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Biopharmaceutical Cleaning Validation Leveraging Acceptable Exposure of Host-Cell Protein to Set Acceptance Limits for Inactivated Product

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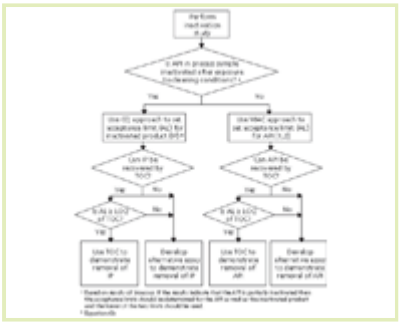

Flowchart for setting acceptance limits for inactivated product.

INTRODUCTION For multiproduct cleaning validation, acceptable carryover of the previously manufactured active pharmaceutical ingredient (API) (product A) into the subsequently manufactured batch (product B) is determined through a maximum allowable carryover (MAC) assessment (1-5). Limitations of the MAC Approach A limitation of the MAC approach is that if the previously manufactured API becomes pharmacologically inactive during cleaning, then there is limited value in verifying removal of the API. Instead, it is more appropriate to demonstrate that the carryover of the inactivated product is...