

## **New SyberWorks Media Center Article: *Can a learning management system (LMS) software provider offer a 21 CFR Part 11 FDA compliant “solution”?***

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SyberWorks, Inc., a leader in custom e-Learning Solutions and the Learning Management System (LMS) industry, today announces an article available in the SyberWorks Online Media Center: *Can a learning management system (LMS) software provider offer a 21 CFR Part 11 FDA compliant “solution”?*, by Dave Boggs, CEO of SyberWorks, and Stepheni Norton, Principal Consultant at 21 CFR Consulting LLC.

Mary Kay Lofurno, Director of Marketing at SyberWorks, states:

***“The white paper provides an in-depth look at FDA Title 21 CFR Part 11 compliance, as it relates to learning management system validation. It also exposes some of the misconceptions that are associated with Title 21 CFR Part 11 compliance and learning management systems.”***

Lofurno continues, “It’s an important read for any compliance, quality, or training personnel who are responsible for managing FDA compliance, because it identifies the internal policies and procedures that are required, along with the technical aspects of learning management system validation.”

The article is located in the SyberWorks Online Media Center at <http://www.syberworks.com/articles/21cfrpart11.htm>.

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### **About the Authors**

#### *Dave Boggs*

Dave Boggs is the founder and CEO of SyberWorks, Inc (<http://www.syberworks.com>). He has been involved with computer-based and web-based training for more than twelve years. Before founding SyberWorks, Dave was the VP of Sales and Business Development for Relational Courseware. He holds a Bachelor of Science degree in Physics from Union College in Schenectady, NY, and an MBA from the Kellogg School of Management at Northwestern University in Evanston, IL.

#### *Stepheni Norton*

Stepheni Norton has more than 11 years of FDA computer-systems quality and compliance experience, in the pharmaceutical, medical device, and biotech sectors. Additionally, she has 16 years of information-technology experience in research and development labs, the legal sector, and pharmaceutical R&D and manufacturing. In her role as Principal Consultant at 21 CFR Consulting ([www.21CFRConsulting.com](http://www.21CFRConsulting.com)), she leads her clients into an elevated state of regulatory compliance through proven validation techniques, and offers her expert guidance to technology

firms that are breaking into the regulated industry software sector. Stepheni is a contributing author to IVT's Journal of Validation Compliance, a periodical that FDA-regulated industries look to for expert advice.

### **About SyberWorks**

SyberWorks, Inc. ([www.syberworks.com](http://www.syberworks.com)) is a leader in the custom e-Learning Solutions and Learning Management System industries for Fortune 1000 corporations, higher education, and other organizations. Located in Waltham, Massachusetts, the company serves the multi-billion-dollar e-Learning market. Since 1995, SyberWorks has developed and delivered unique and economical solutions to create, manage, measure, and improve e-Learning programs at companies and organizations in the United States, Canada, Europe, and other countries.