UNIVERSITY OF GEORGIA | MEDICAL DEVICE REGULATIONS CONFERENCE | FDA

# 9th Annual Medical Device Regulations Conference & Workshop

## November 15-17, 2022

**Day 1: November 15, 2022**

**Open Plenary Session, Medical Device Innovation, and International Updates**

**Day 2: November 16, 2022**

**Compliance and Post-market Activities**

**Day 3: November 17, 2022**

**Workshop**

**DAY ONE: Tuesday, November 15, 2022**

**Moderated by: Grace Gowda & Anna Fallon**

**Registration/Check-In: Conference Registration Desk**

**7:30-8:30 AM**

**Welcome:** Room K

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

**Opening Plenary Session:**

**9:00-9:30 AM:** FDA CDRH Update – Michael Ryan, FDA

**9:30-10:00 AM:** FDA ORA Update –Blake Bevill, FDA

**Morning Refreshment Break:** Kellogg Concourse

**10:00-10:15 AM**

**Medical Device Innovation:**

**10:15–10:45 AM:** Medical Device Software: Rules for handling Patient Data in the EU and US – Frances Cohen, Promenade Software

*Synopsis:* As Medical devices are prolifically connecting to mobile phones and cloud, the handling of the sensitive data is a major source of concern for device manufacturers. Several regulations have been put in place to protect individuals' rights concerning their data in the U.S. and E.U. Patient Personal Health Information (PHI) is federally protected under HIPAA, the FDA scrutinizes medical device cybersecurity for U.S. commercialization, and the GDPR regulates the handling of Personally Identifiable Information (PII) for all residents of the EU, regardless of the company's location. In this talk we will cover some of the expectations for protecting the data based on our experience and expertise as a medical device software services and cloud SAAS provider.

**Medical Device Innovation (contd.):**

**10:45–11:15 AM:** Cybersecurity by Design – Linda Westfall, The Westfall Team

*Synopsis:* Pending

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**11:15–11:45 AM:** The Line Between Medical Device Recalls and Enhancements – Meredith Andress, FDA

*Synopsis:* Firm planned Device Enhancements or changes to the device that would require a recall – What differentiates a medical device enhancement from a recall? The process of recall submission and review by FDA once it is determined if the device enhancement is reportable, and review examples of device recalls and enhancements.

**Lunch Break:** Magnolia Ballroom

**11:45 AM-12:45 PM**

**12:45-1:15 PM:** AI/Machine learning – Yarmela Pavlovic and Cassie Scherer, Medtronic

*Synopsis:* This session will the current U.S. FDA regulatory approach for AI/ML-based medical devices and explore opportunities for further enhancement through evolving developments in regulatory science in the areas of avoiding unintended bias, pre-determined change control plans and labeling for transparency. Additionally, the session will touch on the intersection of U.S. regulatory frameworks with the evolving global regulatory landscape for these types of products.

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**1:15-1:45 PM:** Wearables – Anindita Saha, FDA

*Synopsis:* Pending

**Medical Device Innovation (contd.):**

**1:45 – 2:15 PM**: Impact of 3D Printed Patient-Specific Surgical Rehearsal Models on Patient Outcomes– Smriti Zaneveld, Lazarus 3D, Inc.

*Synopsis:* 3D printing has a variety of applications in healthcare, many of which are focused on prosthetics and surgical instruments. However, 3D printed anatomical models are tackling a new area of medical practice: patient-specific surgical rehearsal. Surgical rehearsal models allow surgeons to practice complex surgical procedures on realistic models before the patient ever enters the operating room. Patient scans allow the models to accurately match the specific anatomy of the patient to ensure that the surgeon is practicing on exactly what they will see in the OR. This talk will explore the impact that these models have on surgeon preparation and improved patient outcomes.

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**2:15 – 2:45 PM**: Innovating the Human Body: Allograft Tissue-based Medical Devices– Melissa O'Connor, StimLabs

*Synopsis:* In a technology-driven age, novel tools used to treat patients are consistently developed and marketed in an effort to improve the medical outcomes of lives in need. What if the next-generation of medical devices is literally within us? Join us as we innovate the human body and explore allograft tissue-based medical devices – the history of human tissue transplant regulation, how tissue transplants are infiltrating the medical device industry, and how you, too, can innovate the field of medicine from within.

