Day 1

Tuesday, Nov. 16, 2021

11:00 AM **Welcome and Introduction**

11:00 AM – 11:15 AM EST

SPEAKER
Steve Niedelman
Lead Quality Systems and Compliance Consultant
King & Spalding LLP
former FDA Deputy Associate Commissioner for Regulatory Operations

11:15 AM **Keynote Address: The FDA Perspective on Inspections: What's Happening Now and What to Expect in 2022**

11:15 AM - 12:00 PM EST

Do you know how to adjust your processes to ensure inspectional readiness? Hear the latest plans and initiatives coming out of the FDA so you can be better prepared for both on-site and virtual inspections.

SPEAKER
Elizabeth Miller, Pharm.D.
Assistant Commissioner
Medical Products & Tobacco Operation
Office of Regulatory Affairs, FDA

12:00 PM **Break**

12:00 PM - 12:15 PM EST

12:15 PM **3 Concurrent Breakout Tracks**
12:15 PM - 2:30 PM EST

Drug & Biologics

12:15 PM **FDA's Oversight of Drug and Biologics Manufacturing Facilities: How FDA Is Using Remote Tools in Addition or in Lieu of Traditional Inspections**
12:15 PM - 1:00 PM EST

The pandemic has forced a slowdown in FDA inspections and the FDA has increasingly turned to remote tools to augment its oversight of facilities. You'll learn the differences between a remote records request, a remote interactive evaluation and a traditional inspection. Discover indicators of whether the FDA will evaluate your facility using remote tools or will show up for an in-person inspection.

MODERATOR
Cynthia Schnedar
Principal, Regulatory Compliance
Greenleaf Health, Inc.

PANELISTS
Kalah Auchincloss
Executive Vice President
Greenleaf Health, Inc.
former Deputy Chief of Staff for two FDA Commissioners

Dan Barreto
President/Owner
PharmQ Global Consulting, LLC
former FDA Investigator

David L. Chesney, MSJ
Principal and General Manager
DLChesney Consulting, Inc.
former FDA District Director in San Francisco

Jack Garvey
Managing Partner
Compliance Architects

Medical Devices

12:15 PM **FDA's New Inspection Affairs Council: MDR Experiences — and More**

12:15 PM - 1:00 PM EST

The FDA plans to implement an agency-wide inspectional affairs council was announced in May when the FDA issued its Resiliency Roadmap for FDA Inspection Oversight. Since then, the council has begun to take shape. How will this council affect inspectional activities?

SPEAKER

John Taylor
President and Principal
Compliance and Regulatory Affairs
Greenleaf Health, Inc.
former Counselor to the Commissioner, OC, FDA

Clinical Trials

12:15 PM **How COVID-19 Has Taught Us to Streamline and Simplify Clinical Trial Processes**

12:15 PM - 1:00 PM EST

With the emergence of the COVID pandemic, the clinical trials industry was faced with the challenge of either suspending important research or adopting new approaches to implementing research. The existing regulatory framework allowed a great deal of flexibility that was underutilized in the old way of doing things. This session will explore the ways in which sponsors, CROs, sites and IRBs collaborated to streamline and simplify clinical trial processes.

MODERATOR

David Borasky, MPH, CIP
Vice President, IRB Compliance
WCG

PANELISTS

Rod Walker
Solution Specialist
Medidata Solutions

Jennifer Peterson
Executive Director, Site Start Up, Regional Head - Country SSU Americas
Syneos Health

1:00 PM **Break**
1:00 PM - 1:45 PM EST

Drug & Biologics

1:45 PM **How to Ensure Your Drug or Biologics Manufacturing Facility Is Ready to be Evaluated by FDA Either Remotely or In-Person**
1:45 PM - 2:30 PM EST

Whether the FDA will evaluate your facility by using remote tools or by using an on-site inspection, it is important to be ready for the FDA's scrutiny. This session will discuss what is new about the FDA's use of remote tools and how you can prepare for both remote record requests and remote interactive evaluations. In addition, drugmakers may have fallen behind on traditional inspection readiness activities due to the pandemic. This session will focus on risk areas to be aware of as you conduct inspection readiness activities.

