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Methodology for Assessing Product Inactivation during Cleaning Part I: Experimental Approach and Analytical Methods

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The experimental approach and analytical methods for assessing inactivation of the API during cleaning are described in Part I. A rational approach for setting safety-based acceptance limits for inactivated product and process residuals is described in Part II. The scope of this paper is limited to biopharmaceutical cleaning processes; nonetheless, the underlying concepts may be useful in designing inactivation studies and setting acceptance limits for other types of pharmaceutical cleaning processes. INTRODUCTION An important regulatory expectation for multiproduct cleaning validation is to demonstrate...