Current Good Tissue Practice Basics for Human Cells, Tissues, and Cellular and Tissue-Based Products

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Manufacturers of HCT/Ps are inspected by the Center for Biologics Evaluation and Research (CBER), with the number of inspections having increased from 111 in 1998 to 383 in 2008 with an average inspection time in 2008 of approximately 40 hours. Approximately 75% of the inspections conducted in 2008 resulted in “No Action Indicated” (NAI), 23% resulted in “Voluntary Action Indicated” (VAI), and the remaining 2% in “Official Action Indicated” (OAI) (4). The high percent of inspections resulting in NAI demonstrates that manufacturers understand the requirements, have established...