, Quality Assurance and Regulatory Affairs will have the proper resources to be more proactive. **Early engagement** helps avoid a majority of potential issues that may impact the overall program, patient safety or product efficacy.

Contact Kymanox

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