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China’s 2011 GMP Regulations–Combatting Poor API/Drug Quality

By **Michael H. Anisfeld**

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US Food and Drug Administration is so concerned about the quality problems associated with foods, cosmetics, medical devices, APIs, and finished dosage forms exported from China to the US that, in 2012, it manned an office in Shanghai with 15 full-time FDA inspectors; each on a two-year assignment from the US to perform good manufacturing practice (GMP) inspections in China. According to FDA, they can perform an inspection in China within two to three days rather than the three months typically used to take to organize an inspection. However, when FDA announces that they intend to perform an inspection,...