PRINCIPLES OF THE CSA FRAMEWORK

CoursWorx

CoursWorx is an online community for Validation and Regulatory Compliance Professionals working in FDA regulated industries.

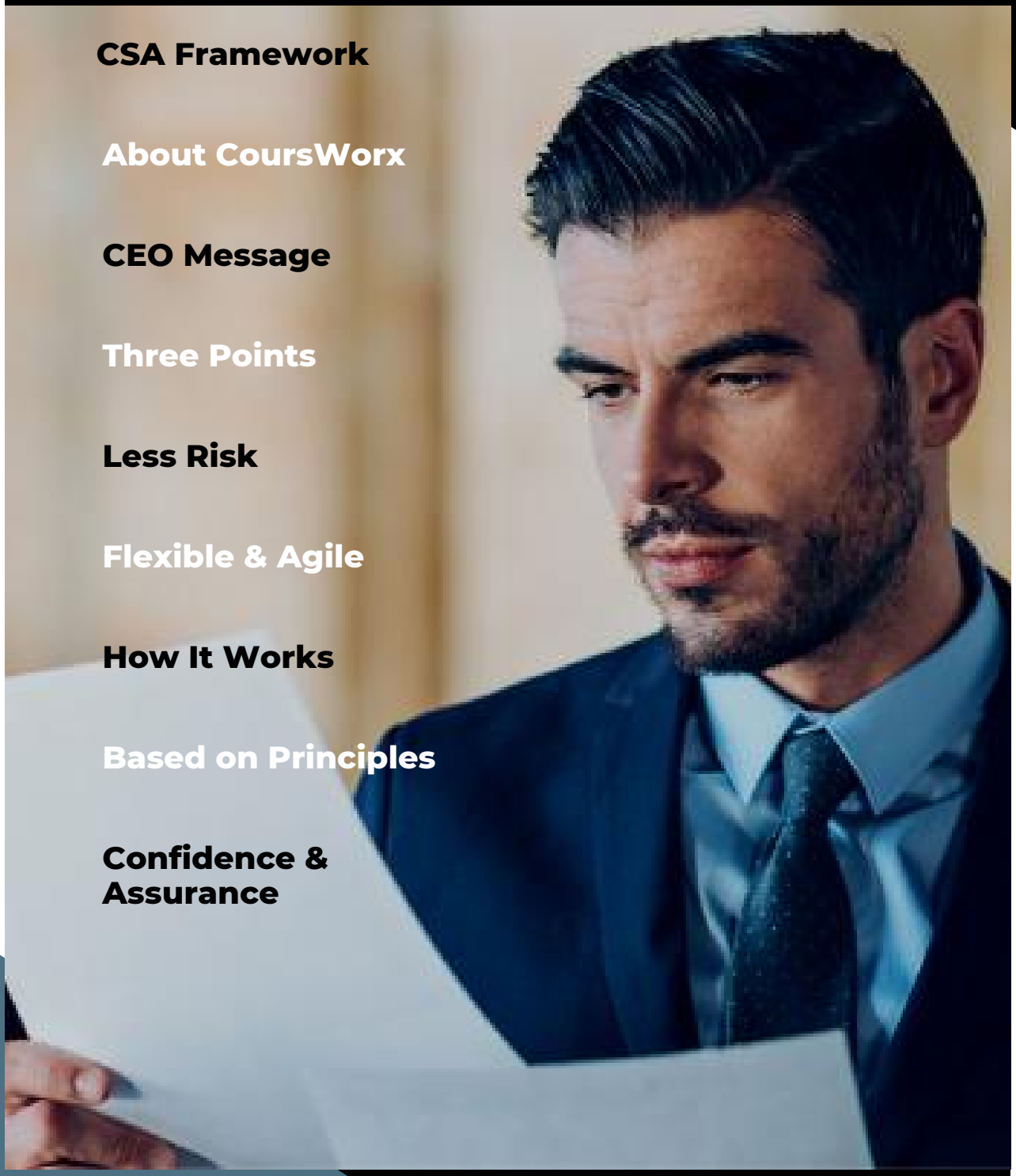
CSA FRAMEWORK