**Afternoon Break:** Kellogg Concourse

**2:45-3:00 PM**

**International Updates:**

**3:00 – 3:30 PM:** Transitioning into MDR and IVDR– Alireza Hemmati, TÜV SÜD Americas, Inc

*Synopsis:* Pending

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**3:30-4:00 PM:** China talk – privacy for digital devices/software – Qianqian Zhu, Immucor

*Synopsis:* Data privacy has been a hot topic in China since the Chinese government actively released data privacy laws and regulations in recent years. Three milestone laws in the privacy regime have been published and come into effect, including the Cybersecurity Law (CSL) (2017), the Data Security Law (DSL) (2021) and the Personal Information Protection Law (PIPL) (2021).This session will introduce the key requirements in the data protection regime and the implications for medical device manufacturers.

**International Updates (contd.):**

**4:00-4:45 PM:** Global Pre-Market Medical Device Regulatory Strategy for ASEAN, Australia– Jenny Lin, PharmaLex Pty Ltd

*Synopsis:* This is a high-level overview of the pre-market submission requirements in Australia and ASEAN countries as compared to the US and EU regulations. The session will capture key factors for considerations in the early development of a medical device, including the classifications, regulatory pathways, documentation requirements, quality system and design control requirements in these jurisdictions. This session aims to highlight the crucial areas to support an integrated pre-market solution that covers multiple countries for efficiency in preparation for market access at an early stage and in parallel to your US or EU submissions.

**Wrap Up:**

**4:45-5:00 PM:** Al Jacks, Axogen and UGA

**Reception:** Pecan Tree Galleria

**6:00-7:30 PM**

**DAY TWO: Wednesday, November 16, 2022**

**Moderated by: Seppe de Galas**

**Breakfast:** Magnolia Ballroom

**7:30-8:30 AM**

**Welcome:** Room K

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

**Compliance and Post-market Activities:**

**8:45-9:15 AM:** Understanding and Managing Global UDI Compliance – Jay Crowley, Medical Device Solutions and Services

*Synopsis:* Currently, multiple regulators have or are launching national UDI requirements and UDI Databases (US, EU, SFDA, NMPA, KFDA, HSA). Other regulators are following close behind. The challenge for device manufacturers is creating and maintaining and compliant a global UDI system, including submitting the required data to these national databases and maintaining this data – and regulatory compliance – over time. At the same time, other users and use cases for UDI (or UDI-like) and UDI data are emerging – including commercial, payment, supply chain, and postmarket surveillance (e.g., registries). This session will discuss these challenges and tips for managing the expanding and evolving global UDI requirements.

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**9:15-9:45 AM:** Understanding Remote Regulatory Assessment (RRA) for Medical Device Facilities – Brittani Franklin, FDA

*Synopsis:* A Remote Regulatory Assessment (RRA) is a voluntary review for medical device facilities being implemented by FDA's Office of Medical Device and Radiological Health Operations (OMDRHO). This presentation will discuss this new inspectional tool FDA will be utilizing moving forward. Attendees will obtain insight geared towards the

**Compliance and Post-market Activities (contd.):**

*Synopsis (Contd.):*

agency's jurisdiction to conduct an RRA, the process of participating in an RRA, and will be able to identify any additional RRA resources.

**9:45-10:15 PM:** 13485 harmonization with QSR (QMSR) – Karen Masley-Joseph, FDA

*Synopsis:* The 'Proposed 820 Transition to QMSR' will present an overview of the proposed rule published in the Federal Register in February of this year and entitled, 'Medical Devices; Quality System Regulation Amendments'

**Morning Refreshment Break:** Kellogg Concourse

**10:15-10:30 AM**

**10:30-11:00 AM:** Transition from EUA to Marketing Authorization for COVID-19 In Vitro Diagnostics – Toby Lowe, FDA

*Synopsis:* Pending

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**11:00-11:30 AM:** Introduction to the Breakthrough Devices & Safer Technologies Programs – Ouided Rouabhi, FDA

