Manufacturing Generic Versions of Controlled Substances

By Ed Price, President, PCI Synthesis

Last Fall, we were pleased to announce that PCI Synthesis received DEA registration for controlled substance development and manufacturing, and we invested in new systems, processes, and training in order to manufacture controlled substances in our Newburyport facility.

By putting in place the infrastructure to manufacture controlled substances, we're able to meet the growing demand for new molecules that make use of the medical value of controlled substances. We now have three suites to handle controlled substances.

But receiving DEA registration was no easy task. We needed to put in place new procedures for a new level of quality control, and vast employee training in how to handle different materials and comply with state and federal regulations.

What Sets a Controlled Substance Apart?

Given the lengthy FDA requirements for all chemical development and manufacturing, it would appear that all chemicals are quite literally "controlled," so what it is about controlled substances that set them apart from other commercially approved ones?

According to the FDA, substances are placed in their respective schedules based on whether they have a currently accepted *medical* use in treatment in the United States, their relative abuse potential, and the likelihood of causing dependence when abused.

PCI Synthesis has approval to develop products that fall in the Schedule II-V range. To put that into context, Schedule I substances, such as Heroin, currently have no accepted medical use in the U.S.; Schedule II includes those, that have a high potential for abuse, such as methadone or oxycodone; and subsequent schedules (III-V) have decreasingly lower chances of abuse. For example, Schedule V substances may include cough preparations, such as Robitusin.

What are Considerations for Manufacturing Controlled Substances?

Becoming a controlled substance manufacturer requires the same requirements as other substances, but with higher diligence and scrutiny in two key areas:

Security. This is one of the most critical areas for manufacturing controlled substances. Contract Manufacturing Organizations (CMOs) must revamp their entire processes and physical features to ensure specific security requirements are met. For example, employees working in any function

within the kilo lab or plant must have thorough background checks, as well as secure restricted access permission for entry into facilities, and cameras in all entry ways.

Quality Control. Conforming to Current Good Manufacturing Practices (cGMP), highly specific processes must be put in place to ensure heightened quality control of the compound you are developing. AT PCI Synthesis, one of our core pillars has always been an unwavering commitment to ensuring quality in everything we do – from cleanroom operations, to calibration of instruments and preventative maintenance in utilities systems, and we've built processes and controls that help us meet our own strict standards, as well as industry regulations. This commitment to quality goes up exponentially when it comes to controlled substances.

What Makes a Generic Controlled Substance?

The difference between a brand-name medicine and a generic equivalent is designed to be transparent. Once the patent expires on a brand-name drug product, it is eligible to be made into a generic drug. To do this, the generic drug manufacturer must ensure that the drug it is producing contains the same active pharmaceutical ingredients (APIs) as the brand-name product, in the same dosage form, at the same dose or concentration, and for the same route of administration. The generic drug, however, may differ in color, shape, taste, inactive ingredients, preservatives and packaging.

According to an AARP Public Policy Institute study, "Generics drugs currently account for almost nine out of 10 prescriptions filled at the pharmacy but only a quarter of total drug costs." Generic versions of controlled substances are no exception. When a brand-name controlled substance comes off-patent, generics are able to replace the brand-name drugs and provide a great alternative at one-third of the cost of the brand-name version, with the same efficacy, safety and FDA scrutiny – if not increased scrutiny.

At PCI Synthesis, we're busily working to meet the need for generic versions of controlled substances which will only grow in demand as costs continue to rise and patents expire on brand-name drugs.

Contact us at (978) 462-5555 or email us at info@pcisynthesis.com to learn more about our state-of-the-art cGMP-compliant facilities for the manufacture of controlled substances. Or check back at our blog, where we will continue to post articles about working with controlled substances to develop generic drugs.