ComplianceOnline Launches 'GMP Compliance' Seminar for Virtual Companies with Ex-FDA Director David L. Chesney

"Managing GMP Compliance and Phase Appropriate GMP Considerations for Virtual Companies" Seminar has been added to ComplianceOnline.com's offering.

SAN JOSE, CA, UNITED STATES, April 13, 2021 /EINPresswire.com/ -- ComplianceOnline is holding a 2-day virtual seminar entitled "Managing GMP Compliance and Phase Appropriate GMP Considerations for Virtual Companies'" on May 10-11, 2021 (11:00 AM to 5:00 PM EDT). The seminar will be presented by Ex-FDA Director David L. Chesney.

The program combines general considerations for Good Manufacturing Practice (GMP) compliance management with the principles of phase-appropriate GMP considerations, with an emphasis on needs of virtual companies. (“Virtual companies” are those who outsource GMP operations to Contract Manufacturing Organizations (CMOs) and Contract Analytical Laboratories.)

Virtual companies typically do not conduct “hands on” manufacturing, but do perform tasks which are governed by GMP, for example, dispositioning final product, managing the supply chain, investigating complaints, and providing training to staff in GMP compliance concepts. Such companies often struggle to decide how to structure their quality management system, which procedures they need or do not need, and how to best manage vendor relationships. In addition, the application of GMP requirements to the manufacture of investigational products requires exercise of judgement over the life cycle from early phase (Phase 1) to peri-approval (late Phase 3). Understanding what is required by FDA and other regulatory agencies is important to assure timely approval, since GMP compliance issues can result in approval delays.

In this two half-day workshop conference, attendees will learn how GMP applies directly to virtual company operations, how to best structure a quality management system in a virtual company, and a method to decide which procedures are necessary at what points in time. You will also learn best practices for quality agreements and vendor management. In addition, you will learn the current guidance from FDA for application of GMP to the manufacture of Phase 1, 2 and 3 clinical trial materials. Though FDA requirements are the primary emphasis, some discussion of EMA (European) requirements and other venues will also be included.

Learning Objectives:

Upon completing this course participants should:
- Understand the fundamentals of GMP for the United States
- Understand how to determine what GMP-governed operations you are performing internally versus what you are outsourcing
- Understand a method to structure your quality management system and decide which procedures you need now versus which ones can wait
- Understand best practices for vendor management
- Learn how to apply GMP concepts to Phase 1, 2 and 3 investigational drugs
- Learn the differences between an FDA GMP inspection, a Pre-Approval Inspection and a Pre-License Inspection and where to obtain guidance for each
- Understand basic principles of FDA inspection authority, what to expect if FDA inspects your virtual firm, and how to manage the presence of FDA personnel on site

Who will Benefit:

This course is designed for persons responsible for GMP compliance management following a virtual model, both pre- and post-market. Though designed with small company needs in mind, the principles are also useful to those in larger companies who manage CMOs, particularly those manufacturing investigational drug API and finished products:

- Senior quality managers
- Quality professionals
- Regulatory professionals
- Compliance professionals
- Production supervisors
- Manufacturing engineers
- Production engineers
- Quality engineers
- Quality auditors

For more information or to register for this seminar, please click here.
Virtual Training Through WebEx
Date: May 10-11, 2021 (11:00 AM to 5:00 PM EDT)

About the Speaker:

David L. Chesney, MSJ, is the Principal and General Manager for DL Chesney Consulting, LLC, providing GMP and GCP compliance consulting and training services to clients world wide. He has 47 years experience, evenly divided between the FDA and the private sector, including over 20 years as Vice President, Strategic Compliance Services for PAREXEL Consulting. Prior to joining PAREXEL Consulting, he served 23 years with the FDA as an Investigator, Supervisory Investigator, Director of Investigations and ultimately as District Director in San Francisco, managing all FDA operations in Northern California, Nevada and Hawaii.

Mr. Chesney has an MS degree in Jurisprudence, concentrating in Pharmaceutical and Medical Device Law from Seton Hall University School of Law, a Bachelor's degree in Biology from California State University, Northridge, plus three years of graduate study in Biology at CSU Northridge and CSU San Diego. Mr. Chesney is a member of the Parenteral Drug Association, where he serves on the faculty of the PDA Training and Research Institute. He is also active in the Food and Drug Law Institute and RAPS.

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 headquartered in Palo Alto, California, and can be reached at http://www.complianceonline.com. 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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