Application of Sterilization by Gamma Radiation for Single-Use Disposable Technologies in the Biopharmaceutical Sector

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INTRODUCTION A relatively recent advance in biopharmaceutical processing has been the use of single-use disposable technologies. Single-use disposable technologies include tubing, capsule filters, single-use ion exchange membrane chromatography devices, single-use mixers, bioreactors, product holding sterile bags in place of stainless steel vessels (i.e., sterile fluid containment bags), connection devices, and sampling receptacles (1). The drivers for the implementation of such technology include improved sterility assurance, greater flexibility for biopharmaceutical manufacturing processes,...

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