Regulatory Compliance

Kymanox Means Ideal Knowledge Transfer

Highlights of Our Regulatory Compliance Experience

Kymanox

Get projects DONE.

Kymanox (ki'-mah-noks') is a diversified organization that helps its clients in the biotechnology, pharmaceutical, and medical device industries achieve their mission-critical objectives. Besides providing contract services, Kymanox also develops and maintains products for use in the same industries, as seen on KymaSTORE.com.

GxP Gap Assessment for Legacy Computer Systems

Kymanox's regulatory compliance subject matter experts performed a comprehensive on-site GXP gap assessment for legacy ERP systems for a leading health care company that provides medical equipment and integrated solutions in several applications, such as patient handling and hygiene, wound healing, and disinfection. Kymanox identified applicable regulations, including 21 CFR Part 11. A draft report was issued based on findings and recommendations with a clear pathway, action item list, and effort estimate to close identified gaps.

Learn More at www.kymanox.com

GMP-Compliant **IT and Quality System Framework**

Kymanox created a Quality System framework with the necessary policies and procedures to support the installation and maintenance of a GMP compliant IT network at a health care company that harnesses re-generative biological processes for their therapeutic potential. Kymanox identified specific regulations that apply to the IT network (21 CFR Part 11) and user requirements. All work was guaranteed to meet current FDA regulations and expectations and was designed to support future GMP software applications. An analysis was performed to determine the benefits, risks, costs, and timelines associated with both a LIMS-based quality system and alternatives such as a turn-key paper-based system for managing critical GMP Quality System functions.

Viral Safety Assessment

Performed a viral safety assessment for a commercial biotechnology company. An extensive risk-based assessment was developed and analyzed using a multi-disciplinary team for a novel cell-based process. Subject-matter experts assisted regulatory professionals in scoring and creating strategies to mitigate several identified risks. A final summary report was developed and provided to support regulatory filings made in the European Union.

Contract Manufacturing Evaluation for Vaccine Developer

Using industry benchmarks, Kymanox completed an operational evaluation of all Contract Manufacturing Organization (CMO) operations available for a proposed vaccine and prepared a comprehensive evaluation report and presentation. A detailed action plan was developed to address all gaps, including regulatory functions, which would impede potential closing of sales or sales deliveries for CMO services. Kymanox addressed all potentially impacted areas of the business, including the organizational structure and all applicable technologies. quality systems, project management, marketing, strategic partnerships, and licensing.

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