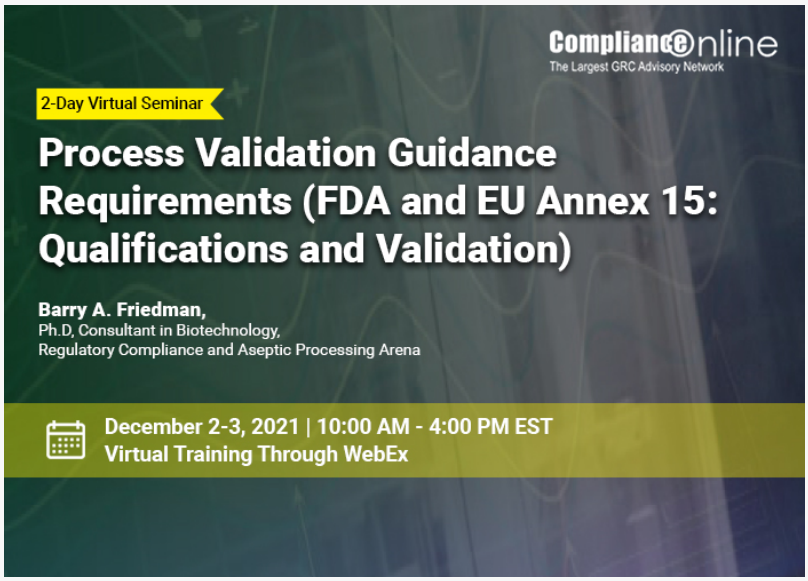
ComplianceOnline Seminar Explains Process Validation FDA/EU Guidance Requirements

"Process Validation Guidance Requirements (FDA and EU Annex 15: Qualifications and Validation)" Seminar has been added to ComplianceOnline.com's offering.



Process Validation Guidance Requirements (FDA and EU Annex 15: Qualifications and Validation)

SAN JOSE, CA, UNITED STATES, November 15, 2021 / EINPresswire.com/ -- ComplianceOnline, the leading provider of training for regulated companies, introduces an educational seminar geared toward Manufacturers of human and animal drugs and biological products. The ComplianceOnline Virtual Seminar, December 2-3, 2021, includes two-day sessions featuring Biotechnology Regulatory Compliance and Aseptic Processing Expert Barry A. Friedman discussing process validation FDA Guidance/EU Guidelines for Industry.

Each manufacturing facility, whether producing small or large molecules requires both an overall Site Validation Plan as well as specific validation plans to manage the multiplicity of validations required to confirm the successful manufacture of each of its products. This seminar will provide a conduit to enhance understanding of the Continued Process Verification.

The seminar will cover the following areas:
- What FDA segments are included and excluded within the "NEW" Process Validation.
- Where does the Process Validation commence?
- What are the Three Stages and Where They Apply within the NEW Process Validation.
- How Stage 1 integrates with Phase 1.
- The Validation approaches that are included within this Guidance document.
- The Statutory and Regulatory Requirements for Process Validation.
- An Introduction to Phase 1 Guidance for Industry and Its Application within the "NEW" Process Validation.

- The Phase 1 Investigational Drug Requirements -- What is and What is NOT Required.
- General Considerations for Process Validation - Stage 2 Process Qualification.
- Regulatory Strategies for Phase 2 and 3 and their Incorporation within Stages 1 and 2.
- General Considerations for Process Validation - Stage 3 Continued Process Verification.
- A Review of EU Annex 15 and its Comparison to FDA's Process Validation Guidance.

The Process Validation Guidelines (January 2011) and the EU Annex 15: Qualification and Validation (October 2015) outline the general principles and approaches the two regulatory bodies to consider appropriate elements of process validation for the manufacture of human and animal drugs and biological products, including Active Pharmaceutical Ingredients (APIs). These guidances align Process Validation activities with a product lifecycle concept and with existing FDA and EU guidances, including the FDA/International Conference on Harmonization (ICH), Guidance for Industry, Q8 (R2) Pharmaceutical Development, Q9 Quality Risk Management, and Q10 Pharmaceutical Quality System.

The lifecycle concept, new to these Guidances, link product and process development, qualification of the commercial manufacturing process, and maintenance of the process in a state of control during routine commercial production. These guidances also support process improvement and innovation through sound science and risk management. The new Process Validation Guideline/Practice incorporate elements of Process Validation as early as the Research and Development phase, and continues onward through Technology Transfer, into the Phase 1 IND Clinical Trial manufacturing phase, and ultimately into Phase 2 and 3, and then commercial manufacturing.

For more information or to register for this seminar, please click here.
Virtual Training Through WebEx
Date: December 2-3, 2021 (10:00 AM - 4:00 PM EST)

About the Speaker:

Barry A. Friedman, PhD, is a Consultant in the Biotechnology, Regulatory Compliance and Aseptic Processing Arena. Dr. Friedman possesses over 30 years of industrial managerial experience in various aspects of biopharmaceuticals and medical devices to include regulatory compliance, expert witness testimony, GLP/GMP, quality control, auditing, sterility assurance, microbiological/analytical validations and fermentation technology.

About ComplianceOnline.com:

ComplianceOnline is a leading provider of regulatory compliance training programs for companies and professionals in regulated industries. ComplianceOnline has successfully trained over 55,000 professionals from 15,000 companies to comply with the requirements of regulatory agencies. ComplianceOnline is a MetricStream portal. MetricStream (www.metricstream.com) is a market leader in Enterprise-wide Governance, Risk, Compliance (GRC), and Quality

Management Solutions for global corporations.

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