

A Risk-Based Approach to Gxp Compliant Laboratory Computerized Systems: ComplianceOnline Seminar

"A risk based approach to GxP Compliant Laboratory Computerized Systems" Seminar has been added to ComplianceOnline.com's offering.

SAN JOSE, CA, UNITED STATES,
December 21, 2021 /
EINPresswire.com/ -ComplianceOnline, the leading
provider of training for regulated
companies is hosting a 2-day virtual
seminar on 'A Risk-Based Approach to
Gxp Compliant Laboratory
Computerized Systems.' The January
24-25, 2022 seminar is led by Carolyn
Troiano, an independent consultant,
with more than 35 years of experience



in computer system validation and compliance in pharmaceutical, medical device, tobacco, and other FDA-regulated industries.

Laboratory Computerized Systems and data management operations are increasing in variety, sophistication and complexity in the GxP environment. Widespread reliance on these systems, along with their potential impact on data integrity, and the trend towards cost efficiency within companies, means that companies need to achieve GxP compliance of laboratory computerized systems– within a reasonable budget and timeline.

The wide diversity of these systems, coupled with their capability for networking, makes it impractical and inefficient to have single approach to achieve GxP compliance for all systems. For example, a High-Performance Liquid Chromatography (HPLC) with a Photo Diode Array (PDA) detector is much more complex than a pH meter and will require a correspondingly more detailed and complex implementation, control and maintenance approach.

This hands-on seminar provides a practical, risk-based approach to laboratory computerized

system specification, verification, and implementation by:

- Examining the system life cycle and its applicability for most laboratory computerized systems
- · Identifying characteristics that distinguish various types of laboratory computerized systems
- Developing a rationale for scaling activities and effort based upon risk, complexity, and novelty
- Defining a strategy for supplier assessments, and the effective leveraging of supplier knowledge, experience, and documentation
- Applying the GAMP® 5 Quality Risk Management (QRM) approach
- Defining necessary operational and maintenance activities
- Recommending an approach to system retirement
- Leveraging deliverables and activities for very similar or identical systems

For more information or to register for this seminar, please <u>click here</u>. Virtual Training Through WebEx Date: January 24-25, 2022 (11:00 AM - 5:00 PM EST)

About the Speaker:

Carolyn Troiano has more than 35 years of experience in computer system validation and compliance in the pharmaceutical, medical device, tobacco and other FDA-regulated industries. She is currently an independent consultant, advising companies on computer system validation and large-scale IT system implementation projects.

About ComplianceOnline.com:

ComplianceOnline is a leading provider of regulatory compliance training programs for companies and professionals in regulated industries. ComplianceOnline has successfully trained over 55,000 professionals from 15,000 companies to comply with the requirements of regulatory agencies. ComplianceOnline is a MetricStream portal. MetricStream (www.metricstream.com) is a market leader in Enterprise-wide Governance, Risk, Compliance (GRC), and Quality Management Solutions for global corporations.

For more information on ComplianceOnline or to browse through our training programs, please visit the <u>website</u>.

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