UNLOCKING THE SECRETS OF COMPUTER SYSTEM VALIDATION FOR GXP

CoursWorx

WHERE YOUR CAREER COMES TO LIFE

EDITOR'S MESSAGE

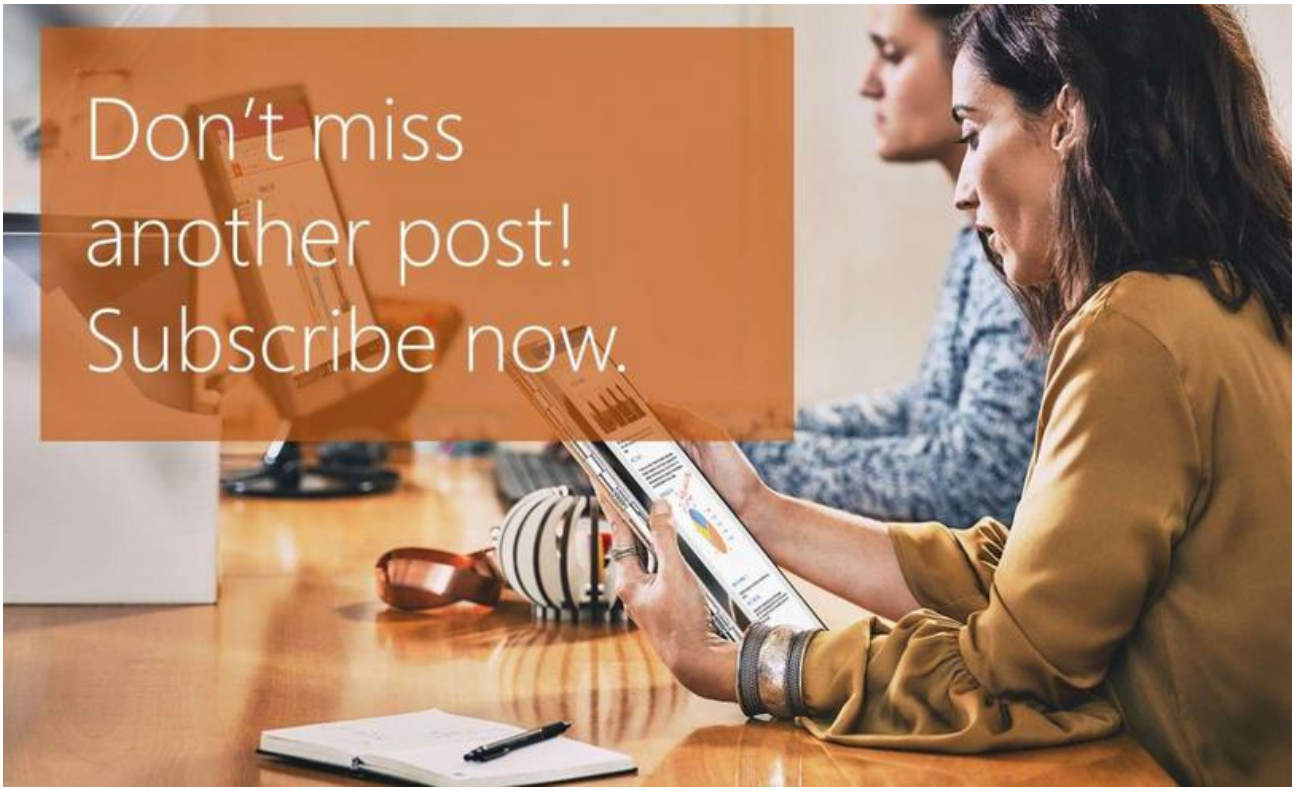
CoursWorx
Where Compliance Connects

Computerized Systems Validation is a requirement in many different parts of life science regulation including around the systems used to support Good Laboratory Practice and Good Clinical Practice.

Adopting a Document Management System that functions as part of your Quality Management System can help a business verify and validate the operation of its required functionality while creating software systems.

