

## FDA 483 Responses—Compliance Considerations

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### KEY POINTS

The following key points are discussed in this article:

- US Food and Drug Administration current good manufacturing practices (CGMPs) provide fundamental requirements for pharmaceutical manufacturing
- The FDA 483 is the official recording of FDA investigator observations from an FDA inspection
- An inadequate inspection response is the primary reason for warning letters being issued in 2008
- FDA's Anita Richardson (Center for Biologics Evaluation and Research) discussed topics associated with writing an effective Form 483 response at the 5th Annual *FDA and the Changing Paradigm for HCT/P Regulation* conference in January 2009
- Responses to FDA 483s are not legally required; however, responses are strongly recommended
- Responses may mitigate an FDA compliance decision for further action
- Responses demonstrate understanding and acknowledgement of the observations
- Responses demonstrate a commitment to correct or voluntarily comply with corrective actions
- Responses establish credibility with FDA
- Failure to respond, inadequate responses, or failure to adhere to promised corrective actions make a firm susceptible to aggressive regulatory or legal actions by FDA such as product seizure, legal injunction, and other actions
- After an inspection, an action plan should be quickly developed to address each observation
- Effective responses should include a commitment statement from senior leadership, should address each observation separately, should provide corrective action accomplished planned, and should be specific, complete, realistic, and deliver on commitments
- Effective responses must be timely, include timeframes for correction, verification methods, monitoring of corrections, and supporting documentation
- FDA has implemented a Warning Letter Close-out Program
- *The Enforcement Story, Fiscal Year 2008* summarizes FDA compliance activities during 2008 and provides useful statistics
- Firms should be very familiar with their incoming materials and product supply chain
- Firms should fully understand the interactions of the processes and systems that impact quality, safety, and effectiveness of their products
- As part of responding to FDA 483 observations, firms should also assess their general internal compliance programs—Why were 483 deficiencies not detected internally?
- FDA 483 observations may be caused or intensified by inadequate audit management (i.e., logistics, timelines of responses, documentation retrieval, etc.) as well as soft “people” skills.

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