8th Annual Medical Device Regulations Conference & Workshop

September 21-23, 2021

Day 1: September 21, 2021

Emergency Use Authorization, Compliance, International Updates

Day 2: September 22, 2021

Medical Device Innovation

Day 3: September 23, 2021

MDR/IVDR Workshop

DAY ONE: Tuesday, September 21, 2021

Welcome:

8:30-9:00 AM: Welcome/Conference Overview – Dean Kelly Smith, UGA

Opening Plenary Session:

9:00-9:30 AM: FDA CDRH Update – Jeffrey Shuren, FDA

9:30-10:00 AM: FDA ORA Update – Judith McMeekin, FDA

Morning Break:

10:00-10:15 AM

Emergency Use Authorization:

10:15–10:45 AM: Transitioning from EUAs to Traditional Submission Pathways – FDA Perspective – Angela Krueger, FDA

Synopsis: In response to the COVID-19 public health emergency, FDA has issued an unprecedented number of emergency use authorizations (EUAs). As EUAs are not a permanent marketing authorization, manufacturers will need to transition their EUAs to other traditional submission pathways, such as 510(k) or De Novo. This session will outline considerations from FDA's perspective regarding transitioning from an EUA product, including challenges, opportunities, and examples.

Emergency Use Authorization (Contd.):

10:45–11:15 AM: An Industry Perspective on Converting EUAs to De Novo's and 510(k)'s – Kim Walker, Global Regulatory, Quality & Clinical Consultant

Synopsis: FDA has not issued their guidance on converting EUAs to pre-market submissions yet but the conversion process has already begun. This session will cover the current EUA conversion process from one industry consultant's experience. Best practices in FDA submissions and communications will also be discussed with a special emphasis on the EUA conversion process.

11:15–11:45 AM: OPEQ COVID Lessons Learned – Michael Hoffmann, FDA

Synopsis: The pandemic has pushed many sectors to adapt to the changing work demands. In response the increased workload, OPEQ has learned several lessons and made improvements in handling EUAs as well as other business processes to more efficiently and effectively address the public health needs of the pandemic.

Lunch Break:

11:45 AM-12:45 PM

Compliance:

12:45-1:15 PM: Remote Regulatory Assessment – Trang Cox, FDA

Synopsis: In our efforts to maintain surveillance activities amidst COVID-19 pandemic, OMDRHO developed and launched a process for RRA to continue our important oversight responsibilities while maintaining the safety and health of the public, industry officials, and our staff. RRA is a meaningful review of information voluntarily provided by a regulated establishment to determine compliance with regulations remotely. This process is designed to allow virtual and interactive engagement between FDA Investigators and firm personnel. Learn what to expect and how to prepare for our voluntary RRA process.

1:15-1:45 PM: Uncovering and Maximizing the Value of FDA Inspection – Lt. Colin Tack, FDA

Synopsis: In this session, an FDA investigator will uncover the value that FDA inspections present to industry stakeholders and patients while providing tips to make the inspection a positive process for your organization. The session will also cover how to use available data generated from inspections of industry peers to improve your organization.

Compliance (Contd.):

1:45 – 2:15 PM: FDA Harmonizing with ISO or MDSAP Implementation – Kim Trautman, Medical Device, IVD, and Combination Product Regulatory and Quality Expert

Synopsis: FDA has committed to revising 21 CFR 820 the Quality System Regulation to harmonize with ISO 13485:2016 Quality Management System (QMS) requirements – this process is not as easy as it sounds.

- Understand where there are similarities and differences in the two QMS requirements
- Explore the FDA required process of rulemaking
- Discuss how FDA might use some aspects of MDSAP and where they will likely need to still do their own types of inspections

Afternoon Break:

2:15-2:30 PM

International Updates:

2:30 – 3:00 PM: China's Revised Regulations on Medical Devices and IVD: Implications for Industry – QianQian Zhu, Immucor

Synopsis: The Regulations on the Supervision and Administration of Medical Devices (State Council Order 739) took effect on June 1, the China National Medical Products Administration (NMPA) and Center for Medical Device Evaluation (CMDE) have issued additional announcements and documents supporting its implementation. Order 739 is the overarching policy for all medical and IVD product registration, identify key changes that would affect regulatory strategies and prepare for necessary adjustments, and gain up-to-date knowledge of current requirements and practices.

