The DEA Benefit of Partnering with CDMO's

Many Pharmaceutical companies are continuing to rely on third-party providers for support at all levels of drug development. As a CDMO Mikart offers advanced, specialized technologies in combination with tailored support to meet the client's changing requirements throughout the product lifecycle.

Equally important, and generally hidden in the background is Drug Enforcement Administration (DEA) Compliance and the world of Quotas. For clients where product development and controlled substances meet, quota management plays a crucial role in moving the process forward. A controlled substance is a substance whose possession and use are controlled by law as a result of its potential for abuse. Controlled substances are placed into schedules by Federal law based on their approved medical use, potential for abuse and safety or dependence liabilities.

For those controlled substances, listed in Schedules I and II, Quotas are required. The purpose of quotas is to provide for the legitimate need of controlled substances, limit the quantity of drugs in Schedules I and II which may be manufactured or produced and ultimately restrict the manufacture and procurement to only those manufacturers registered with DEA.

Throughout the lifecycle of a product there are many stages of development requiring the manufacture of batches including (but not limited to) stability, clinical, process development/optimization, submission, and validation. For those Schedule I and II controlled substances, a manufacturer must justify and obtain quota prior to the manufacture of any batch.

DEA compliance management has become increasingly complex. Managing the unique challenges-controlled substances present can be a challenging task for those companies with limited knowledge and resources. As a CDMO manages a diverse group of clients, they have extensive experience in working with the Drug Enforcement Administration on simple to complex quota submissions. Effective management and navigation of the quota process result in minimal delays in maintaining the timeline for bringing a product through the applicable stages to commercialization. Understanding and complying with federal regulatory requirements is critical to a successful launch. Many companies today producing controlled substances are utilizing a CDMO to gain the needed expertise and efficiency to bring their product to market. Partnering with a CDMO experienced in quota management can prevent costly delays and ensure accurate and timely submission of all required documentation. Pharmaceutical companies are recognizing it takes considerable skill, time, and expertise as well as meticulous planning to survive in a world of increasing regulatory demands and the major role a highly competent CDMO can play on their behalf.