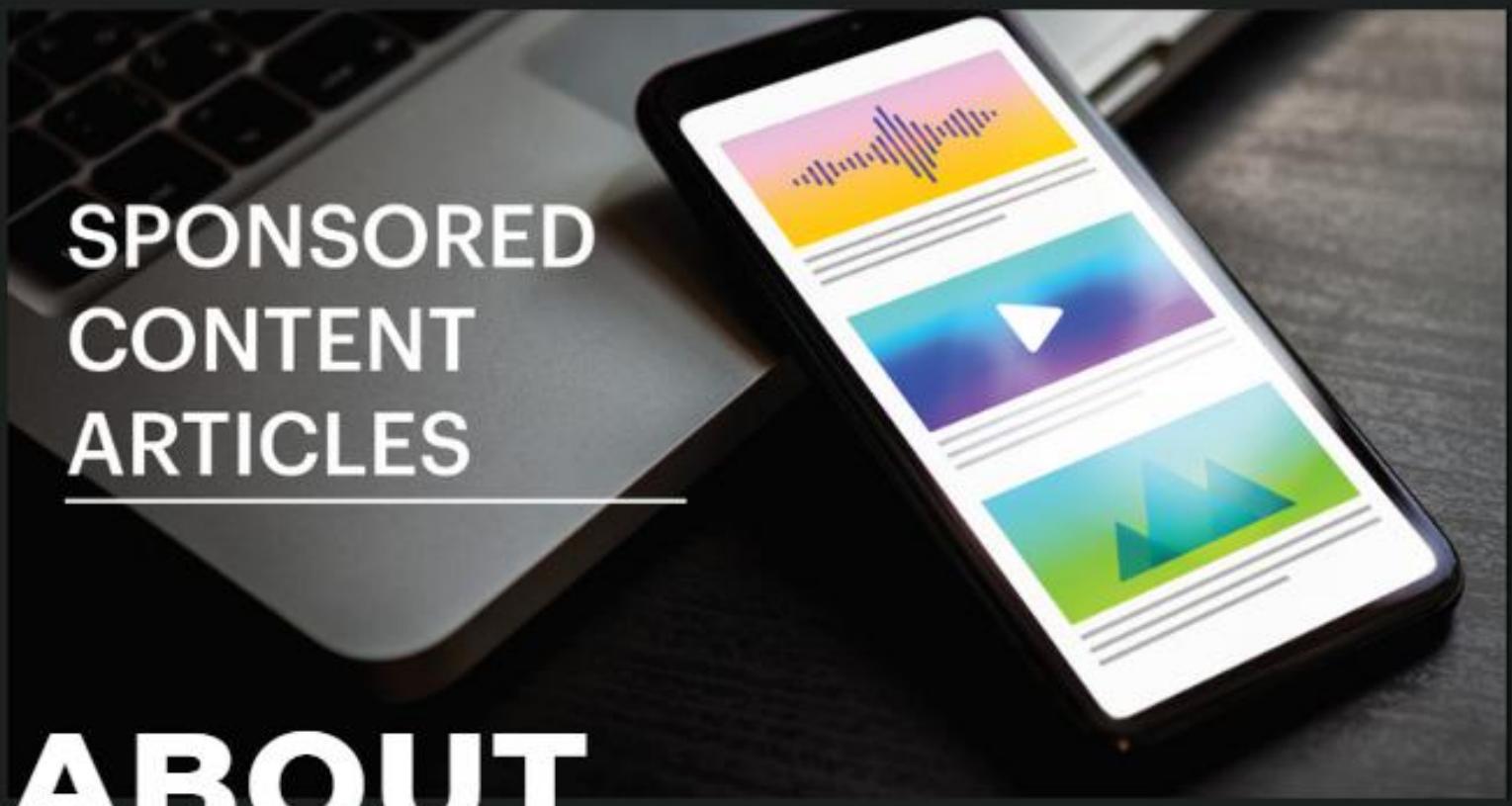
The Principles of the Computer Software Assurance Framework are a set of guidelines that aim to provide confidence in the automation used for production or quality systems in FDA-regulated industries.

