15TH ANNUAL

FDA INSPECTIONS VIRTUAL SUMMIT

WCG FDANEWS

Day 1

Tuesday, Nov. 17, 2020

11:00 AM **Welcome and Introduction**

11:00 AM – 11:15 AM EST

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 2021**

11:15 AM - 12:00 PM EST

Do you know how to adjust your processes to ensure inspectional readiness during the era of COVID-19? Hear the latest plans and initiatives coming out of the FDA so you can best be prepared.

Judy McMeekin
Associate Commissioner for Regulatory Affairs
ORA, FDA (Invited)

12:00 PM **Break**

12:00 PM - 12:15 PM EST

12:15 PM **Three Concurrent Breakout Tracks**

12:15 PM - 2:30 PM EST

Track #1: Drugs & Biologics

Be Ready for the FDA Drug GMP Facility Evaluations & Inspections During the Pandemic

12:15 PM - 1:00 PM EST

COVID-19 has impacted almost everything about how we do business, including the FDA's ability to conduct inspections. Will the FDA begin to use virtual inspections? If so, how will this be done? Get a handle on the tools the FDA is using to evaluate facilities at a time when traditional inspections are out of the question.

Kalah Auchincloss (Panelist)
Senior Vice President
Regulatory Compliance and Deputy General Counsel
Greenleaf Health (Invited)

Steve Lynn (Panelist)
Principal Consultant/Owner
Lynn Consulting, LLC (Invited)

Sarah Barkow (Panelist)
Lead GxP External Engagement
Bristol Myers Squibb
former Lead Consumer Safety Officer and Acting Director
Manufacturing Quality Guidance and Policy Staff
CDER, FDA (Invited)

Cynthia Schnedar (Moderator)
Executive Vice President
Regulatory Compliance
Greenleaf Health
former Director of CDER's Office of Compliance

Lunch Break

1:00 PM - 1:45 PM EST

Ensure Drug GMP Inspection Readiness

1:45 PM - 2:30 PM EST

Are you inspection ready? Solutions start here. Discover how to better address your unique challenges, effectively use virtual audits to ensure inspection readiness and easily pivot when COVID-19 negatively impacts your work force or your supply chain.

David Elder (Panelist)
Executive Vice President
Greenleaf Health (Invited)

David Chesney (Panelist)
Principal and General Manager
DL Chesney Consulting, LLC (Invited)

Vicky Stoakes (Panelist)
President
IntegRx, Inc
former CDRH Chemist
ACNA and Investigator
Atlanta District Office Drug Cadre (Invited)

Cynthia Schnedar (Moderator)
Executive Vice President
Regulatory Compliance
Greenleaf Health
former Director of CDER's Office of Compliance

Track #2: Medical Devices

CDRH Quality Pilot — Implementation of Capability Maturity Model

12:15 PM – 1:00 PM EST

Be prepared for when FDA implements the maturity model as an alternative to the traditional path of a routine FDA inspection. This can also benefit companies participating in the pilot program, to include your site's removal from FDA's routine inspection plans. Understand in this discussion how a manufacturer's implementation of the maturity model benefits you and the FDA.

Francisco Vincenty (Speaker)
Program Manager for the Case for Quality
Office of Compliance
CDRH, FDA (Invited)

Julie Larsen (Moderator)
Principal
Director of Inspection Readiness
BioTeknica Inc.

Lunch Break

1:00 PM - 1:45 PM EST

Cybersecurity Developments

1:45 PM - 2:30 PM EST

If you don't have your cybersecurity under control, you aren't inspection ready. Come hear about the latest cybersecurity areas of focus and concern during FDA inspections and notified body (NB) audits. You'll come away with what you must show in order to demonstrate adequate cybersecurity risk assessment at inspections. Participate to avoid the most frequent cybersecurity errors medical device manufacturers make during inspections.

Eric Henry(Panelist)
Senior Quality & Regulatory Compliance Advisor
FDA & Life Sciences Practice
King & Spalding LLP

Seth Carmody (Panelist)
Vice President
Regulatory Strategy
MedCrypt (Invited)

Armin Torres (Panelist)
Principal
BioTeknica Inc. (Invited)

Julie Larsen (Moderator)
Principal
Director of Inspection Readiness
BioTeknica Inc.