MODERATOR
Cynthia Schnedar
Principal, Regulatory Compliance
Greenleaf Health, Inc.

PANELISTS
Robert (Bob) Rhoades
Managing Partner
Validant

Steven Lynn, MS
Executive Vice President
Pharmaceuticals, Regulatory Compliance Associates Inc.
former Director OMPQ, CDER, FDA

Jonathan Gil
Senior Corporate Counsel
Pfizer

Medical Devices

1:45 PM **Harmonizing QSR and Adjusted Inspection Approaches**

1:45 PM - 2:30 PM EST

The FDA has been planning to harmonize the Quality System Regulation with the ISO 13485:2016 since 2018. The draft rule is expected to be released this year. What should you be doing now to prepare and what changes can be expected in inspection approaches.

MODERATOR

Julie Larsen
Principal, Director of Inspection Readiness
BioTeknica Inc.

PANELISTS

Tina Krenc
Senior Consultant
BioTeknica Inc.

Ballard Graham
Retired
FDA

Clinical Trials

1:45 PM **FDA Expectations for Remote Informed Consent**

1:45 PM - 2:30 PM EST

Do you have a policy of legally obtaining informed consent when the clinical trial subject is not physically present? Is that policy designed to ensure that participants are adequately informed about the research, can easily ask and get answers to questions, and recognize that participation is voluntary. Does your policy on electronic signatures follow the Joint Guidance on Use of Electronic Informed Consent and the revised Common Rule?

SPEAKER

Heather Kim, MS, RAC, CIP
Manager, Quality Assurance
WCG IRB

2:30 PM **Assessing Risk in Recall Situations**

2:30 PM - 3:00 PM EST

When the FDA issues a recall, what kind of risk do you face? Are you exposed to lawsuits from private parties? Have you established a procedure for dealing with recalls that eventually will lead to a terminated recall, where the FDA determines that all reasonable efforts have been made to remove or correct the violative product in accordance with the recall strategy and proper disposition has been made.

MODERATOR

Steve Niedelman
Lead Quality Systems and Compliance Consultant
King & Spalding LLP
former FDA Deputy Associate Commissioner for Regulatory Operations

PANELIST

Grace McNally
Senior Vice President, Regulatory Compliance
Greenleaf Health, Inc.

3:00 PM **Virtual Social Activity**

3:00 PM - 4:00 PM EST

Day 2

Wednesday, Nov. 17, 2021

11:00 AM Welcome and Introduction

11:00 AM – 11:15 AM EST

SPEAKER
Steve Niedelman
Lead Quality Systems and Compliance Consultant
King & Spalding LLP
former FDA Deputy Associate Commissioner for Regulatory Operations

11:15 AM Do's and Don'ts for FDA Inspections: Analysis From Former FDA Investigators

11:15 AM – 12:15 PM EST

Hear valuable advice from former FDA investigators who share what to do — and not to do — during and after an inspection. They'll hash out the best and worst practices they've observed when conducting inspections and the steps can you take to avoid the worst practices and embrace the best. You'll come away with not-to-be-missed steps you can take following an inspection to ensure things go more smoothly during your next one.

MODERATOR
Steve Niedelman
Lead Quality Systems and Compliance Consultant
King & Spalding LLP
former FDA Deputy Associate Commissioner for Regulatory Operations

SPEAKER
David Elder
Principal
Greenleaf Health, Inc.
former Director, Office of Regional Operations, FDA

12:15 PM Break

12:15 PM – 12:30 PM EST

12:30 PM 3 Concurrent Breakout Tracks

12:30 PM – 2:45 PM EST

Drugs & Biologics

12:30 PM Communicating with the FDA: How to Expedite an Inspection and Escape the Queue

12:30 PM – 1:15 PM EST

The pandemic has created a slowdown in inspections, particularly with inspections of sites outside the U.S. Sites that are not deemed mission critical by the FDA are finding themselves stuck in a long queue, waiting for an inspection. Is there any way round this queue? This session will focus on how to communicate with the FDA regarding when your site might expect an inspection and in what circumstances you can provide information that might make that inspection happen sooner rather than later.

