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Methodology for Assessing Product Inactivation During Cleaning Part II: Setting Acceptance Limits of Biopharmaceutical Product Carryover for Equipment Cleaning

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For multi-product biopharmaceutical facilities, setting the acceptable level of process residues following equipment cleaning is an important regulatory, business, product quality, and patient safety consideration. Conventional approaches for setting an acceptance limit for process residues have been based on the assumption that the active pharmaceutical ingredient (API) (depending on the process soil, API refers to the active pharmaceutical ingredient in the drug product, drug substance, or drug substance intermediate) is chemically or functionally intact following the cleaning process. These approaches include Maximum Allowable Carryover (MAC) Health Based Exposure Limits and other “dose” or Permissible Daily Exposure (PDE)-based limits. The concept for cleaning acceptance limits based on intact product originated from the manufacturing of small molecule pharmaceuticals (1). In contrast to pharmaceutical small molecules, biopharmaceutical products are large molecules that are likely to degrade and become inactive when exposed to cleaning conditions. Therefore, an alternative approach to setting cleaning acceptance limits for biopharmaceutical products based on the actual process residues that could potentially be present on production equipment should be considered.

Part I described the methodology to assess and verify API inactivation during cleaning (2). In Part II, alternative approaches for setting acceptable levels of process residue will be described building upon the basis that API inactivation by the cleaning process has been demonstrated.

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

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