The role of ELSIE in evolving current thinking on extractables and leachables

Extractables and Leachables Safety Information Exchange (ELSIE) has been the most influential industry group in developing guidelines for extractables and leachables. In the wake of the ICH convening a new group to develop a concept paper and business plan on their Q3E Impurity Guideline, Dave Elder discusses the strides that ELSIE has made in its guidelines; particularly highlighting their work implementing the PDE principle, which considers the toxicity of leachables when defining limits for intake.