ComplianceOnline
The Largest GRC Advisory Network

2-Day In-Person Seminar by Ex-FDA Official:

Managing GMP Compliance and Phase Appropriate GMP Considerations for Virtual Companies

By: **David L. Chesney**, Principal and General Manager, DL Chesney Consulting, LLC (Former FDA Director)

Location: Irvine, CA | March 26-27, 2020

The Society of Clinical Research Associates (SOCRA - www.SOCRA.org) accepts documentation of candidate participation in continuing education programs for recertification if the program is applicable to clinical research regulations, operations or management, or to the candidate's clinical research therapeutic area. This program offers 12 hours of CE credit.

SPEAKER

David L. Chesney, Principal and General Manager, DL Chesney Consulting, LLC (Former FDA Director)

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.

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

COURSE DESCRIPTION

This 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 day workshop conference you 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

AGENDA

DAY 1 (8:30 AM - 4:00 PM)

08.30 AM - 09.00 AM: Registration

09.00 AM: Session Start

Introduction and objectives

Virtual Company Challenges

- Importance of quality management to business success Requirements

GMP defined and the Legal basis of GMP

- Meaning of the term "Manufacturing"
- CMO Role
- Role of the contracting company
- Specific GMP requirements that apply to virtual companies

Structuring a Quality Management System in a Virtual Company Setting

- Structuring the organization and the Quality Unit
- Structuring a document control hierarchy
- Determining what procedures to have in place
- Development of Quality Standards

Supply Chain Quality Management

- Legal basis for this requirement of GMP
- Vendor selection considerations
- Quality Agreements
- Vendor auditing system (frequency, depth, obstacles to overcome)

FDA Inspections of Virtual Companies

- Authority and scope of access
- Reasons for FDA inspections of virtual companies
- Special considerations for Prre-Approval (NDA/BLA) inspections
- Logistic considerations for managing FDA presence on site
- Answering interview questions
- Regulatory correspondence: Responding to FDA-483s, other post inspection correspondence

DAY 2 (9:00 AM - 4:00 PM)

09.00 AM: Session Start

Phase Appropriate GMP Compliance

- Legal basis
- Applicability to placebos
- FDA vs. EMA inspection considerations

FDA Guideline for Phase 1 GMP Compliance

FDA Guideline for Phase 2 and 3 GMP Compliance (legacy 1992 guideline no longer applicable to Phase 1)

EU Annex 13 – Investigational Medicinal Products

Importance of Data Integrity

GMP data versus "application data" and importance to PAI/PLI Success

Practical application of GMP principles to investigational drug manufacturing

- Facility considerations – size, scale
- Equipment qualification
- Process and analytical method validation issues
- Scale-up issues
- Sterility and environmental control
- Stability issues
- Procedures – level of detail
- Master and batch production and control records
- Change control – at what point does this apply?
- Deviation investigation
- Batch disposition and role of the Quality Unit at the CMO vs the Virtual Company

Final discussion, Q&A

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

Registration Form

Registration Information:

- **Register Online**. Click Here Use your American Express, Visa or MasterCard.
- Get your group to attend the seminar at a discounted price call +1-201 871 0474.
- Call 201 871 0474 or Fax your PO: 253 663 7224 Pay your check to "PMA Conference Management" and Mail the check to: PMA PO Box 2303, Falls Church VA 22042. Please fill this form with attendee details and payment details and fax it to 253 663 7224

Terms & Conditions

Your Registration for the seminar is subject to following terms and conditions. If you need any clarification before registering for this seminar please call us @ 201 871 0474 or email us @ register@pmaconference.com

Cancellations and Substitutions

Written cancellations through fax or email (from the person who has registered for this conference) received at least 10 calendar days prior to the start date of the event will receive a refund – less a $300 administration fee. No cancellations will be accepted – nor refunds issued – within 10 calendar days from the start date of the event. On request by email or fax (before the seminar) a credit for the amount paid minus administration fees ($300) will be transferred to any future ComplianceOnline event and a credit note will be issued. Substitutions may be made at any time. No-shows will be charged the full amount. We discourage onsite registrations, however if you wish to register onsite payment to happen through credit card immediately or check to be submitted onsite. Conference material will be given on the spot if it is available after distributing to other attendees. In case it is not available we will send the material after the conference is over. In the event ComplianceOnline cancels the seminar, ComplianceOnline is not responsible for any airfare, hotel, other costs or losses incurred by registrants. Some topics and speakers may be subject to change without notice.

Seminar Topic: Managing GMP Compliance and Phase Appropriate GMP Considerations for Virtual Companies

Date & Location: .....

Attendee Details:

	Name	Title	Email
Attendee 1			
Attendee 2			
Attendee 3			
Attendee 4			

Email address (so you can receive order acknowledgements, updated news, product information and special offers)

Company Information

Organization .....

.....

Address .....

.....

City .....

State ..... Zip.....

Country .....

Phone ..... Fax .....

Payment Options

☐ Check enclose

☐ Charge to: ☐ Visa ☐ MasterCard ☐ American Express

Credit card no. .....

Expiration date .....

Total amount $ .....

Signature .....
(Signature required on credit card and bill-me orders.)

Print name.....

☐ Bill me/my company $ .....

Purchase order # .....

(Payment is required by the date of the conference.)
Please fill this form with attendee details and payment details and fax it to 201 871 0474