3:00-3:30 PM: Whirlwind of Change: How New Standards, MDR, and Brexit are Impacting Biocompatibility – Thor Rollins, Nelson Labs

Synopsis: With the COVID-19 crisis, the Medical Device Regulations (MDR) have been pushed back one year, this delay has given a respite for those companies that were not quite ready for the increase regulations. This delay put the new MDR requirements in the same time period as the impact of Brexit and new requirements in the ISO 10993 standards. In this talk we will be discussing the current status of biocompatibility submission with MDR and Brexit, and what are others doing to get ready. Attendees will learn:

- What additional requirements are in the MDR?

International Updates (Contd.):

- What is being required now per ISO 10993?
- How Brexit is impacting submissions to the UK?
- Where is the industry currently at and how many companies feel ready for their first submission?
- What have we learned from the first submissions under MDR?
- What are others doing now, to save time and money?

3:30-4:00 PM: Notified Body Update – BSI's Tales from the Trenches – Anthony Rizzo, BSI

Synopsis: This session will provide an overview of current MDR/IVDR transition activities from a notified body perspective. Additionally, current challenges in the availability of Notified Bodies to perform audits and reviews will be discussed.

4:00-4:30 PM: Impact of Pandemic on Imports/Exports – Dan Solis (LA), FDA

Synopsis: Mr. Solis is a recognized expert in FDA import operations who serves as the acting assistant commissioner and director of ORA's Office of Enforcement and Import Operations (OEIO) since March 29, 2020. He provides leadership and direction to all OEIO field import divisions as well as the Division of Food Defense Targeting (DFDT) and Division of Import Operations (DIO) at FDA HQ, providing stability to enhance ORA's responsiveness due to COVID-19 Pandemic impacts to imports/exports. In this presentation, Mr. Solis will walk the audience through the import hurdles and challenges OEIO faces in dealing with demands cascading from these impacts. He will provide insights regarding how the Agency continues to deliver and maintain the safety of our food supply chain, importation of medical devices and how the Agency joins forces with Customs and Border Protection (CBP) in examining adulterated, misbranded, and counterfeit products.

Wrap Up:

4:30-4:45 PM: Al Jacks, UGA

DAY TWO: Wednesday, September 22, 2021

Welcome:

8:30-8:45 AM: Welcome and Day 2 Overview – Dr. Michael Bartlett, UGA

Medical Device Innovation:

8:45-9:15 AM: Life-Cycle Approach for Breakthrough Designation FDA vs. Industry? – John Doucet, MCRA

Synopsis:

- Understand the purpose and benefits of the breakthrough device program and how FDA reviews designation requests
- Understand key strategies for increasing the likelihood of obtaining the designation
- Understand how to best use the unique mechanisms for interacting with the FDA reserved for breakthrough devices

---

9:15-9:45 AM: Bringing Additive Manufactured Medical Devices to Market: Challenges Faced by Industry – Ayishwariya Menon, Medical Device & Healthcare Consultant

Synopsis: With the increased adoption of additive manufacturing (3D printing), the complexity of the method continues to challenge medical device manufacturers as they attempt to meet regulatory requirements to bring their devices to market. This session will introduce additive manufacturing and review the currently available devices. Challenges faced by industry unique to the additive manufacturing process will be discussed, using the most widely used devices as examples, with a focus on the pre-market phase.

9:45-10:15 AM: Digital Health, AI Medical Devices and Software as Medical Device: A Regulatory Update – Bakul Patel, FDA

Synopsis:

Morning Break:

10:15-10:30 AM

Medical Device Innovation (Contd.):

10:30-11:00 AM: Transforming Tissue into Treatment: An Overview and Update of Human Tissue Product Regulation – Melissa O'Connor, StimLabs

Synopsis: This presentation will provide an overview of the history leading to the promulgation of regulations intended to prevent the introduction, transmission, and spread of communicable disease through the transplantation of human derived tissue products, regulated as Section 361 Human Cells, Tissues, and Cellular and Tissue Based Products, otherwise known as HCT/Ps. The current regulations regarding screening and testing of donors, registration and listing, current Good Tissue Practices for HCT/P manufacturing, and the regulatory path to market for these products will be described. Additional information will be presented regarding how HCT/Ps can also be classified as a medical device or a drug, as well as recent regulatory changes in classification for certain types of HCT/Ps.

