FEBRUARY
8 & 9, 2023

Manchester
Grand Hyatt
San Diego
San Diego, California

CURRENT HOT GMP TOPICS

(to help keep you out of trouble with the FDA)

A powerful program with some of the industry's most experienced experts to improve performance at work and help your company successfully navigate this critical arena

Conference produced by

PHARMA CONFERENCE INC

The top producer of premier pharmaceutical conferences since 1995

The Manchester Grand Hyatt waterfront hotel in downtown San Diego

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About the Conference

Current Hot GMP Topics is an intensive two-day interactive conference that brings attendees the latest information on GMPs. This is slated to be a powerful program with some of the industry's most experienced experts. Top FDA personnel (invited), former FDAers, thought leaders, and industry experts will be providing the most up-to-date and thought-provoking concepts in this ever-changing world of FDA.

Current Hot GMP Topics will allow ample opportunity for individual questions to be answered by the presenters, all of whom have extensive experience with GMPs, inspections, data integrity, and other topics that affect good manufacturing practices. Like all Pharma Conference programs, **Current Hot GMP Topics** is designed to provide an informal, relaxed learning environment to help improve your performance at work and help your company successfully navigate this critical arena. Attendees will receive not only intensive training and current, critical information, but practical utilization techniques, as well.

Who Should Attend?

- Anyone required to follow the GMPs regulated by FDA in the pharmaceutical and biologics industries

Why Attend?

- To keep current in ongoing FDA requirements conforming to good manufacturing practices
- To hear the latest information coming from FDA ORA
- To get hard, reliable information from some of the foremost experts in GMP matters

This exciting new program is being held at the Manchester Grand Hyatt waterfront hotel in downtown San Diego. A variety of exciting San Diego attractions are just minutes from the doorstep, including the San Diego Zoo, Balboa Park, Seaport Village, and Gaslamp Quarter. Click here to see more about the hotel.

To receive emails on our upcoming programs, add reception@pharmaconference.com to your address book.

About the Speakers

Jennifer L. Bragg
BA, JD | Former FDA
Partner
Skadden, Arps, Slate, Meagher & Flom LLP and Affiliates

Ms. Bragg, head of the firm's Washington, D.C. litigation practice, is a nationally recognized lawyer advising Food and Drug Administration (FDA)-regulated companies facing government investigations and related enforcement challenges. She advises pharmaceutical and medical device companies with complex regulatory issues to minimize litigation and enforcement risks and to overcome transactional hurdles. She conducts due diligence and related counseling with transactions in the life sciences and health care industries, and has litigation and trial experience.

Jerry L. Chapman
BS, MBA
Senior GMP Quality Expert
Redica Systems

Mr. Chapman brings over 40 years' experience in the pharma industry, including 31 years at Eli Lilly, where he worked in product development, biosynthetic human insulin manufacturing, and site and corporate quality. He designed and implemented a comprehensive GMP Intelligence process to identify, analyze, and archive pertinent drug GMP regulations, inspection findings, trends, and best practices in the U.S. and internationally. At Redica Systems, Mr. Chapman works with the machine learning and data science teams building computer models that examine enforcement actions and other data and produce analyses the way an expert would in the past using hard copy documents and a highlighter.

David L. Chesney
BS, MSJ | Former FDA
Principal & General Manager
DL Chesney Consulting, LLC

Mr. Chesney is a worldwide expert in GMP/GCP compliance, investigations, and training, with 30+ years in Industry and 23 years in FDA. Previously, he served for over 20 years as Vice President and Practice Lead, 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, Mr. Chesney is a member of PDA, where he serves on the faculty of the PDA Training and Research Institute. He is a member of the Food and Drug Law Institute, where he serves as the faculty for FDLI's continuing education programs.

Alonza Cruse
BS | FDA
Director
Office of Pharmaceutical Quality Operations, Office of Regulatory Affairs

Mr. Cruse is Director of the Office of Pharmaceutical Quality Operations within the FDA Office of Regulatory Affairs. The office is responsible for all pharmaceutical inspections, working in conjunction with FDA's Center for Drug Evaluation & Research and Center for Veterinary Medicine. From 2013-2015 Mr. Cruse served as the Director (Acting) of the Office of Medical Products & Tobacco Operations within ORA. From 2000-2015, he was the Director of FDA's Los Angeles District Office. Prior to this, Mr. Cruse was Director of New York District Import Operations. He first joined ORA in 1983 as a microbiologist.

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About the Speakers

Pat Day
BSEE, MSIE
Data Governance Consultant
Lachman Consultants

Mr. Day has over 25 years' experience in pharmaceutical manufacturing and services with two major pharma operating companies. He obtained his BS in Engineering from Drexel and his Masters in Industrial Engineering from Penn State University. He is currently employed at Lachman Consultants focusing on data integrity helping companies in the pursuit of great data governance using Lean Compliance tools, a risk mindset, and leadership principles to not only be compliant but deploy practical strategies for maximum value.

Douglas B. Farquhar
BA, JD
Director
Hyman, Phelps & McNamara, PC

Mr. Farquhar is a nationally recognized lawyer with more than 30 years experience as a prosecutor and defense and regulatory attorney for medical device and pharmaceutical product regulation and enforcement. Since 1997, he has advised pharmaceutical and medical device manufacturers and wholesalers, compounding pharmacies, and individuals on a wide range of enforcement activities. Mr. Farquhar also advises companies and individuals on adverse findings after FDA and other regulatory agency inspections. He has a broad-based understanding of the investigatory process, having negotiated settlements and resolutions for both industry and government.

