

## **Practices to Support FDA Computer System Validation**

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**Date :** May 01, 2018 - 10:00 AM

**Event URL :** <http://www.BostonEventsList.com/events/practices-to-support-fda-computer-system-validation-may-2018>

**Organizer :** Compliance4All DBA NetZealous

**Venue :** online

**Location :** 161 Mission Falls Lane, Suite 216,,  
Fremont, California, USA, ZIP: 94539  
Phone: 8004479407

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**Ticket Price: One Dial-in One Attendee Price: \$150.00**

Overview:

We will cover the importance of maintaining the documentation from every computer system validation effort in a "current" state. The system must be maintained in a validated state throughout its entire life cycle, and the accompanying validation documentation must also be maintained.

Why should you Attend:

This session will address the specific way of documenting your computer system validation work to ensure it meets FDA requirements and can pass an inspection. There are specific requirements that must be followed in order for the Agency to consider the documentation valid, and without following these, there is a great risk of invalidating work.

Areas Covered in the Session:

Computer System Validation (CSV) and the System  
Development Life Cycle (SDLC) Methodology

"GxP" - Good Manufacturing, Laboratory and Clinical  
Practices

21 CFR Part 11, Electronic Records/Electronic Signatures  
(ER/ES)

Data Archival to ensure security, integrity and compliance

**Who Will Benefit:**

Information Technology Analysts

Information Technology Developers and Testers

QC/QA Managers and Analysts

Analytical Chemists

Laboratory Managers

Automation Analysts

**Speaker Profile:**

Carolyn (McKillop) Troiano has more than 35 years of experience in the tobacco, pharmaceutical, medical device and other FDA-regulated industries. She has worked directly, or on a consulting basis, for many of the larger pharmaceutical and tobacco companies in the US and Europe, developing and executing compliance strategies and programs.

Event Fee: One Dial-in One Attendee Price: US\$150.00

**Contact Detail:**

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**Event Categories :**