FDA U.S. FOOD & DRUG ADMINISTRATION
OFFICE OF REGULATORY AFFAIRS
OFFICE OF MEDICAL DEVICE & RADIOLOGICAL HEALTH OPS

Working Together – Keeping Informed

June 23, 2021
10:30 am – 5:00 pm (Times may change)

AGENDA

Office of Medical Devices and Radiological Health Operations (OMDRHO) Update

Speaker: Joseph Matrisciano Jr. - Program Division Director and District Director *(Division 1 Office of Medical Devices and Radiological Health Operations and New England District Office | ORA | FDA)*

AccessGUDID, Are You There Yet? & Why You Should Be: Understanding UDI & the latest deadlines

The Unique Device Identifier (UDI) implementation dates have passed. What comes next? Join us for a discussion of the state of UDI in 2021. We'll discuss current guidance, timelines, and what to expect from the inspection process. Representatives from Office of Regulatory Affairs (ORA) and the UDI Team will be available to answer questions.

Speaker: CDR Stephen Smith - Medical Devices Specialist Investigator *(Division 1 | OMDRHO | ORA | FDA)*

Uncovering and Maximizing the Value of FDA Inspections

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.

Speaker: LT Colin Tack – Investigator *(Division 1 | OMDRHO | ORA | FDA)*

Effective Communication with FDA Before, During and After an Inspection

Do you worry you're going to do more harm than good when communicating with FDA? Have you ever gotten a response and said "Um, not what I was asking…?" Or wondered how on earth you report a recall when FDA is onsite and not aware that you have a problem? Or do you just want to be sure you are communicating as effectively as possible? If you answered yes to any of those questions, then this session is for you.

We will discuss communicating with FDA before, during, and after an inspection. Specific topics include:

- Changes in communication due to FDARA and Covid-19 tips for communicating during an inspection
- When to contact CDRH versus ORA personnel
- How to respond to a 483, and
- How to communicate on 510(k) issues found during inspection

Speaker(s): Debara Reese - Medical Device Specialist Investigator *(Division 1 | OMDRHO | ORA | FDA)* & Karen Archdeacon - Compliance Officer *(Division 1 | OMDRHO | ORA | FDA)*

Risk Management and the Total Product Lifecycle

In this presentation, an experienced FDA investigator will explain the importance of using production and post-production information to ensure medical device safety risks are appropriately identified, estimated, and mitigated throughout the total product lifecycle. LCDR Peter will discuss how to leverage data sources such as complaint files, nonconforming product reports, and public FDA databases to increase patient safety and lower the cost of poor quality for your organization.

Speaker: LCDR Thomas Peter - Medical Device Specialist Investigator *(Division 1 | OMDRHO | ORA | FDA)*

FDA Review of Class I and II Recalls

Looking for feedback on Recalls? The FDA will present the results of an in-depth analysis of Class I and Class II recalls, and provide considerations for the application of those results to the medical device industry. The application considerations will include best practices and corrective actions feedback for industry. This presentation will provide insights from our recent review of Class I and Class II recalls that may assist industry in navigating recalls in the future.

Speaker: Meredith Andress - Recall Coordinator *(Division 2 | OMDRHO | ORA | FDA)*

ORA/CDRH Resources Available to Industry

This forum is aimed at improving communications between FDA and Industry by sharing information about the regulatory process and providing resources to the medical device community in a user-friendly format. Information includes Coronavirus webpages and Medical Device Databases, Industry Notices and Guidance Documents, Industry and Consumer Assistance, CDRH Learn, Device Advice, and other Educational Resources.

Speaker(s): Justine Corson - Investigator *(Division 1 | OMDRHO | ORA | FDA),* LCDR David Sullivan- Investigator, (Division 1 / OMDRHO/ORA/FDA) & Ruth Bediakoh - Consumer Safety Officer *(Postmarket and Consumer Branch/Division of Industry and Consumer Education (DICE)/CDRH | FDA)*

Let's talk Remote Regulatory Assessment (RRA) for OMDRHO

COVID-19 pandemic has changed how we continue our important oversight responsibilities while maintaining the safety and health of the public, industry officials, and our staff. In our efforts to maintain surveillance activities, OMDRHO developed and launched a process for RRA. 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.

Speaker: Shari Shambaugh - Program Division Director *(Division 3 |OMDRHO | ORA | FDA)*