Peter D. Smith
BS | Former FDA
Principal
Smith GMP Consulting

Mr. Smith, Principal, Smith GMP Consulting, began an independent consulting company upon retiring from PAREXEL in April 2018 after 23+ years. He continues to work with clients in the pharmaceutical and biologics industry worldwide. Mr. Smith joined PAREXEL (then KMI) following a 22-year FDA career. At the FDA, Mr. Smith worked as an Investigator, specializing in pharmaceutical GMP/GCP and medical device inspections and later served as Associate Director, International and Technical Operations Branch, Division of Field Investigations at FDA headquarters, where he managed the Foreign Inspection Program. He is a highly experienced public speaker and trainer in GMP and FDA inspection readiness topics.

James L. Vesper
PhD, MPH
Director of Learning Solutions
ValSource, Inc.

Dr. Vesper designs and develops instructional courses and workshops for the pharmaceutical industry. He previously worked at Eli Lilly establishing and leading their GMP training organization and was the founder/president of LearningPlus. As a consultant and trainer, he works globally for a variety of pharma manufacturing firms and has provided training for US FDA, PIC/S, and the World Health Organization. He has written six books and numerous peer-reviewed articles and book chapters on GMP and learning topics.

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Agenda

Wednesday, February 8, 2023
Morning Session: Moderator – David Chesney

8:00 – 9:00	Registration*	
9:00 – 9:40	Enforcement Areas of Primary Concern	Douglas Farquhar
9:40 – 10:20	Hot GMP Topics from FDA for the Pharmaceutical Industry – Part 1	Alonza Cruse, ORA, FDA – invited
10:20 – 10:40	Break*	
10:40 – 11:30	From Data Integrity to Data Governance, the Path to Success	Pat Day
11:30 – 12:20	CDMO Management Contract Manufacturing Issues: Selection, Auditing and Oversight of CMO/CDMO Organizations, Quality Agreements	Peter Smith
12:20 – 1:20	Lunch*	

Afternoon Session: Moderator – Peter Smith

1:20 – 2:10	Responding to 483/Warning Letters	Jennifer Bragg
2:10 – 2:55	When to Speak to FDA About Issues During Inspections	Douglas Farquhar
2:55 – 3:15	Break*	
3:15 – 4:00	Phase-Appropriate GMP (Applying GMPs to the Manufacture of Investigational Drugs)	David Chesney
4:00 – 4:30	Question and Answer Session	Today's Speakers
5:00 – 6:00	Networking Reception*	

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Agenda

Thursday, February 9, 2023
Morning Session: Moderator – Peter Smith

9:00 – 9:50	A Deep Dive into Industry-Wide Recall Data Using AI	Jerry Chapman
9:50 – 10:40	Understanding FDA Compliance Resources: Demystifying FDA Inspection Guidance Documents	Peter Smith
10:40 – 11:00	Break*	
11:00 – 12:00	How to Avoid Consent Decrees or Comply with Them	Jennifer Bragg
12:00 – 1:00	Lunch*	

Afternoon Session: Moderator – David Chesney

1:00 – 1:40	Structuring Quality Investigations – Failures, Deviations and Complaints	Douglas Farquhar
1:40 – 2:20	Human Error as a Root Cause	James Vesper, PhD
2:20 – 2:40	Break*	
2:40 – 3:20	Hot GMP Topics from FDA for the Pharmaceutical Industry – Part 2	Alonza Cruse, ORA, FDA – invited
3:20 – 4:00	How to Message GMP Compliance to Top Management/C Suite ICH/Q10	David Chesney
4:00 – 4:30	Question and Answer Session	Both Days' Speakers

*Denotes Non-Educational Activity

Continuing Education

Conference qualifies for 11.0 hours of CE credit.

Registration

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Fees

	Industry	U.S. Gov't & Press
EARLY DISCOUNT: Payment Received By December 31, 2022	❑ $2495	❑ $1795
Payment Received After December 31, 2022	❑ $2695	❑ $1795

Includes conference materials, continental breakfasts, breaks, lunches and networking reception per agenda

Cancellation Policy: 30 days or more for a full refund less $250 USD cancellation fee; under 30 days, no refund, but attendee substitutions may be made at any time. Cancellations and substitutions must be made in writing via email to Pharma Conference (registration@pharmaconference.com). In the event of any civil disorder, extremely adverse weather conditions, or other Acts of God, Pharma Conference reserves the right to reschedule the meeting dates in the interest of attendee safety.

Payment

- All credit card transactions are processed in US Dollars (your bank will convert to your local exchange rate when billing)
- You will receive a confirmation via email as soon as the registration is processed. In order to receive the early registration price, payment must be made by the deadline specified in the brochure. (Taxpayer ID #27-1438344)
- Registrations must be accompanied by full payment.

Payment Terms: Conference attendees must be paid in full prior to conference start date.

Hotel

Manchester Grand Hyatt San Diego
1 Market Place, San Diego, California 92101
(619) 232-1234
$289 single/double

A limited number of rooms have been blocked at the special rate listed per night. Rate is available 3 nights either side of the conference dates, based upon availability of rooms. Hotel reservations must be made on or before January 17, 2023, in order to guarantee the special rate. Individuals are responsible for making their own hotel reservations. You must mention the title of the program AND Pharma Conference when making your reservation in order to obtain these special rates. Please do not use travel agents for reservations.

Reservations:
Call (800) 233-1234 and ask for the *Current Hot GMP Topics - Pharma Conference* room block or make hotel reservations online at:
https://www.hyatt.com/en-US/group-booking/SANRS/G-GMPT
(If link isn't clickable, copy and paste the URL in your browser)

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