FDA U.S. FOOD & DRUG ADMINISTRATION
OFFICE OF REGULATORY AFFAIRS

Office of Medical Device and Radiological Health Operations (OMDRHO) Presents 2022 Annual Virtual Conference

Working Collaboratively to Advance Public Health

Join our outreach efforts demonstrating OMDRHO's commitment to quality and continued improvement. Our conference provides opportunity to discuss current topics collaboratively to further advance public health.

Wednesday July 13, 2022
9:00 AM - 5:30 PM ET

AGENDA

PROGRAM KEYNOTE

Speaker: Program Director *(FDA|ORA|OMPTO|OMDRHO IO)*

PART 820 TRANSITION UPDATE

Speaker: Karen Masley-Joseph – Senior Advisor *(FDA|ORA|OMPTO|OMDRHO IO)*

On February 23, 2022, the US Food and Drug Administration (FDA) issued a proposed rule to amend the device current good manufacturing practice (CGMP) requirements of the Quality System (QS) Regulation to align more closely with the international consensus standard for Quality Management Systems for medical devices used by many other regulatory authorities around the world. The FDA proposes to do so primarily by incorporating by reference the 2016 edition of the international standard specific for medical device quality management systems set by the International Organization for Standardization (ISO), ISO 13485. For today's webinar, FDA will discuss the proposed rule and share resources on where to find more information.

ARTIFICIAL INTELLIGENCE AND MACHINE LEARNING IN MEDICAL DEVICES

Speaker: Shawn Forrest, M.S. – Digital Health Specialist *(FDA|CDRH|OSPTI|DDH)*

Digital health technologies can empower consumers to make better-informed decisions about their own health and provide new options for facilitating prevention, early diagnosis of life-threatening diseases, and management of chronic conditions outside of traditional health care settings. Artificial Intelligence and Machine Learning (AI/ML) are becoming an increasingly powerful tool in these efforts. This topic will provide insights on the current trajectory of FDA's innovation and regulatory oversight of this important field including Good Machine Learning Practices (GMLP) and the AI/ML Software as a Medical Device Action Plan.

OCI (OFFICE OF CRIMINAL INVESTIGATIONS)

Speaker: Gregory Williams – Special Agent/Senior Operations Manager *(FDA|OCI)*

The Office of Criminal Investigations is the criminal law enforcement section of the FDA. Established in 1991, OCI investigates criminal activity involving FDA-regulated products and works to bring criminal cases before the Department of Justice for prosecution. OCI investigates violations of the Federal Food, Drug, and Cosmetic Act that involve the distribution of foreign counterfeit, unapproved, and misbranded FDA-regulated products to include medical devices. This presentation will offer insight on OCI's role within the FDA and discuss aspects of the shared criminal and regulatory enforcement authority regarding medical devices. Additionally, the presenter will examine recent criminal activities associated with medical devices and COVID-19 device products.

RISK MANAGEMENT – USE OF PRODUCTION AND POST-PRODUCTION DATA

Speaker: LCDR Thomas Peter M.S.E. – Consumer Safety Officer *(FDA|ORA|OMPTO|OMDRHO|Division 1)*

As medical devices are designed, developed, manufactured, and distributed on the global market, a residual risk with regard to the medical device's safety and performance remains throughout the product life cycle. The U.S. Food and Drug Administration (FDA) has in place a post-market surveillance program to monitor the safety and quality of medical products. Medical device manufacturers play a significant role in ensuring the benefits of a device continue to exceed its risks as more information becomes available. Today, we will explain the importance of using information from sources such as complaints, MDRs, and production data to ensure medical device safety risks are appropriately identified, estimated, and mitigated.

EUA DEVICE TRANSITION DRAFT GUIDANCE

Speaker: Ryan Ortega (PhD) – Regulatory Advisor *(FDA|CDRH|OPEQ|RPCPS)*

FDA plays a critical role in protecting the United States from threats such as emerging infectious diseases, including the Coronavirus Disease 2019 (COVID-19) pandemic. Section 564 of the FD&C Act authorizes FDA, after the HHS Secretary has made a declaration of emergency or threat justifying authorization of emergency use, to authorize the emergency use of an unapproved product or an unapproved use of an approved product for certain emergency circumstances. FDA recognizes that it will take time for device manufacturers, healthcare facilities, healthcare providers, patients, consumers, and FDA to adjust from policies adopted and operations implemented during the declared COVID-19 public health emergency to normal operations. The webinar will discuss FDA's 2021 draft guidance that describes a proposed device transition plan, among other things, to help avoid disruption in device supply and ensure that devices authorized under an emergency use authorization (EUA) meet applicable requirements after the termination of the relevant COVID-19 EUA declaration.

