MEDTECH INSIGHT
CITELINE COMMERCIAL

09 May 2018 | **Interviews**

NSF's Trautman Talks MDSAP, Swapping FDA's QSR For ISO 13485, Regulatory Convergence, EU's MDR & IVDR, And More

by Shawn M. Schmitt

Former longtime US FDA official Kim Trautman, now with NSF International, sat down with *Medtech Insight* at MedCon 2018 for a podcast interview to discuss an array of industry issues, including the burgeoning Medical Device Single Audit Program, international regulatory convergence, FDA's percolating plan to replace the Quality System Regulation with ISO 13485, what keeps her up at night (hint: it's EU's new Medical Device and IVD Regulations), and other important issues that device-makers need to keep a sharp eye on.

When it comes to understanding the intricacies of international regulatory issues and possessing high-level quality systems knowledge, former US FDA official Kim Trautman may be second to none.

Early on in her career at the agency – between 1991 and 1996 – Trautman crafted the Quality System Regulation, which has been the bedrock rule for making safe and effective medical devices in the United States for 22 years and counting – *although that might soon change*, as you'll hear in the interview below. (Also see "*US FDA Commissioner: Agency Will Propose New Rule That Blends Quality System Regulation, ISO 13485*" - Medtech Insight, 9 May, 2018.)

After Trautman's success in drafting the QSR, she went on to enjoy a long stint as FDA's quality systems guru. Late in her career at the agency, she took on a top-level role in international regulatory affairs. And, in early 2016, she was named executive VP of medical device international services at global firm NSF International.

Recently at MedCon 2018 in Cincinnati, Trautman sat down with *Medtech Insight* to talk about an

array of industry issues, including the burgeoning Medical Device Single Audit Program, international regulatory convergence, FDA's percolating plan to replace the Quality System Regulation with ISO 13485, what keeps her up at night (hint: it's EU's new Medical Device and IVD Regulations), and other important issues that device-makers need to keep a sharp eye on.

Listen to the podcast via the player below:

Click here to explore this interactive content online

Skip to:

- The latest on MDSAP: 1:33
- International regulatory convergence: 13:43
- FDA transitioning to International Medical Device Regulators Forum (IMDRF) codes for adverse event reporting: 16:00
- Will FDA replace its Quality System Regulation with ISO 13485?: 17:26
- Challenges related to the EU's Medical Device and IVD Regulations: 26:10
- FDA's pilot program to measure the capability of manufacturing sites using the CMMI maturity model: 29:53

Medtech Insight articles germane to this podcast:

- *US FDA Commissioner: Agency Will Propose New Rule That Blends Quality System Regulation, ISO 13485*
- *Bye-Bye QSR? FDA May Swap Its Quality System Regulation For ISO 13485 'In The Coming Years,' Official Says*
- *Challenges Prompt Canada To Adapt MDSAP Transition Plan*
- *US FDA Ponders Using MDSAP Audit Results In Lieu Of Pre-Approval Facility Inspections*
- *Brazil Requires Certification For Wireless Device Registration*
- *EU Regulatory Reads, April 2018: Specific MDR Aspects Start to Come Under Fire*
- *Chasing Quality Isn't Easy. But An FDA Pilot Aims To Boost Quality By Appraising The Capability Of Manufacturing Sites*\
- *Device-Makers Like Baxter Are Lining Up To Let CMMI Evaluate Their Manufacturing Site Capabilities. Here's What To Expect If You're Appraised*