The framework is intended to supplement the FDA's guidance on General Principles of Software Validation, except for Section 6, which is superseded by this framework.

The framework also aligns with the seven principles for software assurance proposed by the Software Engineering Institute, which addresses the challenges of acquiring, building, deploying, and sustaining software systems to achieve a desired level of confidence for software assurance.

TABLE OF CONTENTS

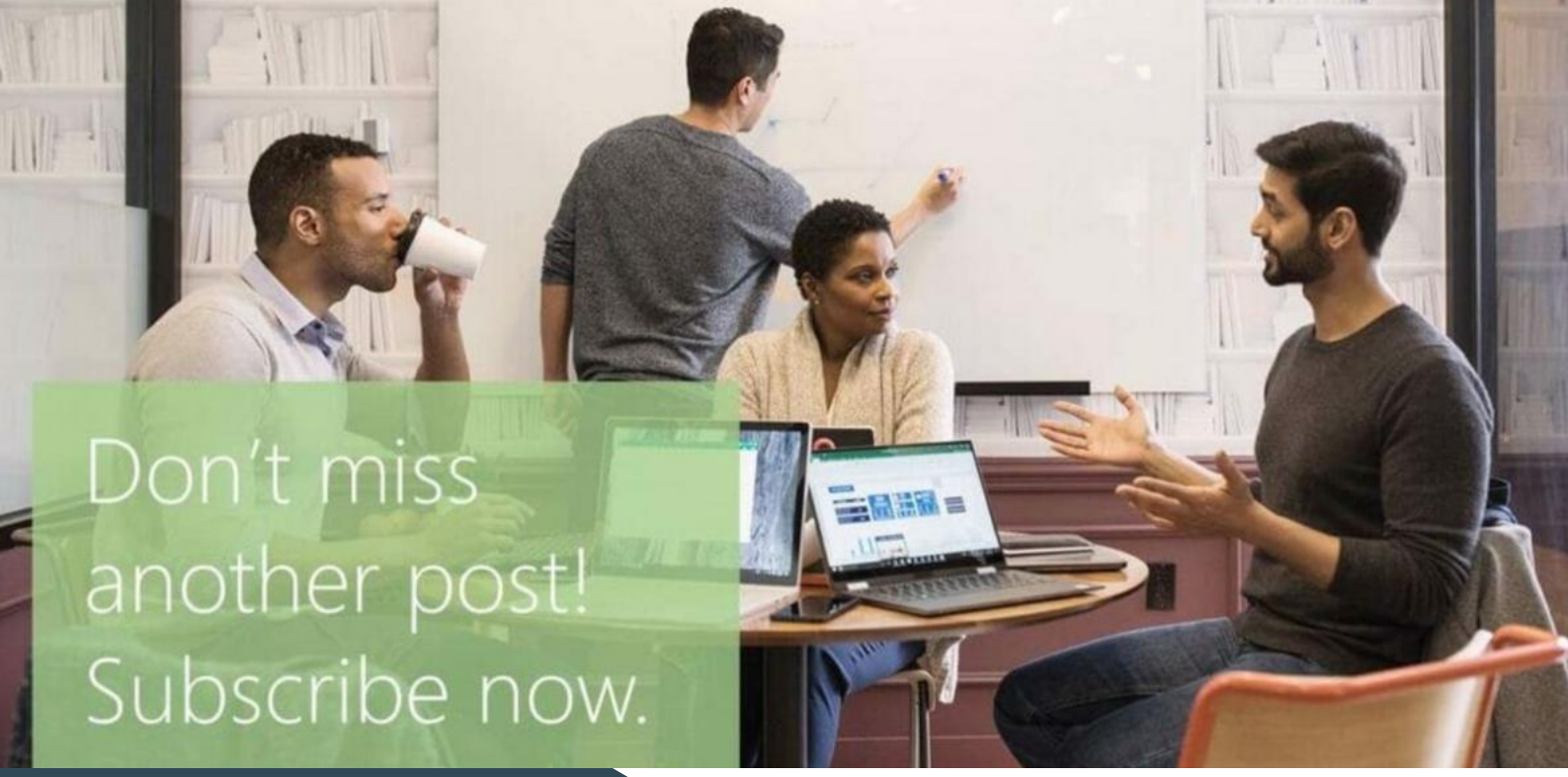




ABOUT COURSWORX

CoursWorx is an online community for Validation and Regulatory Compliance Professionals working in FDA-regulated industries.

