WEBINAR

# Computer Software Assurance

## A FOCUS ON CRITICAL THINKING

**MARCH 16, 2021 • 1:00 PM EST**

Regulatory guidance on **Computerized System Validation (CSV)** has remained consistent for years, with much of the core guidance dating back to the early 2000s. However, in a recent study, the FDA has identified several industry challenges that could be improved upon by eliminating redundancy and focusing on the system's critical elements. In response to this evaluation, the FDA has agreed to streamline these points with their new and anticipated Computer Software Assurance (CSA) guidance. This update is expected to shift the industry's focus away from documentation, in favor of a greater emphasis on critical thinking, risk assessments, and testing. Apart from introducing CSA, this presentation will also discuss risk assessments for CSA validations and different types of testing methodology.

## LEARNING OBJECTIVES:

- √ Introduction of Computer Software Assurance (CSA)
- √ Comparison of different risk assessment methodologies
- √ Reviewing the importance of critical thinking
- √ Comparison of different testing methodologies

## ABOUT AGILENT:

Agilent

Agilent is a leader in life sciences, diagnostics and applied chemical markets. The company provides laboratories worldwide with instruments, services, consumables, applications and expertise, enabling customers to gain the insights they seek. Agilent's expertise and trusted collaboration give them the highest confidence in our solutions.

## ABOUT YOUR PRESENTERS:

**Matt Abrahms**
Americas Compliance Application Expert
Agilent Technologies

Matt Abrahms is a laboratory compliance specialist focused on instrument qualifications and computer system validation.
He is a frequent speaker at Agilent's compliance seminars and is a certified instructor for the USP's performance verification test.
He has performed over 100 instrument qualifications in a GMP environment and works closely with Agilent's customers to comply with new regulatory updates. As a specialist he collaborates with Agilent's solutions unit and service teams to ensure the quality of Agilent's compliance delivery.

**John Marino**
Compliance Consultant
Agilent Technologies

John has over 30 years of experience in regulated environments in the Pharmaceutical, Medical Device and Bio-Tech industries and holds a B.S. in Biology. Three quarters of John's career has been spent on the customer side of the industry in IT, R&D/QC Laboratories and Quality Assurance positions, deploying, supporting and qualifying/validating regulated computerized systems. The other quarter has been spent providing consultative compliance service programs from the vendor side of the industry within Software Quality Assurance.
His experience includes supporting/validating both standalone and enterprise laboratory informatics systems, as well as instrument qualification, preventive maintenance, disaster recovery and database migrations. He has also held a Software Quality Assurance position at Beckman-Coulter and he currently serves as the Compliance Consultant at Agilent Technologies.

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