Thresholds and Best Practices for Parenteral and Ophthalmic Drug Products (PODP)

February 2011 Workshop

Acknowledgments

In 2006, the Product Quality Research Institute's (PQRI) Leachables and Extractables for Orally Inhaled and Nasal Drug Products (OINDP) Working Group established Thresholds and Best Practices that revolutionized the safety qualification process for these dosage forms by providing clear, concise, coherent, and comprehensive strategies and tactics for safety assessment. The success of these strategies has led to the proposal for Reporting and Qualification Thresholds for Leachables in PODP, submitted to the PQRI Steering Committee in March 2007. The proposal was approved and the Work Plan entitled *Development of Scientifically Justifiable Thresholds and Best Demonstrated Characterization Practices for Leachables and Extractables in Parenterals and Ophthalmic Drug Products (PODP)* was submitted and subsequently approved in April 2008.

The PODP Working Group has moved forward, guided by the principle that the OINDP recommendations could be transformed into PODP recommendations by considering such factors as dose, duration, patient populations, and other product/user attributes. Toxicologists considered the safety profiles of nearly 500 known extractables/leachables compounds and analytical chemists examined extractable analysis methods for characterizing materials commonly utilized in PODP packaging systems. Both groups of scientists utilized the generated information to begin the process of drafting PODP recommendations. The individuals responsible for the planning, data acquisition and presentation of accumulated data are acknowledged herein:

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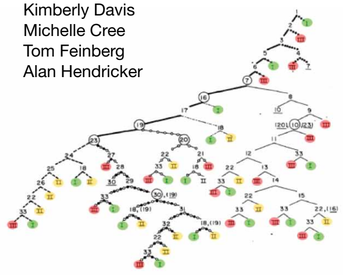

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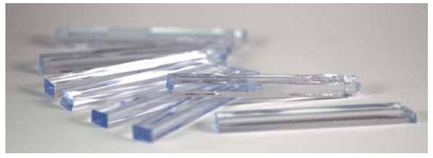

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