

Mobitor announces validation effort for FDA regulated System

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As part of its on-going commitment to medical device manufacturers and distributors, Mobitor Corporation has launched an initiative to help customers comply with Food and Drug Administration requirements. Mobitor has developed a package of documents and services that will significantly reduce the time and expense associated with the FDA software validation process.

FDA requires that all systems and equipment involved in the manufacturing, packaging, holding, and distribution of pharmaceuticals or medical devices be verified to perform accurately, reliably, and consistently, and that the data supporting these processes is secure. FDA does not certify any software vendor or application, but rather, holds the software user responsible for ensuring that their own system implementations are validated.

"The Mobitor SOPIC system has validated part/lot tracking, patient identification, and many other total quality management capabilities that fall within the scope of FDA regulation. Because validation can be a tedious and costly process, we saw it as an area where we could help our customers improve their efficiency with Mobitor," said Lakshman Watawala, Mobitor CTO and Chief Architect.

Watawala explained, "Validation consulting firms with no previous exposure to Mobitor SOPIC and/or the customer's unique business environment must spend considerable time developing the information needed to construct the validation documents. This can substantially increase the total cost of the validation project. We eliminated this cost component by leveraging our familiarity with both Mobitor SOPIC software and our customers' operations to build a validation document package that can be tailored to the customer's installation. To our knowledge, no other Field Automation vendor offers such a package."

The scope of the validation covers all Mobitor SOPIC software functions related to the management, tracking and distribution of regulated materials under FDA jurisdiction. The documentation addresses performance validation issues including: qualification testing, quality assurance, software configuration management, training, security, electronic records, and electronic signatures.

Validation consulting services typically provide intensive testing of the system to ensure data integrity. Testing considerations include functional performance, accuracy when data is concurrently entered from multiple terminals, and data integrity in the event of high volume transactions, unexpected computer shutdowns, etc.

"In addition to meeting FDA requirements, our validation package actively promotes total quality management practices, which include reliable lot tracking and documented distribution processes that ensure product safety, and continuous process improvement," concluded Watawala. "We believe this model will help our customers realize major savings in time and money in their pursuit of sales and distribution excellence."