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Denise Dion

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Every year, the U.S. FDA updates the Investigations Operations Manual (IOM) for its network of inspectors and field investigators. Fortunately, FDA makes this incredibly useful collection of agency policies, guidelines and checklists readily available to anyone, including companies subject to scheduled and unannounced visits by FDA.

In essence, the IOM gives you a continually updated “playbook” for what to expect the next time FDA knocks on your door.

The IOM tells agency personnel what to do – and, just as importantly, how to do it – for all things related to inspections, investigations and imports. The Manual also defines the difference between an inspection and an investigation.

Written by Denise Dion, a former editor of the IOM and expert investigator during her 18-year career at the FDA, this Advisory will help you use the IOM to assess your facility’s inspection readiness. It also will help you develop SOPs that anticipate and complement FDA’s inspection process. You’ll be better able to understand what FDA inspectors will look for and why, and you’ll be able to select the most relevant IOM inspection protocols and integrate them into your own internal audit programs.

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