PURCHASING CONTROLS

Speaker: Jeff Wooley – Compliance Officer *(FDA|ORA|OMPTO|OMDRHO|Division 3)*

The medical device industry has a direct impact on patients and their health, and the manufacturers have the final responsibility for the medical devices that they distribute. This includes responsibility over the materials, components and services used. Today's presentation provides examples where failed components and contaminated materials have directly related to device failures and adverse events, including deaths. In the global market with connected economies, accountability is important, and manufacturers are responsible for establishing and maintaining that accountability as it relates to everything received for their finished device. Current supply chain issues may require going to new suppliers to re-establish sources of raw materials and services. This presentation is aimed at knowing what to do when changing suppliers and what controls need to be applied on new suppliers such as contract manufacturers, specification developers, and initial importers.

MEDICAL DEVICE IMPORTS

Speakers: Brigitte Strelnik – Consumer Safety Officer *(FDA|ORA|OEIO|DIO)*
Dennis Hoang, MPA, MPH - Compliance Officer *(FDA|ORA|OEIO|DWCI)*

All products offered for entry into the United States must be declared to U.S. Customs and Border Protection (CBP). CBP refers all FDA-regulated products to the FDA for review. All imported shipments of FDA-regulated products, including medical devices, are electronically screened by the FDA before they enter the U.S. and must comply with the same standards as domestic products. The importer is responsible for making sure these products comply with FDA laws and regulations. The FDA determines whether products are admissible into U.S. commerce and may refuse entry or utilize other enforcement actions for products or firms that violate or appear to violate any provisions of the Federal Food, Drug, and Cosmetic Act (FD&C Act) and other related acts. Most importers choose to hire licensed representatives, known as customs brokers or entry filers, when offering the products for entry. The entry filers can assist the importer by submitting necessary entry information and appropriate payments to CBP on behalf of the importer. FDA utilizes electronic import systems to review and validate entry data and information. FDA's information technology systems help automate and expedite the import review process. They allow FDA to focus its resources using a risk-based approach. This presentation will discuss the required information for the importation of medical devices and FDA's recent work on COVID-19 related imports such as personal protective equipment and test kits.

ORA/CDRH RESOURCES AVAILABLE TO INDUSTRY

Speaker: James Hildreth – Director, Investigations Branch *(FDA|ORA|OMPTO|OMDRHO | Division 2)*

In this age of advanced data analytics, Medical Device manufacturers have more resources available for gathering and analyzing publicly available data to aid in decision-making and product surveillance. Since 2010, the FDA launched initiatives to enhance transparency of operations and decision-making processes. These initiatives resulted in the implementation of new tools for analyzing and visualizing large, complex FDA datasets. FDA publicly available databases enable a better understanding of the FDA's compliance actions and can be instrumental to the medical device industry in conducting product surveillance and identifying regulatory trends. With the implementation of application programing interfaces, the FDA makes the datasets downloadable directly to firms' systems. This presentation will discuss the FDA's Transparency Initiative and will provide an overview and **demonstration** of publicly available tools that can be used to retrieve, download, and analyze FDA data, including inspections, 483 observations, compliance, recalls, total product lifecycle data, Medical Device Reports, and other information. The speaker will also highlight CDRH's educational tool, which includes learning modules covering both premarket and post-market topics and will introduce you to CDRH's Division of Industry and Consumer Education.

APPLYING STATISTICS TO QUALITY SYSTEMS

Speaker: Michelle Glembin –Medical Device Senior Operations Officer *(FDA|ORA|OMPTO|OMDRHO |Division 2)*

The FDA's Quality System Regulation, 21 CFR 820.250, requires device manufacturers to establish and maintain procedures for identifying valid statistical methods, to ensure that sampling methods are valid and suitable for their intended use, and to review the sampling plans when changes occur. The webinar will include topics such as integration of risk in sampling plans and discuss concepts such as attributes sampling, acceptance quality limit, lot tolerance percent defective, and Operating Characteristic Curve. The presenter will also provide examples of deficiencies observed during inspections related to sampling methods.

Moderator: Trang Cox – Director, Investigations Branch *(FDA/ORA/OMPTO/OMDRHO/Division 3)*