

SyberWorks Learning Management Systems and Veracord Equip Regulatory Industry with 21 CFR Part 11 Applications

Waltham, Massachusetts – September 22, 2009

SyberWorks, Inc., a leader in custom e-learning Solutions and the Learning Management System (LMS) industry, announces its second in a series of Webinars, 21 CFR Part 11 and Its Application in a Compliant Environment.

Veracord and its division, 21 CFR Consulting, partner with SyberWorks to deliver regulatory, compliance and validation expertise in the Life Sciences industry. Together, Veracord and 21 CFR Consulting join forces to offer the 21 CFR Part 11 Webinar presented by SyberWorks, October 27.

21 CFR Part 11 and Its Application in a Compliant Environment

Date: Tuesday, October 27, 2009

Time: 11:00 a.m. to 12:00 p.m. PT / 2:00 p.m. to 3:00 p.m. ET

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21 CFR Part 11 is perhaps the most misunderstood regulation across the Life Sciences industry, yet it has tremendously broad implications. Newly appointed FDA Commissioner, Margaret Hamburg, recently promised swift and aggressive enforcement—action not seen under the Bush administration.

The October 27 Webinar discusses practical applications that enable companies to formulate an audit-proof roadmap to Part 11 implementation. Equipped with this knowledge, organizations, large and small, take a leading position to control paper trails electronically, and keep pace with streamlined approaches to compliance and validation issues that more urgently face the FDA-regulated sectors. The presentation will cover part 11 requirements for validation, audit trails, record retention, record copying, and legacy systems.

“21 CFR Part 11 is important because electronic data processing is important, particularly for the life sciences industry,” states David Park Schutz, CEO of Veracord and its 21 CFR division. “An organization that can move from paper to electronic records while complying with the Part 11 rules can create tremendous value by increasing the efficiency and speed of drug development, approval, and production.” Park adds, “The relationship between Part 11 requirements and security best practices can be leveraged to enhance an organization’s IT investment.”

Dave Boggs, CEO of SyberWorks says, “The ability to manage audit paper trails electronically mitigates risk, improves productivity, and applies the leverage needed to make process improvements happen. Since the responsibility for compliance falls squarely upon the participating company and not the application vendor themselves, it’s important for companies to understand the regulation and how it is applied to their validation and compliance process.”

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About Veracord

Headquartered in San Jose, CA, Veracord (www.veracord.com) serves the FDA regulated life science industry, which includes pharmaceutical, biotechnology, and medical device companies. Veracord offers compliance consulting services nationwide, specializing in validation, IT compliance, clinical, medical, and regulatory affairs. Veracord's signature reflects an uncommon commitment to clients, from handshake to project completion. Strengthened by its industry experience, including mastery of national and international regulations, Veracord leverages cost-effective, risk-based approaches to validation, with critical-thinking as standard strategy. Through Veracord's multi-level expertise, clients succeed on several fronts, including across-life-cycle-operations efficiency, cost reduction, and audit-proof compliance. For more information visit: www.veracord.com

About SyberWorks

SyberWorks, Inc. (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.