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Compliance Corner: Leverage MDSAP Companion Doc To Master Your Next Audit, Train Staff, Expert Advises

by Shawn M. Schmitt

Longtime industry expert Connie Hoy says medtech companies that sign up for an audit through the Medical Device Single Audit Program will have a leg-up if they prepare beforehand by reading the MDSAP Companion Document. The doc can also be used to train workers on what an MDSAP auditor will be looking at and asking for.

Medtech companies that sign up for an audit through the Medical Device Single Audit Program will have a leg-up if they prepare beforehand by reading the *MDSAP Companion Document* and training staff on its relevant parts, an industry expert advises.

MDSAP, created by the International Medical Device Regulators Forum (IMDRF), allows firms to undergo one audit by an accredited third party to satisfy quality regulations for the US, Canada, Brazil, Japan and Australia. The auditing approach maps to international quality systems standard *ISO 13485*.

Similar in spirit to the US Food and Drug Administration's *Quality System Inspection Technique (QSIT)* for agency investigators, the 123-page companion doc details how an MDSAP audit unfolds. It outlines the processes that auditors will focus on during an audit and the tasks – or steps – they must accomplish when reviewing a particular area.

"The companion document lays out, word-for-word, what questions you're going to be asked by the auditor, in what order they're going to be asked, and what objective evidence they're going to want to look at," said Connie Hoy of Hoy & Associates Regulatory Consulting.

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> *"What more could you possibly want to be prepared?" – Connie Hoy*

Hoy, who previously was executive VP of clinical development and regulatory affairs for device maker Cynosure, said manufacturers that read and digest the document will have an advantage by understanding in advance the general direction of the audit, as well as where any gaps might lie in their quality system.

"When I [worked at Cynosure and] got my hands on the companion document, I was really happy. It looked very familiar because it follows ISO 13485," Hoy said.

"But I was very, very happy that the document lays out, 'First they're going to ask you this, and then they're going to want to look at this piece of objective evidence, and then they're going to move on and link it to another process, and ask you this, and look at this objective evidence,'" she said. "What more could you possibly want to be prepared?"

Hoy also urges device makers to use the companion doc as an MDSAP training tool.

"So, make sure you read this document," she said. "You want to read it, and read it, and read it. You want to highlight sections. Highlight the things you think you're missing. And use it as a training tool – but don't give it to everybody in your company."

That's because handing out such a large document could prove intimidating for workers.

Compliance Corner: 8 Handy Tips From An MDSAP Auditor To Help You Ace Your Next Audit

By Shawn M. Schmitt

29 Oct 2018
NSF International's Brian Ludovico offers up advice for device-makers facing an audit under the Medical Device Single Audit Program.

Read the full article here

The companion doc "is more than a hundred pages of 'Oh my gosh' – and if you're an engineer and you're not used to reading that type of document, it can be daunting. So you don't want to just give them the entire thing."

Instead, Hoy recommends that firms use software like Adobe to cut and paste relevant sections

into a smaller, easier-to-digest document.

“By doing that, I created training tools right out of the companion document,” she said. “And so when I met with purchasing, for example, and said, ‘OK guys, this what the MDSAP auditor is going to be looking at,’ I didn’t give them a hundred pages – I gave them seven, and used it as my training tool to help train my organization.”

Hoy’s comments came during FDAnews’ 14th Annual FDA Inspections Summit.