

Enhancing IVD Packaging Efficiency

FDA's Center for Drug Evaluation and Research (CDER) established Quality by Design (QbD) principles because manufacturing efficiencies in the pharmaceutical industry were not as state-of-the-art as in others. QbD seeks to increase quality and efficiency while decreasing waste and the need for intensive regulatory oversight.

QbD is defined as the systematic design of product formulations and related manufacturing processes to ensure a predefined quality by understanding how the variables in formulation and manufacturing affect the quality of a finished drug product. It ensures that the risks consumers face are minimized while production efficiency is enhanced.

Drug industry packaging engineers and drug formulators can now make packaging designs via proactive selection and use of active packaging components as the QbD basis for arriving at drug product stability solutions.

If quality control systems could be verified early on, the timeline for bringing a new IVD device to market could be reduced significantly by using this method.

IVD Applications

As in the pharmaceutical industry, decisions regarding active packaging for use with IVD devices (i.e., the use of sorbents) can also be made early. Packaging protection for IVD devices can be very complex because of multiple reagents and biologically active reactants with challenging stability profiles. IVD device manufacturers and the packaging engineers must consider numerous variables in determining the best package design and components to maintain the device's chemical stability and related function for as long as possible.

Packaging selection for each new IVD device can utilize a scientific QbD-based solution. Working in tandem with a packaging vendor that offers chemical, engineering, and design expertise can potentially shave 6-12 months off of time to market.

Taking The Entire Product Lifecycle Into Account.

This shows the importance of a sound packaging strategy integrating into all operations responsible for a product's lifecycle, from formulation to packaging and transportation, and ultimately to use by the medical technologist or consumer. Factors such as the IVD device's chemical properties; the ingress rate of moisture, oxygen, and hydrocarbons through and contained within a package; the design of a package; materials of construction; and the choice of sor-

bent are all critical factors in protecting the device's physical and chemical integrity.

Calculating Stability By Pseudo-Empirical Modeling. The device's integrity comes in part from an approach dubbed "calculations through operations." It incorporates sophisticated pseudo-empirical modeling that can help researchers identify the right conditions to ensure the effectiveness of their IVD devices. This mechanism, the "calculations" component of the approach, can be performed early in the development process, guiding packaging decisions and helping to avoid costly errors.

Consider this example: An analysis of a blood-glucose test strip packaged in a high-density polyethylene container and closure system would take into account the moisture vapor transmission or oxygen transmission into the bottle over time, the moisture adsorption isotherm for the test strips, and the absorption profile for the sorbent. Linking these variables together mathematically predicts the conditions within a package over time in a given environment. This resulting information will ultimately determine how manufacturers can maintain an IVD device's chemical and physical characteristics during its shelf life.

Maintaining Stability With Intelligent Sorbents. The data derived from the use of pseudo-empirical modeling informs the development of the best active packaging solution, which takes into account the IVD device, its chemistry, and its required shelf life. Referred to as the "operations" component of the calculations-through-operations concept, the process of integrating the desired sorbent solution into a product's packaging is critical in maintaining IVD device stability and therefore test result consistency.

In most cases, the goal of a sorbent is to prevent chemical and physical degradation of the IVD device from taking place within its package. Additionally, with newer IVD device reaction times and device and packaging configurations coming onto the market, sorbents are required to perform multiple functions that address the specific needs of a given application. **IVD**



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