MODERATOR
Cynthia Schnedar
Principal, Regulatory Compliance
Greenleaf Health, Inc.
former Director of CDER's Office of Compliance

PANELISTS
Cathy Burgess
Partner
Alston & Bird LLP

Paula Katz
Of Counsel, Covington & Burling LLP
former Director of Guidance and Policy for the OMPQ
CDER, FDA

Medical Devices

12:30 PM RRAs: Let's Take a Deep Dive

12:30 PM – 1:15 PM EST

The FDA has reworked its business operations in response to challenges in conducting on-site inspections/assessments during the COVID-19 global pandemic to audit / survey medical product manufacturers from remote. This presentation will discuss the FDA's use of remote regulatory assessments (RRAs) and what medical device manufacturers should be doing to prepare for RRAs, what can they expect to happen during an RRA and best practices to support electronic document requests and interface.

SPEAKER
Julie Larsen
Principal, Director of Inspection Readiness
BioTeknica Inc.

Clinical Trials

12:30 PM **Clinical Inspections Post-COVID**

12:30 PM – 1:15 PM EST

Did COVID change clinical inspections forever — and is there no going back? This session will discuss some positives resulting from conducting inspections remotely. And it will look at what inspectors will be looking for in terms of informed consent and data submissions post-COVID.

MODERATOR
David Borasky, MPH, CIP
Vice President, IRB Compliance
WCG

1:15 PM **Break**

1:15 PM – 2:00 PM EST

Drug & Biologics

2:00 PM **Inspection Compliance — What's Happening Now and What to Expect in 2022**

2:00 PM – 2:45 PM EST

Ever wanted to be a fly on the wall of the FDA's Center for Drug Evaluation and Research (CDER) Office of Compliance? This is your exclusive opportunity to hear about the latest in trends, the impact of COVID-19 on FDA operations and new guidance concerning manufacturing quality.

SPEAKER
Donald D. Ashley, J.D.
Director
Office of Compliance
CDER, FDA

Medical Devices

2:00 PM **Responding to FDA Enforcement Actions**

2:00 PM – 2:45 PM EST

Enforcement actions can jeopardize a company's regulatory submissions, limit and/or prevent products from international distribution and additional enforcement actions. Properly responding to FDA warning letters is critical. This session will discuss and explore the best practices in formulating an appropriate response.

MODERATOR

Julie Larsen
Principal, Director of Inspection Readiness
BioTeknica Inc.

PANELISTS

Ballard Graham
Retired
FDA

Jodi K. Scott
Partner
Hogan Lovells US LLP

Nancy Singer
President
Compliance Alliance LLC

Clinical Trials

2:00 PM **Don't Let Your Vendors Jeopardize Your Inspections**

2:00 PM – 2:45 PM EST

Have you sufficiently vetted your vendors so they'll pass muster during inspections? What reporting requirements and data submission do you require from your vendors? Have you set up regular meeting with you vendors and are they aware of regulatory requirements?

SPEAKER

David Borasky, MPH, CIP
Vice President, IRB Compliance
WCG

2:45 PM **Artificial Intelligence: Are You Ignoring Its Upside?**

2:45 PM – 3:45 PM EST

Adaptive technologies are a growing toolset for healthcare providers to use in both diagnosis and treatment but the implementation of artificial intelligence/machine learning (AI/ML) in medical devices may be intimidating to manufacturers. This session will describe some of the current and projected opportunities that AI/ML presents to the industry and will outline the evolving regulatory landscape for implementing and supporting this technology.

MODERATOR

Steve Niedelman
Lead Quality Systems and Compliance Consultant
King & Spalding LLP
former FDA Deputy Associate Commissioner for Regulatory Operations

PANELISTS

Eric Henry
Senior Quality Systems and Compliance Consultant
King & Spalding LLP

Robert L. Banta
Associate Senior Consultant, QA, Global Device Quality Assurance
Eli Lilly and Company

3:45 PM **Closing Remarks**

3:45 PM – 4:00 PM EST

SPEAKER

Steve Niedelman
Lead Quality Systems and Compliance Consultant
King & Spalding LLP
former FDA Deputy Associate Commissioner for Regulatory Operations

4:00 PM **Conference Adjournment**

4:00 PM EST