Enablement of Patient Centric Solutions Through Integrating Drug - Device Development

Fran L. DeGrazio, Vice President of Scientific Affairs & Technical Services

The many facets of patient centric solutions involves focusing the drug product design and development according to distinct requirements relative to the delivery system. The therapeutic effect, together with concordance and adherence to the treatment, is vital to positive patient outcomes, while dose accuracy is critical for the delivery system. Evidence for component suitability and device performance with the drug product must be aligned throughout the lifecycle of the product. The development and manufacturing of drug products will follow quality by design (QbD) approaches, while that of medical devices require design controls per 21CFR 820. Despite these differences the final product and delivery system must be integrated for regulatory approval. There are a multitude of factors that can impact the drug product critical quality attributes (CQAs) and the device essential performance requirements (EPRs). The regulations concerning drug products and medical devices diverge but risk management is a common element for both. Efficiencies can be gained throughout the supply chain based on mutual stakeholder needs and planning. A case can be made to integrate delivery devices during early phases of drug development in order to ensure drug product quality. These complex processes have mutual milestones which can be simplified in a manner which facilitates product and process understanding and support life cycle management which are described here in.