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Perspective on Challenges Facing Injectable Products

The outlook for sterile injectable products continues to expand as do the many challenges facing pharmaceutical manufactures. Research and development efforts are now focused on patient centric therapies and the quality of medicines will be judged accordingly. Influencing factors include the drive to lower medical costs by enabling at-home self administration and promoting adherence with delivery devices designed to meet patient needs. In addition, approvals of biologics are on the rise and being facilitated by FDA expedited approval pathways for novel drugs. The injectable route of administration is common to many biologics which contributes to the increased need for qualified delivery system. A key consideration during drug product development is the interaction between multiple components that will collectively affect performance and quality of the final product. Building quality into drug products also includes efficient manufacturing capabilities. The lack of scientific understanding and inadequate manufacturing controls has led to shortages according to FDA. Combined challenges are linked to qualifying components, processing and filling, complex supply chains, and evolving globalization. These variables can generate an abundance of risked factors which can result in long development times, product recalls, and shortages of lifesaving medicines. Risk management and quality by design (QbD) paradigms have become the standard approach for drug development but the fact remains that therapies can only be effective if the medicine can be successfully delivered to the patient. Integral to the drug product are the protection of medicines and safe delivery to the patient, which are essential elements for achieving positive outcomes. The progression of the QbD paradigm should bring together drug development and manufacture with containment and delivery systems. These concepts can be applicable to the final drug product and its critical material attributes, such as components of delivery systems. A comprehensive science based program for product and process understanding will allow efficient manufacture of quality products to be safely delivered to the patient.

Biography

Diane Paskiet has over twenty years of experience in packaging analysis. She has served as a project advisor in support of qualification studies associated with drug containment systems for regulatory filings. Her current responsibilities include coordination of study plans for technical support of packaging components and R&D. Previous to this role she was in charge of site operations for West-Monarch Analytical Laboratories. She is serving a five year term on the United States Pharmacopeia (USP) Packaging, Storage and Distribution Expert Committee and a co-recipient of the USP award for Innovative Response to a Public Health Challenge. She is Chair of the PQRI Parenteral and Ophthalmic Drug Product (PODP) Leachables and Extractables Working Group and a faculty member of the PDA Training Institute, as well as author/co-author of papers on the subject of pharmaceutical packaging.

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