

Validation Consultant Connie Curts to be Featured on Close Up Radio

LEE'S SUMMIT, MISSOURI, UNITED STATES, February 26, 2020 /EINPresswire.com/ -- Regulations compel due diligence to protect the public. Under FDA regulations, all healthcare related hardware, software, and instrumentation must go through a series of procedures to ensure it works consistently, accurately, can provide reliable raw data, and has strong electronic security to prevent changes or deletions. The combination of regulated procedures is referred to as "validation."

Connie Curts is a validation consultant. She specializes in developing validation documentation for FDA-regulated equipment dedicated to pharmaceutical research.

"Everything that goes into a study to develop pharmaceuticals needs to be accurate, so all procedures must be followed specifically without deviation," says Connie. "What I do is create the documents to define the intended usage for clients. There are user requirements against which you'd test the system to determine its accuracy. I create those test protocols, somebody else executes those protocols, and yet another person is reviewing the results to make sure the system demonstrates its performance."



An IT professional by trade with a background in engineering, Connie develops the documentation for completeness and clarity, so clients know what they need to do to remain in compliance and everything is handled consistently and tracked through chain of custody.

"It's a tremendously complicated process, which is partly why drugs, especially new drugs, are so expensive," says Connie. "With validation, you have to be very careful because in the long run, as with everything in health care, a patient's life could be at stake."

When the FDA comes in and does an audit of a new system, they want to see all necessary due diligence.

"Sometimes it can be contentious with the FDA," says Connie, "but I tend to believe that most people really are trying to do their best and be as detailed and accurate as possible. They are as concerned for the patient as much as anyone."

Connie says she has always been fascinated by mathematics. She holds a bachelor's degree in electronics engineering technology through Missouri Institute of Technology. As the computer age changed and industries changed, her career evolved to focus on regulations in one industry.

"I prefer to tinker with things, make them work, debug them," says Connie. "I also love teaching and giving back to the next generation, everything I could about my experiences and best practices for good laboratory procedure."

She was one of 95 international collaborators on the book entitled Computerized Systems Used in Nonclinical Safety Assessment: Current Concepts in Validation and Compliance.

Close Up Radio will feature Connie Curts in an interview with Jim Masters on February 28th at 2pm EST

Listen to the show on [BlogTalkRadio](#)

If you have any questions for our guest, please call (347) 996-3389

Lou Ceparano
Close Up Radio
+1 (631) 850-3314

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