

Highlights of Our Process Validation Experience



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.

Process Validation Master Plan (PVMP)

When a biotechnology client whose therapeutics are used as a cancer treatment needed a critical path Process Validation Master Plan (VMP) authored, Kymanox was able to succeed where three previous companies had struggled.

The PVMP was successfully created and submitted to the Food & Drug Administration (FDA) as part of a briefing package.

Not only were there no deficiencies observed in the process validation, but the FDA positively commented that the VMP was very thorough and lauded the new approach to risk management created by Kymanox.

Cleaning Validation

Kymanox defined the testing requirements and acceptance criteria for the removal of active product and excipient following cleaning of the following product types:

- azalide, (subclass of macrolide antibiotics)
- broad-spectrum microbicide
- topical medication for controlling the progression of glaucoma or ocular hypertension by reducing intraocular pressure
- rho-kinase inhibitor
- synthetic resolving analog
- aminoglycoside antibiotic for treatment of types of bacterial infections

Cleaning limits were determined using the minimum batch size that may be produced on the equipment train. Maximum Allowable Carry Over (MACO) limits were calculated using two approaches, therapeutic dose and default limit, and were determined based on the most conservative result.

Swab limit target values were established by dividing the MACO by the total surface area. Rinse limits were calculated by multiplying swab limit target values by rinse areas and dividing by rinse volume. The analysis was conducted with rinse and swab samples to verify that product residue levels were reduced to an acceptable level. Rinse samples were submitted for TOC (qualitative indication of the removal of active and excipients) and conductivity (qualitative indication of the removal of excipients).

All equipment was also visually inspected.

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