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GMP event for
all pharmaceutical companies!

GMPs FOR CURRENT TIMES

MARCH 26 – 27, 2019 | SAN DIEGO, CALIFORNIA

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About the Program

GMPs for Current Times is an intensive two-day interactive program that brings attendees the latest information on GMPs. Top FDA personnel, thought leaders, and industry experts representing major pharmaceutical companies, consulting groups, and former FDAers will be providing the most up-to-date and thought-provoking concepts in this ever-changing world.

GMPs for Current Times 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, **GMPs for Current Times** is designed to provide an informal, relaxed learning environment to help improve your performance at work and to 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 in the new administration
- To get hard, reliable information from some of the foremost experts in GMP matters

About the Speakers

Gary Bird, PhD – Dr. Bird is currently President, PharmaConsult-US, LLC, and Managing Partner, PharmaConsult Global, Ltd., an international cooperative supplying GXP quality consulting services. He served as Director of Corporate Quality for GTx, Inc. (Memphis, TN, USA) from 2003 until 2013 and was responsible for confirming all non-clinical (GLP), manufacturing (GMP), and clinical trial (GCP) related activities were conducted in compliance with appropriate laws and regulations. He has held previous positions with Eli Lilly and the FDA where he represented both PhRMA and the FDA in the International Conference on Harmonization negotiations on four different agreed guidances.

David L. Chesney, BS – Mr. Chesney is the Principal and General Manager for DL Chesney Consulting, LLC. He was formerly the Vice President, Strategic Compliance Services for PAREXEL Consulting. Prior to joining PAREXEL Consulting (then known as KMI) in 1995, he served 23 years with the FDA. Between 1972 and 1988, Mr. Chesney 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 his time with PAREXEL, Mr. Chesney provided compliance consulting and training services to clients world wide.

Alonza Cruse, BS – Mr. Cruse is Director, Pharmaceutical Quality Program within the FDA Office of Regulatory Affairs. His 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, Mr. Cruse was the Director, FDA's Los Angeles District Office. Mr. Cruse first joined ORA in 1983 as a microbiologist.

Richard J. Davis, BS – Mr. Davis operates Richard Davis & Associates LLC, providing quality assurance and supply chain services to the international pharmaceutical industry. He was formerly employed by Bristol Myers Squibb and the DuPont Pharmaceutical Company as Senior Vice President for Quality Assurance and Regulatory Compliance. At DuPont he was responsible for worldwide quality assurance and regulatory compliance. Prior to this, Mr. Davis was the Regional Director for the Mid-Atlantic Region of the FDA from 1977 to 1994. He joined the FDA in 1961 and served in a number of positions before his appointment to Regional Food and Drug Director.

John M. Hyde, BS, BBA, MS – Mr. Hyde is Chairman and Founder of Hyde Engineering + Consulting, Inc., a firm of 220+ engineers and scientists, founded in 1993 and specializing in process engineering, process and equipment validation, and compliance consulting for biopharmaceutical and pharmaceutical manufacturers. The company has operations in the United States, Europe, Singapore and India. For nearly two years prior to the formation of Hyde Engineering + Consulting, Inc., Mr. Hyde was Senior Project Engineer with Synergen, a biopharmaceutical research and manufacturing company. From 1982 to 1992, Mr. Hyde was Manager, Process Design with Seiberling Associates, Inc., an engineering firm specializing in the design and start-up of biopharmaceutical, food and beverage process systems and the application of CIP technology.

Scott J. MacIntire, BS – Since November of 2014, Mr. MacIntire has been the Director of the Division of Enforcement/Office of Enforcement and Import Operations at FDA's Office of Regulatory Affairs (ORA), where he works closely with FDA centers to include the Center for Drug Evaluation and Research, Center for Biologics and Office of Chief Counsel in determining regulatory strategies for follow up action. He also serves as the Agency focal point for guidance on recall plans and procedures, directs and coordinates ORA's activities related to the investigation of health fraud, and provides management and oversight of the Agency's debarment program. Prior to his current position, Mr. MacIntire was Director of the Chicago District Office from 2004 to 2014.

Charles T. Morton, BS – Mr. Morton is an Associate Director in Global Security at Merck where he leads supply chain security initiatives to enable the secure and efficient movement of Merck products and materials worldwide. He has over 20 years of combined experience in law enforcement, homeland security, supply chain security, and corporate security management. Mr. Morton is a former Vice President and North America Security Manager at Panalpina and served at the Transportation Security Administration (TSA) as Director of the HAZMAT Threat Assessment Program and is the former TSA Branch Chief for Highway Cargo Security.

Peter D. Smith, BS – 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) in 1994 following a 22-year FDA career. He held various positions with PAREXEL, with his final position as Vice-President Technical in the Strategic Compliance group. At the FDA, Mr. Smith worked as an Investigator, specializing in pharmaceutical GMP/GCP and medical device inspections in the field and later serving as Associate Director, International and Technical Operations Branch, Division of Field Investigations at FDA headquarters in Rockville, MD, where he managed the Foreign Inspection Program. During his FDA career, he conducted inspections of pharmaceutical plants in Europe, Asia, South America and Australia. He is a highly experienced public speaker and trainer in GMP and FDA inspection readiness topics.

