Strategies for Setting Rational MAC-Based Limits Part III–Leveraging Characterization and Toxicological Data

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The first two parts of this series described strategies for setting rational acceptance limits based on the conventional maximum allowable carryover (MAC) approach (1, 2). This article describes strategies for setting rational acceptance limits for process residues based on characterization and toxicological data. These strategies are based on clearance, acceptable daily exposure (ADE), and degradation of the previously manufactured or contaminating active pharmaceutical ingredient (API) (i.e., the API in the product that is manufactured before the execution of cleaning). Download "Strategies...