WEBINAR PROCESS VALIDATION



WEBINAR DETAILS

Program Title: Life Science Process Validation Guidance: New Concepts, Purpose And Insight

Program Date: February 22, 2024, at 1:30 pm EST

Program Sponsor: CoursWorx

Presenter: Stephanie Brandford, Founder of

Brayearst Validation Consulting





WEBINAR DETAILS

Join us for an exclusive educational seminar on Process Validation and gain critical insights that can shape the future of your work:

A Can't-Miss Event

Process validation is a requirement but knowing when to validate or revalidate a process is essential. If you do not validate risk properly, you may face enforcement actions such as fines or recalls.

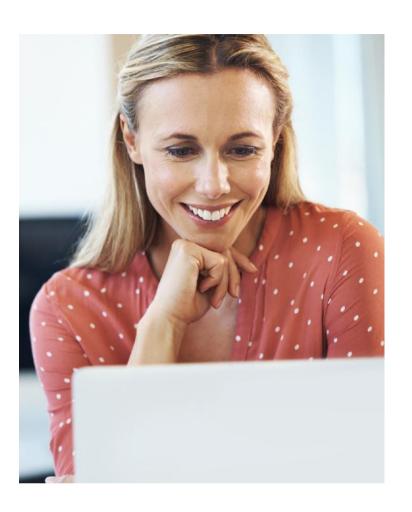
However, too much validation is costly in both time and money.

This webinar will cover the basics of this important topic for those who are new to quality or new to process validation.

The process validation webinar will touch on the following topics as an orientation.

- · Overview of Process Validation: Understand the concept of process validation, its purpose, and its scope within quality management systems. This sets the foundation for your journey.
- · Processes Requiring Validation: Gain clarity on which processes typically require validation, emphasizing special processes with real-life examples for practical insight.
- · Conducting a Validation Key Stages: Dive deep into the three critical stages of validation: Installation Qualification (IQ), Operational Qualification (OQ), and Performance Qualification (PQ). This is the core of process validation.
- · Maintaining a State of Validation: Discover strategies for monitoring and controlling processes post-validation, addressing changes in process or product, and knowing when revalidation might be necessary.
- · Summary of Validation Activities: Conclude with a summary of the key activities and takeaways in process validation, reinforcing the primary learning objectives you can apply immediately.





Learning Objectives

- Learn why process validation is not just a requirement but a strategic imperative.
- Understand the key stages and criteria for successful process validation.
- Gain insights into maintaining a State of Validation for ongoing compliance.

Areas Covered in the Webinar:

- The significance of process validation
- Compliance requirements and guidelines
- Identifying processes requiring validation
- In-depth exploration of validation stages
- Strategies for post-validation process control

Who Will Benefit:

- Validation Specialists
- Quality Engineers
- Manufacturing Engineers
- Regulatory Compliance Experts
- Quality Managers new to medical devices or process validation
- Operations/Manufacturing
 Managers new to medical devices
 or process validation
- Medical device consultants new to process validation

Stephanie

Brandford



Presenter

Stephanie Brandford commenced her professional journey after earning a bachelor's degree in chemical engineering from Carnegie Mellon University. In her initial engineering roles, she engaged in tasks related to regulatory compliance for the Environmental Protection Agency, while also applying statistical process control methodologies within the realm of manufacturing processes.



Upon transitioning from the chemical industry to the medical device sector, she adeptly transferred these skills into an entirely new career trajectory.

Functioning as a validation engineer, Stephanie skillfully employed her compliance-driven mindset to meet the exacting requirements set forth by the Food and Drug Administration.

Following her transition to a new employer, she further enriched her statistical foundation by successfully obtaining certification as a Six Sigma Black Belt. Throughout her tenure, she leveraged these technical proficiencies while simultaneously broadening the scope of her responsibilities.

As Stephanie's journey with the organization progressed, she ascended to a leadership role overseeing a team of validation engineers dedicated to diverse projects spanning multiple areas of manufacturing.

As founder of Brayearst Validation Consulting, Stephanie brings a wealth of experience in regulatory compliance and statistical process control. With a background in chemical engineering and Six Sigma Black Belt certification, Stephanie has excelled in various areas of validation, offering practical insights to a global audience.

Join Stephanie on February 22, 2024, for an enriching webinar experience.



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

<u>CoursWorx</u> 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.

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