How to Guarantee You Get a Warning Letter from FDA! A GMP Inspection Process Guide for European Companies

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FDA’s mission statement states in part that FDA’s purpose is “protecting the public health by assuring the safety, efficacy, and security of human and veterinary drugs, biological products, medical devices, our nation’s food supply, cosmetics, and products that emit radiation (1).” This mission is performed in two parts: first the scientific review and approval of the drug to ensure that it is safe and effective; and the second the inspection of manufacturing facilities to ensure that the drugs produced in them are of correct quality, by assuring that they have been manufactured in accordance...