Editor-in-Chief
Jon Nugent

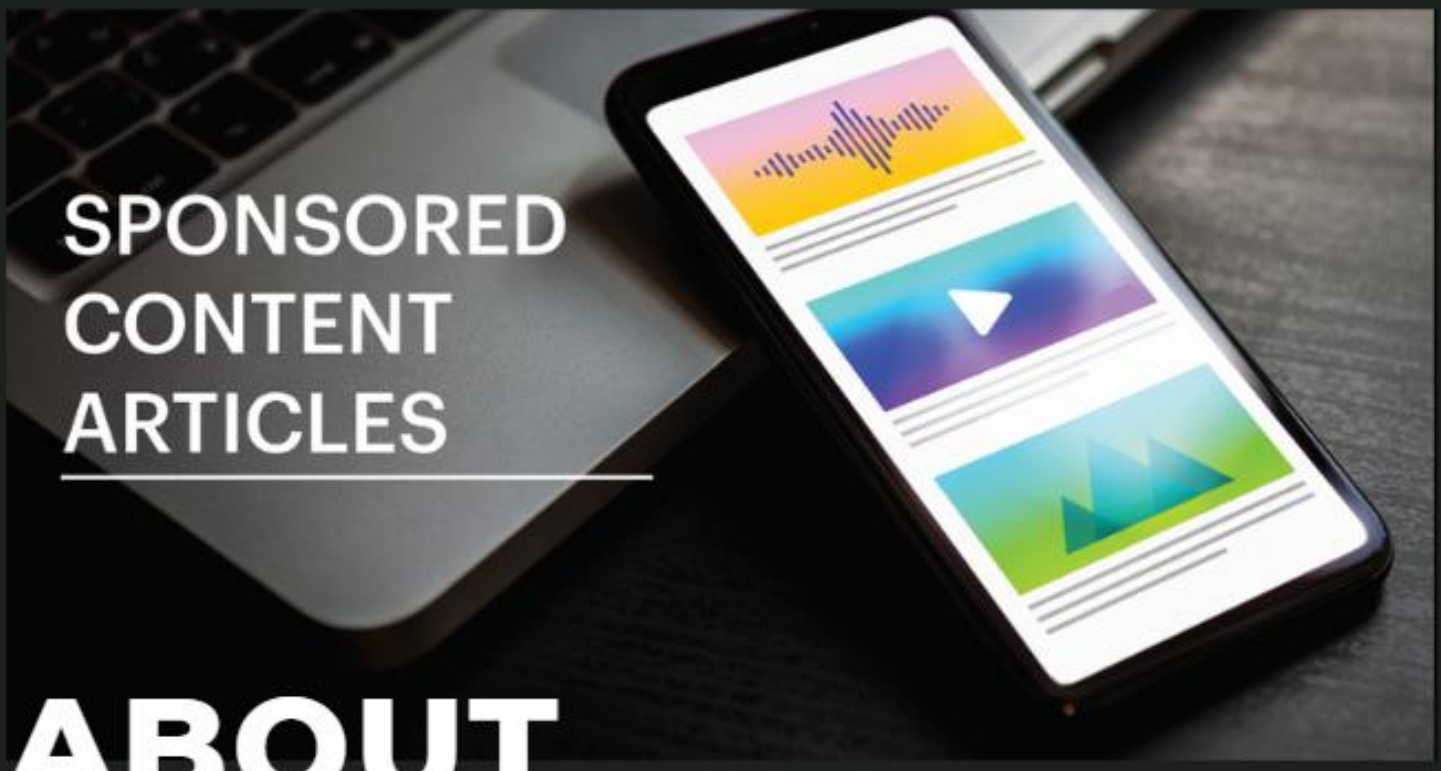
DOCUMENTATION, COMMUNICATION, TRACEABILITY AND ACCOUNTABILITY



DATA INTEGRITY IS KEY

To demonstrate that required controls have been observed and ensure potential non-conformance in end products can be identified and corrected - there must be accountability and traceability in data and documentation throughout the product lifecycle

Knowing that data and documentation is accurate, up-to-date and accessible (and that they cannot be changed or tampered with) gives a high level of confidence to companies and regulators. It tells regulators that required activity has been undertaken and faithfully recorded by the right people at the right time.



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.