11:00-11:30 AM: Wound Care Product Landscape: From Human Tissue to Honey – James Bertram, FDA

Synopsis: Treatment of skin wounds poses continued challenges and substantial risks to patients. In addressing these challenges and patient needs, there is diversity in wound care product design and availability, including but not limited to solid wound dressings, gels, liquids and cell and tissue-based products. This presentation with provide an overview of the regulatory landscape of these products, including a summary of the process by which FDA considers and ultimately determines product jurisdiction across the Agency.

Open Forum:

11:30 AM-12:00 PM: FDA Recruitment Talk – Kathleen Sinninger, FDA

Lunch Break:

12:00-12:30 PM

Panel Discussion - All Speakers Invited

12:30-1:45 PM:

Synopsis: Open forum questions from the audience to the panel of experts on the topics they presented and other related topics. This discussion will promote interactions and exchange of information for all conference participants.

Closing Remarks:

1:45-2:00 PM – Seppe de Gelas, UGA

MDR/IVDR Workshop (Solely Sponsored by UGA)

DAY THREE: Thursday September 23, 2021

Welcome:

8:00-8:15 AM: Welcome and Workshop Overview - Ms. Kim Walker, Global Regulatory, Quality, and Clinical Consultant

MDR/IVDR Workshop:

8:15-9:15 AM: Economic Operators role Distributors, Importer. EC-REP – Seppe de Gelas, UGA

Synopsis: With the MDR and IVDR in Europe, roles within chain down to market are more regulated and more formal. This section with explore these roles and the derived constraint applicable to US manufacturers. We will discuss the possible solutions and related workloads.

9:15-10:00 AM: PRRC Expectations and Implementation; How to Select/Prepare Your PRRC – Philippe Etter, Medidee

Synopsis: One of the key roles brought by MDR/IVDR is the one of PRRC – Person Responsible for Regulatory Compliance. We will discuss how a US based company can organize this function, and can possibly split it between various people inside the company or with contracted help. We will also review training requirements.

Morning Break:

10:00-10:15 AM

MDR/IVDR Workshop:

10:15-10:45 AM: MDR Technical Documentation Submissions – Lessons Learned, Anthony Rizzo, BSI

Synopsis: This session will provide a look at the review process, some common gaps/questions from MDR technical documentation reviews, and some steps to improving submissions.

MDR/IVDR Workshop (Contd.):

10:45-11:15 AM: Typical gaps – Biological safety – Thor Rollins, Nelson Labs

Synopsis: Three main reasons trigger attention on this topic as part of MDR deployment. On one hand, the simple re-execution of conformity assessments under MDR induces a tighter review by Notified Bodies of aspects that may have been settled ages ago on legacy products. Secondly the evolution of 10993-x standards family has pushed ahead the notion of BRA – Biological Risk Assessments. Finally, the new requirement of the GSPR related to leachable or nano, induce new area of attention. In this section, we will explore general methods for planning the work.

11:15-11:45 AM: Typical gaps – Clinical Evaluation, PMCF – Richard Curno, Medidee

Synopsis: In this section we will browse a suite of classical areas of attention in the clinical part of technical documentation for Medical Devices and IVDs. We will review the new expectations in terms of clinical update and reporting and the changes of format. Besides the new requirements applicable to the content of CER or PERs, we will also discuss the nature of expected interaction with Notified Bodies on that matter.

11:45-12:15 PM: How to Manage MDR/IVDR Quality System Changes – Anthony Rizzo, BSI

Synopsis: This session will provide an overview of the MDR/IVDR quality system expectations and the top ten gaps from a Notified Body's perspective.

12:15-12:45 PM: Brexit – SwissXit – Michael Maier, Medidee

Synopsis:

We will discuss in this section the impact of Brexit and SwissXit on US manufacturers, what are the options for compliance, the available services, theirs limits and the organizational impact. We will also consider the impact on the process/QMS of the companies.

Lunch Break:

12:45-1:15 PM

MDR/IVDR Workshop (Contd.):

1:15-2:45 PM: Technical Documentation upgrade planning exercise – review of a sample anonymized Tech Doc to find gaps and plan changes – Philippe Etter, Medidee

Synopsis: During this hands-on phase, the participants will have to look for major gaps in the technical documentation of an existing product and will have to express their tactics for addressing these gaps. After the program, they will be debriefed. Two different cases (one IVD, on Medical Device) will be available.

Closing Remarks:

2:45-3:00 PM - Philippe Etter, Medidee