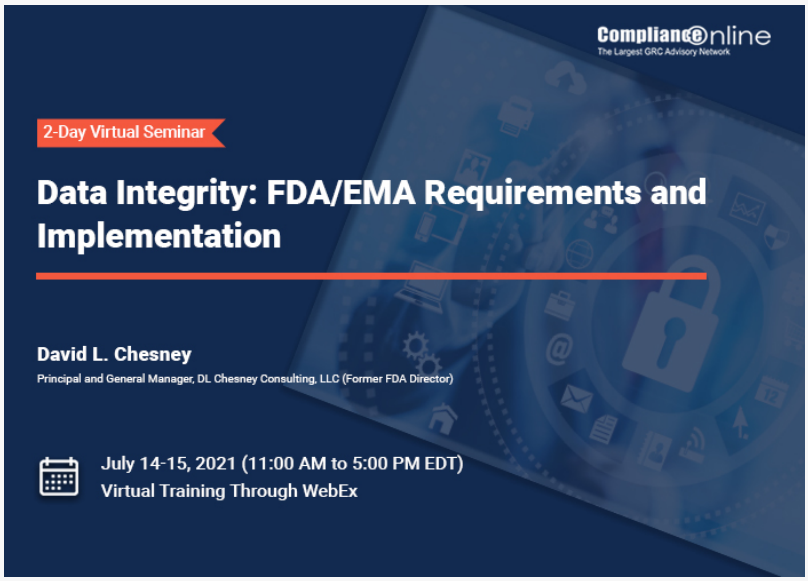
# ComplianceOnline's Hosts Seminar on FDA/EMA Data Integrity Requirements and Implementation with Former FDA Director

*"Data Integrity: FDA/EMA Requirements and Implementation" Seminar has been added to ComplianceOnline.com's offering.*



Data Integrity: FDA/EMA Requirements and Implementation

SAN JOSE, CA, UNITED STATES, June 25, 2021 /EINPresswire.com/ -- ComplianceOnline, the world's leading provider of training for regulated companies will be holding a seminar titled 'Data Integrity: FDA/EMA Requirements and Implementation.' This seminar to be held on July 14-15, 2021, will be presented by former FDA Director David L. Chesney.

The integrity of data generated in support of marketing authorizations and GMP, GCP, and GLP regulated activities is foundational to sound decision-making and regulatory compliance. Data integrity lapses are among the most serious concerns that pharmaceutical regulatory authorities have. Enforcement penalties can be severe from a business standpoint, and in extreme cases can even impact individuals who are held responsible for the occurrence of data integrity problems. In recent months the topic of data integrity has been at the forefront of concern among worldwide pharmaceutical regulatory agencies. The FDA, EMA, TGA, and others have published guidelines setting forth their requirements and expectations for the maintenance of data integrity, as has at least one leading industry organization (PDA).

The use of computer systems in virtually every aspect of data acquisition, storage, and analysis can help preserve data integrity and reduce or eliminate many errors, but the same technology can also create unique problems that must be prevented and managed.

In this two-day workshop conference you will learn the meaning of "data integrity"; be exposed to some of the histories that influence current regulatory requirements and expectations; see a

comparison of the current guidance from leading regulatory agencies including the FDA, EMA, TGA, and key industry associations such as the Parenteral Drug Association; see a recap of the enforcement options available to the FDA, including the imposition of the Application Integrity Policy (also known as the "Fraud Policy"); discuss and learn from selected current real-life case histories; and hear advice for how to prevent, detect and react to data integrity problems to minimize business and regulatory risk.

Learning Objectives:

Upon completing this course participants should:

- Understand the meaning of the term “data integrity” and the importance of the acronym “A.L.C.O.A.” to regulatory agencies
- Understand the difference between innocent lapses and deliberate wrongful conduct
- Be aware of some of the key historical events that form the basis for regulators’ concerns about data integrity
- Understand some of the common motivations for deliberate wrongful conduct that results in data falsification
- Understand the impact of the use of computer systems on the maintenance of data integrity, and what types of system controls are mandated by various agencies around the world
- Be aware of the possible business and regulatory consequences of noncompliance
- Understand the important steps to take to prevent, detect and react to data integrity problems

Who Will Benefit:
This course is designed for people who generate, review, and archive data in support of marketing authorization applications to health regulatory agencies such as the FDA, EMA, and TGA, and those who generate, review and archive GMP, GCP, and GLP data in manufacturing, clinical trials, and pre-clinical testing laboratories. The following personnel will benefit from the course:

- Senior Quality and Regulatory affairs managers
- Clinical and Manufacturing Quality professionals
- Regulatory Affairs professionals
- Compliance professionals
- In House Legal Counsel
- Production supervisors
- Manufacturing personnel
- Production personnel
- Laboratory Managers
- Clinical Operations Personnel
- Drug Safety (Pharmacovigilance) Personnel
- R&D and Quality Control Scientists

•Quality auditors

For more information or to register for this seminar, please click here.
Virtual Training Through WebEx
Date: July 14-15, 2021 (11:00 AM to 5:00 PM EDT)

About the Speaker:
David L. Chesney is the Principal and General Manager of DL Chesney Consulting, LLC.
His career includes 23 years with the FDA and over 21 years in GMP and GCP consulting worldwide. In his consulting practice, Mr. Chesney helps clients prevent quality and compliance problems through proactive assessment and planning, and when necessary, with remediation planning and health regulatory authority communications.

Until recently, he served as Vice President, Strategic Compliance Services for PAREXEL Consulting, a business unit of PAREXEL International LLC. Prior to joining PAREXEL Consulting in 1995, Mr. Chesney served 23 years with the FDA, where he advanced from Investigator to Supervisory Investigator and Director, Investigations Branch, working in the Boston, Seattle and Philadelphia District Offices. In 1991, he was appointed the District Director, FDA San Francisco District Office, where he served until joining PAREXEL in 1995. For 19 years, he led the Strategic Compliance Consulting group, and also personally provided regulatory enforcement related consulting services to the pharmaceutical, medical device and biologics industries, plus technical assistance to legal counsel in FDA regulatory matters. Mr. Chesney has a bachelor's degree and postgraduate credits in biology from California State University, Northridge and San Diego, and received a Certificate in Health Care Compliance from Seton Hall University School of Law.

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.

For more information on ComplianceOnline or to browse through our training programs, please visit our website.

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