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Agenda

Tuesday, March 26, 2019
Morning Session: Moderator – Gary Bird, PhD

8:00 – 9:00	Registration*	
9:00 – 9:30	**The History of GMPs**	David Chesney
9:30 – 10:20	**Focus of FDA Compliance 2019**	Alonza Cruse, ORA, FDA, invited
10:20 – 10:40	Break*	
10:40 – 11:30	**FDA Enforcement Update** • Consent Decrees • Warning Letters • Product Seizures • Criminal Actions • Trends in 483 Citations	Scott MacIntire, ORA, FDA, invited
11:30 – 12:20	**Worldwide Compliance Challenges for 2019 and Beyond**	Peter Smith
12:20 – 1:20	Lunch*	

Afternoon Session: Moderator – David Chesney

1:20 – 2:10	**Internal Audit Programs and Audit Effectiveness** • How Do I Find Discrepancies? • Identifying Problem Issues • Frequency and Scope of Audits • Training and Evaluation of Audit Process	Richard Davis David Chesney
2:10 – 2:55	**Current Hot Pharma Supply Chain Security Issues**	Charles Morton
2:55 – 3:15	Break*	
3:15 – 4:00	**Preparing for and Successfully Managing an FDA Inspection**	David Chesney
4:00 – 4:40	**Are Cleaning Validation Issues Impacting Your Company**	John Hyde
4:40 – 5:15	**Question and Answer Session**	Today's Speakers

Wednesday, March 27, 2019
Morning Session: Moderator – David Chesney

9:00 – 9:45	**A Review of Recent FDA Inspection Trends**	David Chesney
9:45 – 10:30	**Properly Handling Communications with FDA Following an Inspection**	Richard Davis
10:30 – 10:50	Break*	
10:50 – 11:30	**Quality Organization Issues**	Peter Smith
11:30 – 12:30	Lunch*	

Agenda

Afternoon Session: Moderator – Gary Bird, PhD

12:30 – 1:10	**Current Process Validation Issues**	John Hyde
1:10 – 1:55	**Current Data Integrity Issues**	Gary Bird, PhD
1:55 – 2:15	Break*	
2:15 – 3:00	**Current Data Integrity Issues (continued)**	Gary Bird, PhD
3:00 – 3:30	**Do You Know Your Quality Culture? (A 30 Minute Awakening to Make It Better)**	Richard Davis
3:30 – 4:00	**Question and Answer Session**	Both Days' Speakers

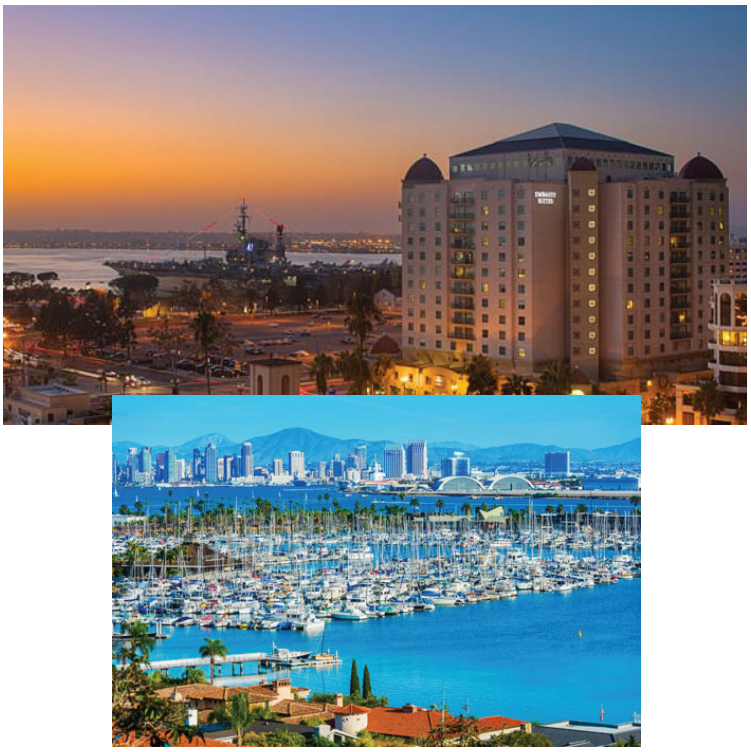
*Denotes non-educational activity

Continuing Education

This conference qualifies for 11.0 hours of continuing education credit.

About the Venue

An all-suite hotel located in the heart of downtown San Diego, Embassy Suites by Hilton San Diego Bay - Downtown is located across the street from the Headquarters, Seaport Village and the Embarcadero. The hotel is also just blocks from the historic Gaslamp Quarter. When looking to explore all this wonderful city has to offer, SeaWorld® and the San Diego Zoo are just minutes away.



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Fees

	Industry	U.S. Gov't & Press
EARLY DISCOUNT: Payment Received By January 1, 2019	❑ $2195	❑ $1595
Payment Received After January 1, 2019	❑ $2395	❑ $1595

Includes program materials, breaks and lunches per agenda (complimentary breakfast buffet included in your room rate)

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- 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: Program attendees must be paid in full prior to program start date.

Hotel

Embassy Suites by Hilton San Diego Bay Downtown
601 Pacific Highway | San Diego, California 92101 | (619) 239-2400

Single/Double rate $199
Hotel Cutoff date March 5, 2019

A limited number of rooms have been blocked at the special rate listed per night, including a complimentary Breakfast Buffet and a complimentary Nightly Reception. Rate is available 3 nights either side of the program dates based upon availability of rooms. **Hotel reservations must be made on or before March 5, 2019**, 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.** Please contact Phillip.Richardson@hilton.com if you have any trouble making your hotel reservation.

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For additional information, contact Pharma Conference Inc:
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