**Project Management of Product Complementary Device (PCD) Development**

Successful Design, Engineering, Manufacture, Assembly, and Testing of Critical Device Constituent Parts of Combination Products

**Executive Summary**

Product Complementary Devices (PCDs) are a subset of medical devices that are typically developed to address an identified issue with drug products, medical devices, and combination products already on the market. The development pathway for a PCD closely follows what is required for medical devices, but often encounters aggressive market approval deadlines and usability risks related to the inclusion of off-the-shelf components.

Through years of experience in medical device and PCD development, Kymanox has developed best-practice project management techniques designed to mitigate key risks. Kymanox ensures that PCDs are developed on-time and satisfy all user, patient, and market needs by conducting concept and research initiation prior to beginning PCD development, leveraging existing design controls where available, and forging relationships with component suppliers early in the development process.

**Introduction**

Product Complementary Devices (PCDs) are defined as medical devices or convenience kits which are intended to be used only in combination with a separate drug product or medical device. Examples of PCDs include “drug administration refill kits” designed to replenish drug reservoirs in an implantable pump, and “metered dosing aids” designed to dispense highly precise volumes of drug when used in combination with a prefilled syringe.

The development pathway for a PCD often is a simplified version of the typical medical device development pathway that utilizes similar design controls. Design inputs are defined based on identified user needs and use-related risks of the PCD. PCD design outputs are created to satisfy user needs and design inputs. Verification and validation testing is conducted to prove that the PCD design is safe and effective, and design transfer ensures that the PCD is ready for commercial launch.

Under United States Food and Drug Administration (FDA) regulations, requirements for PCDs are governed by what medical device classification (Class I, II, or III) each PCD holds. Most PCDs classified as Class II require regulatory submission through the FDA Premarket Notification 510(k) process, whereas PCDs classified as Class I devices typically are exempt from this requirement. Class III PCDs require Premarket Approval (PMA) submissions. PCDs that are classified as biologics,
or are intended to support biologics drugs and combination products, are regulated by the FDA Center for Biologics Evaluation and Research (CBER) and require submission of an Investigational New Drug Application (IND) and/or a Biologics License Application (BLA)².

**Common Issues with PCD Development**

Often, key risks associated with the development of PCDs are related to aggressive market approval deadlines. A PCD may be necessary to address an identified issue (e.g., risk to patients) in a complementary drug product, medical device, or combination product that is already on the market, and must itself be brought to market quickly. A tight development schedule may lead to abbreviated design controls, increasing the risk that an unsafe or ineffective PCD is put on the market.

For similar reasons, PCDs may utilize off-the-shelf components or components that are manufactured by an external party. However, this practice limits the PCD manufacturer’s ability to:

- Ensure long-term supply of components
- Limit the frequency of change to the components
- Improve the product to address identified issues in the market
- Adequately investigate product complaints due to a lack of understanding of the off-the-shelf components and their individual manufacturing processes

These risks may impact patients because a slowed rate of complaint evaluation, insufficient root cause investigation, and sub-standard risk evaluation framework may cause inferior products to be in use for longer periods of time.

Another related risk is that the PCD may not interface well with its intended complementary drug or device that was developed for an alternate intended use. This could cause unforeseen patient risks associated with device-drug compatibility or usability issues when the patient population changes in the market.

**Project Management of PCD**

Multiple project management techniques can be employed during PCD development to help mitigate the potential usability and schedule risks identified above. A cross-functional concept and research phase can be added to the PCD development plan to collect critical knowledge regarding the PCD. Existing design controls from the intended complementary product can be leveraged during development of the PCD. Also, appropriate relationships between the PCD manufacturer and component suppliers can be established up-front and early into the PCD development process.

Concept and research initiation prior to beginning development of a PCD is a critical project management practice that helps drive successful device design control. Research initiatives can include:

- Identification of existing documentation and supplier relationships
- Evaluation of the components proposed for inclusion in the PCD (e.g., preliminary functionality testing)
- Review of similar products that have already gained market approval
- Voice of customer interviews with key stakeholders and intended users of the PCD to help to identify critical requirements the PCD must satisfy
The end goal of concept and research initiation is to collect information which will ultimately drive user need identification and design input requirement generation, ensuring that the PCD will be safe and effective in its intended use and will interface well with its intended complementary drug or device.

Another useful practice to employ involves leveraging all existing information and design controls available for both the PCD’s intended complementary product, and for any off-the-shelf components that may be included in the PCD. For example, existing risk assessments for a complementary device can be leveraged when conducting PCD risk activities, increasing the likelihood that the PCD will interface well with the complementary device or drug. If the PCD includes off-the-shelf components then component 510(k) clearance summaries and design verification testing reports (where available) may be leveraged as evidence of design verification for the PCD eliminating the need to repeat testing and shortening the PCDs development schedule.

If the PCD includes off-the-shelf components, another useful management practice includes establishing appropriate relationships with component suppliers early into the development process. This allows the supplier to recommend components that are best suited for the PCD’s intended use, maximizing the likelihood that the selected components will interface with the PCD’s complementary device or drug and will be safe and effective once the PCD is on the market. Additionally, quality agreements will set expectations (e.g., content and timelines) for component complaint communication and investigations, which will allow the manufacturer to conduct sufficient investigations of the complaints, evaluate the level of impact on the PCD, and take appropriate corrective and preventive measures.

Conclusion

PCDs are valuable products to develop because they allow manufacturers to address an identified issue in the complementary drug product, medical device, or combination product that is already on the market. However, PCD development inherently carries potential risks related to aggressive development schedules and the use of off-the-shelf components.

Through extensive experience in PCD development, Kymanox has identified best-practice project management techniques to help mitigate these risks. Conducting cross-functional concept and research initiation prior to beginning PCD development, leveraging all existing complementary device and off-the-shelf component design controls, and engaging component suppliers early into the development process all help to ensure that PCDs are developed on-time, interface well with their complementary products, and are safe and effective for their intended use.
References