With over 12,000 LinkedIn members, CoursWorx provides expanded networking and learning opportunities no matter what your location, industry (pharma, medical device or biotech), or compliance interests may be.



CEO MESSAGE

Jon Nugent

In a world where people long for human interaction, learning is a constant connector. Give yourself and your workforce new ways to connect, learn critical skills and share learning through our online community.

CoursWorx's online community has been designed to:

- Bring people together for a shared learning experience aligned with organizational needs, goals, and culture.
- Grow vital career and human skills across your organization with leading-edge content from expert authors alongside experienced facilitators.
- Deepen employee learning experiences and boost engagement without the need for travel or premium-priced specialized programs that live outside your learning ecosystem.

Our Mission - Being part of a community will help you evolve as a competent professional and enhance your life.

Providing a platform where you are part of a professional community that will give you access to your peers and experts to learn and grow is Our Mission. CoursWorx provides you with an open playground with many routes to develop professionally and to achieve the future you want.

SUBSCRIBE

THREE POINTS

1. The framework's focus is on the intended use of the software and determines if it is used directly for or to support the production or the quality system and use it to manage different risks with validation.

2. CSA (Computer Software Assurance) is a new approach to software validation that differs from the traditional CSV (Computer System Validation) in several ways. CSA supersedes Section 6 of the FDA's General Principles of Software Validation, which describes the validation of automated process equipment and quality system software

3. The framework takes a Risk-based approach. Once the software's intended use is identified, FDA recommends using a risk-based analysis to determine appropriate assurance activities. For a software feature that poses a high risk (a quality problem that may compromise safety), greater rigor and objective evidence collection are recommended.

LESS RISK

Less Rigor

An effort with less rigor and less objective evidence is acceptable for software with less risk.

Computer system assurance (CSA) is a framework designed to help manufacturers within the life sciences industry achieve computer system validation (CSV).

CSA helps pharmaceutical manufacturers ensure that the software they use for production or quality system purposes is suitable for its intended use and meets the regulatory requirements.

FLEXIBLE & AGILE

A Range of Methodologies

CSA provides a flexible and agile framework, enabling pharmaceutical manufacturers to employ a range of principles and methodologies, such as risk-based testing, unscripted testing, continuous performance monitoring, data oversight, and external validation activities, such as those conducted by software suppliers

CSA allows pharmaceutical manufacturers to focus on critical thinking and applying the right level of testing to higher-risk activities, while reducing the documentation burden and duplication of effort.

CSA supports continuous learning and improvement of the software assurance process and practices by monitoring the software performance and feedback from users and stakeholders

HOW IT WORKS

Leverage Supplier Activities

Use the supplier's software assurance activities and documentation to support the validation process and reduce duplication of effort.

Risk-based Approach

Apply the appropriate level of rigor and testing based on the risk of the software to patient safety and product quality.

Scalable Methods

Use various methods and techniques to establish software assurance, such as code reviews, static analysis, dynamic testing, etc.

Objective evidence

Provide objective evidence to demonstrate that the software meets its intended use and fulfills the regulatory requirements.

CONFIDENCE & ASSURANCE

Lifecycle management

Manage the software throughout its lifecycle, from planning to retirement, and address any changes or updates that may affect its performance or functionality.

Continuous learning

Monitor the software performance and feedback from users and stakeholders, and use the data to improve the software assurance process and practices.

★★★★★

In summary, CSA is a more critical thinking-driven and efficient approach compared with the CSV approach.

CSA aims to provide more confidence and assurance in the software used for production or quality system purposes in the FDA regulated industries.

JOIN THE COMMUNITY

Compliance

Connect

A Professional Community for Validation and Regulatory Compliance Professionals

Sponsored by:

CoursWorx

Where Compliance Connects