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 **Deploying the Right Tools: Virtual Clinical Trials Toolbox**
12:15 PM – 1:00 PM EST

Ensure your virtual clinical trials run as efficiently as possible with the best approaches. You'll hear about — and be able to incorporate — the telemedicine innovations that have been implemented during the pandemic, including study visits and medical dispersal. Also discuss the various perspectives on virtual clinical trials from sponsors, sites and IRBs that you can integrate to bolster your own processes.

David Borasky (Moderator)
Vice President
IRB Compliance
WCG

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

1:45 PM **Quality by Design: Build Quality into Clinical Trials to Proactively Identify and Mitigate Risks**
1:45 PM - 2:30 PM EST

This session is a must for anyone looking to improve quality, mitigate risk and improve clinical trial success. When you proactively measure your trial in real time, you can avoid any retrospective reactions following an inspection. Delve into developing a risk-based approach that will enable you to more easily define the risks involved and devise proper methods to mitigate them. Case studies will show you as well the fundamental failures that would have been prevented by using a quality-by-design approach.

Sharon Reinhard, M.S. (Speaker)
Executive Director
Merck Research Labs Quality Assurance
Merck & Co., Inc. (Invited)

David Borasky (Moderator)
Vice President
IRB Compliance
WCG

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 **Going Mobile: Strategies for Managing Remote Audits and Inspections**
12:15 PM – 1:00 PM EST

Efficiency is the name of the game when you master remote audits and inspections. Enable yourself, your team and entire organization to select the appropriate technology, set parameters (hosting and implementing audits) and establish state-of-the-art processes — all helping you get to market faster.

David Borasky (Moderator)
Vice President
IRB Compliance
WCG

1:00 PM **Lunch Break**
1:00 PM – 1:45 PM EST

1:45 PM **Obtaining and Documenting Informed Consent When the Patient Isn't in the Room**
1:45 PM – 2:30 PM EST

Informed consent is made even more problematic when it's virtual. During this session, you'll discover how research teams can ensure a smooth pivot to virtual informed consent processes and how to remain compliant with regulatory requirements during the pandemic. You'll even find out how to anticipate the future of informed consent best practices to avoid more disruption.

David Borasky (Moderator)
Vice President
IRB Compliance
WCG

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**