2:30 PM **What's a Regulatory Meeting and How Do You Prepare for It?**
2:30 PM – 3:00 PM EST

When the FDA asks you to attend a regulatory meeting concerning compliance issues, will you know what to do and what that means? Do you know how to prepare for a compliance meeting and what will happen? Do you know the possible outcomes of a regulatory meeting on compliance issues? This is the way to stay compliant.

Steve Niedelman (Speaker)
Executive Director and CER Business Unit Lead
Regulatory & Quality Solutions (R&Q)

Cynthia Schnedar (Speaker)
Executive Vice President
Regulatory Compliance
Greenleaf Health
Former Director of CDER's Office of Compliance

David Chesney (Speaker)
Principal and General Manager
DL Chesney Consulting, LLC (Invited)

3:00 PM **Virtual Social Event — Beer and Cheese Tasting**
3:00 PM – 3:45 PM EST

You'll receive a sampling of craft beer and fine cheeses in advance of this enjoyable and entertaining session. An expert will talk us through the pairings via Zoom.

Day 2

Wednesday, Nov. 18, 2020

11:00 AM **Welcome and Introduction by Chairperson**

11:00 AM – 11:15 AM EST

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 – 12:00 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 the next one.

David Elder (Panelist)
Executive Vice President
Greenleaf Health (Invited)

David Chesney (Panelist)
Principal and General Manager
DL Chesney Consulting, LLC (Invited)

Vicky Stoakes (Panelist)
President
IntegRx, Inc
former CDRH Chemist
ACNA and Investigator
Atlanta District Office Drug Cadre (Invited)

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

12:00 PM **Break**
12:00 PM – 12:15 PM EDT

12:15 PM **Three Concurrent Breakout Tracks**
12:15 PM – 2:30 PM EDT

Track #1: Drugs & Biologics

Managing Risks and Ensuring Quality in Your Global Supply Chain
12:15 PM – 1:00 PM EDT

Don't let your company be at the mercy of your global supply chain — there are steps you can take to address the challenges. Learn how others have managed the supply chain during the pandemic. Come away with solid strategies for ensuring such challenges don't result in drug shortages.

Dara Corrigan (Panelist)
Vice President
Government Affairs and Policy
Fresenius Kabi
former Associate Commissioner for Global Policy
FDA (Invited)

Paula Katz (Panelist)
Special Counsel
Covington & Burling LLP

Cynthia Schnedar (Moderator)
Executive Vice President
Regulatory Compliance
Greenleaf Health
former Director of CDER's Office of Compliance

Lunch Break
1:00 PM – 1:45 PM EST

Inspection Compliance — What's Happening Now and What to Expect in 2021
1:45 PM – 2:30 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 the FDA operations and new guidances to be aware of concerning manufacturing quality.

Don Ashley (Speaker)
Director
Office of Compliance
CDER, FDA (Invited)

Cynthia Schnedar (Moderator)
Executive Vice President
Regulatory Compliance
Greenleaf Health
former Director of CDER's Office of Compliance

Track #2: Medical Devices

Managing Virtual MDSAP Inspections
12:15 PM – 1:00 PM EST

The medical device single audit program (MDSAP) is supposed to streamline processes and minimize disruptions, enabling you to get your devices to market faster. If virtual MDSAP inspections are throwing you a curve ball, this session is essential. You'll get a handle on how remote MDSAP assessments are being conducted, best practices for managing remote inspections and the biggest virtual MDSAP challenges companies face — and how to mitigate them.

Julie Larsen (Moderator)
Principal
Director of Inspection Readiness
BioTeknica Inc.

Lunch Break
1:00 PM – 1:45 PM EST

Managing Medical Device Recalls

1:45 PM – 2:30 PM EST

The hard truth is that there's been an increase in medical device recalls in 2020. How can you avoid or lessen one? This session looks at the primary drivers of this increase. Is the COVID-19 pandemic a contributing factor? Do you know what to inspect in a recall inspection? And to report or not to report — and if reporting, when? The answers to these questions and more will be revealed, so you can be prepared.

Beverly Lorell (Speaker)
Senior Quality & Regulatory Compliance Advisor
FDA & Life Sciences Practice
King & Spalding LLP

Julie Larsen (Moderator)
Principal
Director of Inspection Readiness
BioTeknica Inc.

2:30 PM **Closing Remarks**

2:30 PM – 2:45 PM EST

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

2:45 PM **Adjournment**