*Synopsis:* This presentation will provide an introduction to the Breakthrough Devices Program and Safer Technologies Program. The Breakthrough Devices Program is a voluntary program for certain medical devices and device-led combination products that provide for more effective treatment or diagnosis of life-threatening or irreversibly debilitating diseases or conditions. The Safer Technologies Program (STeP) is a voluntary program for certain medical devices and device-led combination products that are reasonably expected to significantly improve the safety of currently available treatments or diagnostics that target an underlying disease or condition associated with morbidities and mortalities less serious than those eligible for the Breakthrough Devices Program. The goal of both programs is to provide patients and health care providers with timely access to these medical devices by expediting their development, assessment, and review, while preserving the statutory standards for premarket approval, 510(k) clearance, and De Novo marketing authorization, consistent with the Agency's mission to protect and promote the public health. This presentation will include an explanation of the principles and benefits of each program, eligibility considerations, and program features available to Breakthrough and STeP devices. The presentation will also cover how to request entrance into each program and provide an overview of the review process.

**Compliance and Post-market Activities (contd.):**

**11:30-12:00 PM:** Current Compliance Trends in Office of Medical Device and Radiological Health Operations (OMDRHO) – Salvatore Randazzo, FDA

*Synopsis:* This presentation will present a high-level overview of the OMDRHO organization, and the processes surrounding regulatory enforcement. This includes a discussion of current regulatory trends, compliance rates by inspection classifications, and a look at the top FDA 483 observations. Additionally, there is coverage of the different regulatory tools available to FDA when enforcing the requirements of the FD&C Act and regulations, their regulatory significance, and the processes by which to submit responses to FDA for 483 observations and Warning Letters.

**Lunch Break:** Magnolia Ballroom

**12:00-1:00 PM**

**1:00-1:45 AM:** Integrating ongoing post-market surveillance data (internal/external) into risk management for product life cycle – Kim Trautman, MEDIcept Inc.

*Synopsis:* Integrating real world data from users is instrumental in order to comply with current Regulatory Authority explicit requirements and expectations. Active and passive real world data collection must be evaluated for Adverse Event Reporting. The IMDRF Adverse Event codes provide a global foundational basis to link Post Market Surveillance Systems and Risk Management Systems, as well as improving continuous data monitoring and analysis for other risk-based decision making. This technical discussion will provide practical application and discussion points to assist deeper regulatory knowledge and provide global strategic advantages.

- Learn the practicality of establishing a linkage between premarket technical documentation, including risk management data, early in design and development with post market surveillance data to be collected.
- Understand the value of utilizing the IMDRF Adverse Event Codes in premarket risk management activities.
- Explore a few technical tools that can be used in Risk Management that can tie adverse event coding to establish a robust continuous lifecycle of data measuring, monitoring, and updating.
- Trigger discussion on best methods of using real world data for continuous data updating for post market risk-based decisions.

**Panel Discussion:** Moderated by: Grace Gowda

**1:45-2:45 PM –** All Speakers

**Closing Remarks:**

**2:45-3:00 PM –** Grace Gowda, UGA

## Workshop (Solely Sponsored by UGA)

## Total Product Life Cycle Management from Medical Devices Containing Software

**DAY THREE: Thursday, November 17, 2022**

**Moderated by: Anna Fallon**

**Breakfast:** Magnolia Ballroom

**7:30-8:30 AM**

**Welcome:** T&U Room

**8:30-8:45 AM:** Welcome and Workshop Overview – Seppe de Galas

**MDR/IVDR Workshop:**

**8:45-9:15 AM:** Overview – Total Product Lifecycle (TPLC) – Philippe Etter, Medidee

*Synopsis:* Pending

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**9:15-9:45 AM:** Design and Development – Chris Rolfes, GCMI

*Synopsis:* Design and development of a medical device with software has many facets, and it is best to know what is needed from the start. A typical first stage is planning, where user needs and technical requirements are laid out. This lays the foundation for design, verification & validation, regulatory submission and post market activities. This talk will provide a high level overview of design and development considerations, including risk analysis, failure mode analysis and software planning that will help guide product development and increase safety.

