

## Improving Quality and Compliance.

### FDA Globalization Act Further Tightens the Supply Chain

The House Committee on Energy and Commerce recently issued a revised discussion draft to the FDA Globalization Act of 2008, increasing the regulation of pharmaceutical production.

Under the proposal, registered establishments that manufacture, prepare, propagate, compound, or process a drug are required to implement a quality risk-management plan that is designed to ensure safety and quality. The revised draft provides additional requirements for quality risk-management plans, extends annual registration requirements to excipient producers, allows for increased inspection, and requires electronic statements for the supply chain of a drug.

Read more about the increased regulation [here](#).

### RFID Tags Create Risks for Medical Devices

Dutch researchers recently reported that interference from radiofrequency identification (RFID) systems may cause medical device malfunctions, according to June issue of the Journal of the American Medical Association.

The Netherlands' Ministry of Health conducted more than 100 tests on 41 different medical devices from 22 manufacturers, including B. Braun's Infusomat infusion pump, Medtronic and Biotronik external pacemakers, GE's Marquette MAC 5000 12-lead electrocardiogram device, as well as monitors, anesthesia devices and ventilators.

Read their results [here](#).

### Effective Quality Systems Begin with Employee Feedback

While it may seem like an elementary suggestion, FDA quality systems expert, Kim Trautman, points out that many device manufacturers try to implement too many procedures, which can often complicate the quality system. Many times, quality systems professionals are left looking at SOPs with unclear action steps, which is why it's important for companies to ask workers to sound the alarm when they become overwhelmed. Managers "need to go to the people who are doing the processes and determine what procedures they're utilizing, how they're utilizing them, and whether the SOPs are confusing or bouncing them around to too many different places," Trautman says.

### GHTF Releases Guidance on IVD Medical Device Classification

The Food and Drug Administration (FDA) has recently announced the availability of several proposed and final documents that have been prepared by Study Groups 1 and 5 of the Global Harmonization Task Force (GHTF). These documents represent a harmonized proposal and recommendation from the GHTF Study Groups that may be used by governments and organizations developing and updating their regulatory requirements for medical devices.

View the FDA announcement [here](#).

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