About us

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

Vision

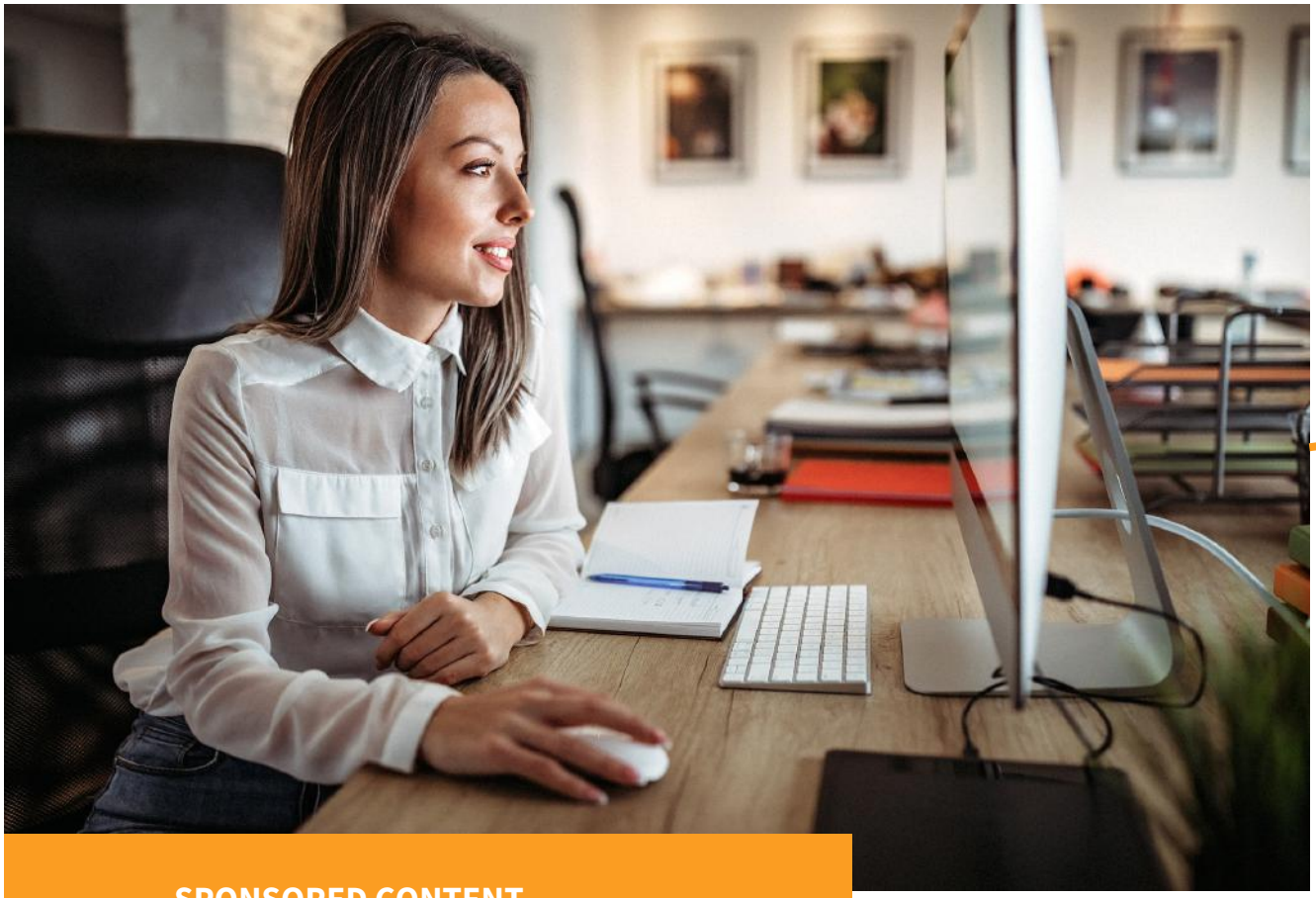
In a world where people long for human interaction, learning is a constant connector. Give yourself and your workforce new ways to connect, learn critical skills, and share learning through our online community.

Mission

We're on a mission to empower validation and regulatory professionals who work in life science. If you're looking to enhance your career opportunities, expand your network, and learn new skills, then CoursWorx is for you.

Subscribe

With over 12,000 LinkedIn members, CoursWorx is one hallmark of a professional. Subscribing to CoursWorx can help you along your journey as a professional – no matter where you are in your career.



SPONSORED CONTENT

Good Documentation Practices (GDocP) are central to all GxP Underpinning all GxP, therefore, are the record-keeping and documentation requirements that keep processes trackable and companies fully accountable for the integrity of their data and the quality of their end products.

This is referred to by the FDA and others as: GdocP - Good Documentation Practice. It should be noted that GDocP is not a ‘standard’ in its own right, but is a key part of all the practices described above.

Sponsored content is a type of promotional media that's paid for by an advertiser, but created and shared by another brand, influencer, or publisher.

GXP: If it isn’t documented - it didn’t happen

To be compliant with GxP organizations need to specify, document and log every critical action made by every employee in the development, manufacture and delivery of a product or project by every employee.

But they should do this in a way commensurate with the risk that non-conformance poses.

And in a way that is ultimately auditable. Quality Systems are needed to implement and validate GXP.

To ensure all these required actions are understood and observed across an organization, companies need Quality Management Systems to be in place.

These Quality Management Systems need to trigger validation processes to take place when new features are added, which are automatically documented as part of your change control process.

They can trigger validation processes to take place when new features are added, which are automatically documented as part of your change control process.

Defining and setting up these systems early on will help companies more successfully pass audits and inspections that increasingly focus on validation as a proactive measure against systems and product failure.

CoursWorx
Where Compliance Connects

LIFE SCIENCE VALIDATION
AND REGULATORY COMPLIANCE

Subscribe

Monthly Subscription Plans for Validation and Regulatory Compliance Professionals and Businesses

We deliver in-depth content from authoritative authors and sources because that's what our subscribers demand.

Professional

- Access to Training
- Job Board
- Engage with Peers
- Discounted Events
- Subscriber Only Content

$2/month

Small Business

- Professional Development
- Sponsorship Opportunities
- Visibility For Your Business
- Access To Job Candidates
- Exclusive Resources

$15/month

Corporate

- Sponsorship Opportunities
- Relevant Connections
- Access To Opportunities
- Thought Leadership
- Job Board Posting

$39/month

If you want to grow your career, expand your network, grow your business or learn new skills, subscribing to CoursWorx can be a smart move.

Validation for electronic Quality Management Systems

It should be noted that electronic Quality Management Systems themselves are ‘computerized systems’ that require validation.

ISO 13485 Clause 4.1.6, for example, states that “software applications shall be validated prior to initial use and, as appropriate, after changes to such software or its application” A good supplier will be able to supply validation requirements.

Quality Systems are needed to implement and validate GXP To ensure all these required actions are understood and observed across an organization, companies need Quality Management Systems to be in place.