

## The Changing Face of FDA Inspections for Sterile Products



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By

**Jan 9, 2013 2:26 pm EST**



Courtesy of FDA

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**INITIATING THE INSPECTION** A typical inspection has a minimum of two investigators, typically someone that understands quality and the manufacturing process while the other investigator is qualified for evaluation of laboratory activities. The inspections have typically been planned, with a notice provided to the plant prior to initiation of the inspection. Especially for foreign inspections, documents were provided identifying various documents that the investigators would like to see as part of the inspections. Some typical inclusions for these documents are: Listing of site standard operating...

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