



# SyberWorks and Focus Compliance & Validation Services Announce Risk-Based Approach to FDA Computer Systems Validation Webinar

Waltham, Massachusetts - March 10, 2010

SyberWorks, Inc., a leader in custom e-Learning Solutions and the Learning Management System (LMS) industry, announces a Webinar, A Risk-Based Approach to FDA Computer Systems Validation.

Focus Compliance & Validation Services, will partner with SyberWorks to present the fundamentals of conducting risk-based approach to computer systems validation with emphasis on identifying hazards; ranking risk and identifying mitigations. Professionals in the Life Sciences, Medical Device, Pharmaceuticals, Medical Manufacturing and other FDA regulated industries are encouraged to attend via Webinar on April 20th.

# A Risk-Based Approach to FDA Computer Systems Validation

Date: Tuesday, April 20, 2010

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

**Click Here** and register for this Webinar.

Mark Walker, Vice President of Focus Compliance & Validation Services states, "Computer Systems are integral to the production and manufacturing of pharmaceuticals, medical devices, and biotechnology. During our webinar with SyberWorks, we will provide the fundamentals of identification of Hazards, Ranking of Risk and identifying Mitigations for the purpose of targeting validation of a computer system to determine if it is fit for its intended use. We look forward to this opportunity to work with SyberWorks"

Dave Boggs, CEO of SyberWorks says, "This webinar is the second in a series of webinars in which we are partnering with Focus Compliance & Validation Services to offer computer validation training for professionals associated with companies in the pharmaceutical, life sciences, biotechnology, medical device manufacturing or any other industry regulated by the FDA. This webinar is important because it reviews an aspect of FDA computer validation used by most companies today.

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### **About Focus Validation & Compliance Services, Inc.**

Headquartered in Knoxville, TN, Focus Compliance& Validation Services, Inc. (<a href="www.focuscvs.com">www.focuscvs.com</a>) is dedicated to providing regulatory compliance, validation, and process engineering services to the pharmaceutical, biotechnology,







and medical device industry. Focus CVS is an innovative solutions provider to the U.S. Food & Drug Administration (FDA) regulated industry.

Focus CVS delivers services and tools helping clients understand how to integrate good software-based engineering practices into their product-development methodologies for the purpose of FDA regulatory compliance.

Based on FDA and other regulatory agencies' governance and guidance criteria and first-hand experience, Focus CVS defines applicable risk-based validation principles and best practices. These principles and best practices apply to processes that are used in, and the facilities and controls that are used for, Design, Manufacturing, Packaging, Labeling, Storage, Installation, Support, Servicing, and Retirement of regulated software-based products. Through integration of these principles, clients avoid and mitigate regulatory-agency scrutiny and comply with the Federal Food, Drug, and Cosmetic Act. For more information, visit www.focuscys.com.

#### The SyberWorks Learning Management System/Learning Content Management System

SyberWorks Training Center (STC) is a Web-based Learning Management System (LMS)/Learning Content Management System (LCMS) that provides complete solutions for managing and tracking all types of training at your organization — from e-Learning courses to traditional classroom training and self-paced study programs. The STC includes extensive testing and assessment tools, reporting, management, communication and collaboration tools, and quality control capabilities — all in one integrated database application that is highly scalable to precisely meet your organization's needs. The SyberWorks Training Center LMS/LCMS can be purchased as an enterprise license or hosted application.

#### **About SyberWorks**

SyberWorks, Inc. (<a href="www.syberworks.com">www.syberworks.com</a>) 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.