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**9:45-10:15 AM:** Device Classification and Submission Management – Andy Meadows, Meadows Design

*Synopsis:* This session will focus on classifying your device and preparing your 510k submission. We will look at how to determine your device classification and identify a predicate device. We will then review the sections of a traditional 510(k) and how they relate to eachother, how the classification of your device affects the content of your 510(k) submission and your development processes, and how the exercise works to ensure the safety and efficacy of your device.

**Morning Refreshment Break:** Kellogg Concourse

**10:15-10:30 AM**

**MDR/IVDR Workshop (contd.):**

**10:30-11:00 AM:** Glucose Meter/Insulin Pump Case Study – Seppe de Gelas, UGA

*Synopsis:* Continuous glucose monitoring (CGM) is wearable technology that makes it easier to track blood sugar levels over time. Most CGM devices take readings every five minutes, all day and night. All CGM systems use a transmitter to wirelessly send the glucose data from the sensor to a device where it can be viewed. Depending on the CGM system, glucose data from the sensor is sent to either a handheld device called a receiver (could even be a smart phone), an app on your smartphone or an insulin pump.

CGM data (real-time glucose levels, trends and history) can be downloaded to a computer or a database at any time. The patient can choose to share this (medical sensitive) information with his /her family, health care provider, diabetes association or even insurance company.

Some CGM devices allow also to connect directly with a portable insulin pump. Such an insulin pump is a small device with the ability to deliver insulin continuously (basal) or quickly (bolus) for carbohydrate intake. There's a variety of insulin pumps on the market, offering options to meet individual needs.

Linking the CGM to the insulin pump is the holy grail for diabetes control and called the closed-loop system or artificial pancreas, allowing the diabetes patient to almost forget his / her disease.

This case study will try to address two major challenges using CGM and automated insulin pumps:

1)CGM devices are collecting a significant number of data points from a (diabetic) patient on an ongoing basis. Due to the link with internet using a smart phone these datapoints can shared with different stakeholders. Each of these stakeholders have a different use and interest of these data. Data protection and patient data integrity is key in this whole data flow.

2)Linked CGM and insulin pumps does raise a valid question on (medical) decision making and liability. This decision making will need to be clearly understood by the patients and the health care practitioner. Only recently CGM & insulin pump manufacturers have made the step towards a structured integration of both technologies.

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**Starts at 11:15 AM: Breakout –** Anna Fallon, Renova Biomedical and UGA

**New Device –** App to monitor food (patient enters food intake) that can interact with glucose meter and insulin pump to modify insulin delivery

*Synopsis:* Pending

**Lunch Break:** Magnolia Ballroom

**11:30-12:30 PM**

**Ends at 1:15 PM: Breakout (contd.) –** Anna Fallon, Renova Biomedical and UGA

*Synopsis:* Pending

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**1:15-1:45 PM:** Changes to Devices by Classification (Addresses classification of recalls) – Nick Walker, FDA

*Synopsis:* Pending

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**Workshop (Contd.):**

**1:45-2:15 PM:** Overview of Medical Device Cybersecurity – Linda Ricci, FDA

*Synopsis:* Pending

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**2:15-2:45 PM:** Algorithm Change Protocols and Predetermined Change Control Plans submitted to FDA for Software as a Medical Device (SaMD) products – Alex Smith, Hogan Lowells

*Synopsis:* In 2021, FDA finalized their Artificial Intelligence/Machine Learning (AI/ML)-Software as a Medical Device (SaMD) Action Plan. Within the plan, FDA described a their current thinking on Predetermined Change Control Plans and Algorithm Change Protocols for SaMD products. During his time at Hogan Lovells, Alex has assisted several companies with submitting these plans to FDA for not only medical devices, but several vaccine and drug products which use AI algorithms. In this session, Alex will provide an interpretation of FDA's current positions on change control related to software devices.

**Closing Remarks:**

**2:45-3:00 PM –** Anna Fallon, Renova Biomedical and UGA

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