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*Webinar on*

# International Codes And Medical Device Reporting

# Areas Covered

- *Knowledge of the IMDRF and the coding*
- *Knowledge of the US FDA reporting system and coding*
- *Understand the mapping of the coding from IMDRF to FDA*

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This webinar Learn how the codes are mapped to FDA codes and how you adapt to them in your facility.

**PRESENTED BY:**

*Mary Weick-Brady is retired from the US Food and Drug Administration/Center for Devices and Radiological Health. Her experience at the FDA included working managing the staff and the contractors responsible for the adverse event reporting interpretation and review of the events reported.*

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On-Demand Webinar

Duration : 60 Minutes

Price: $200

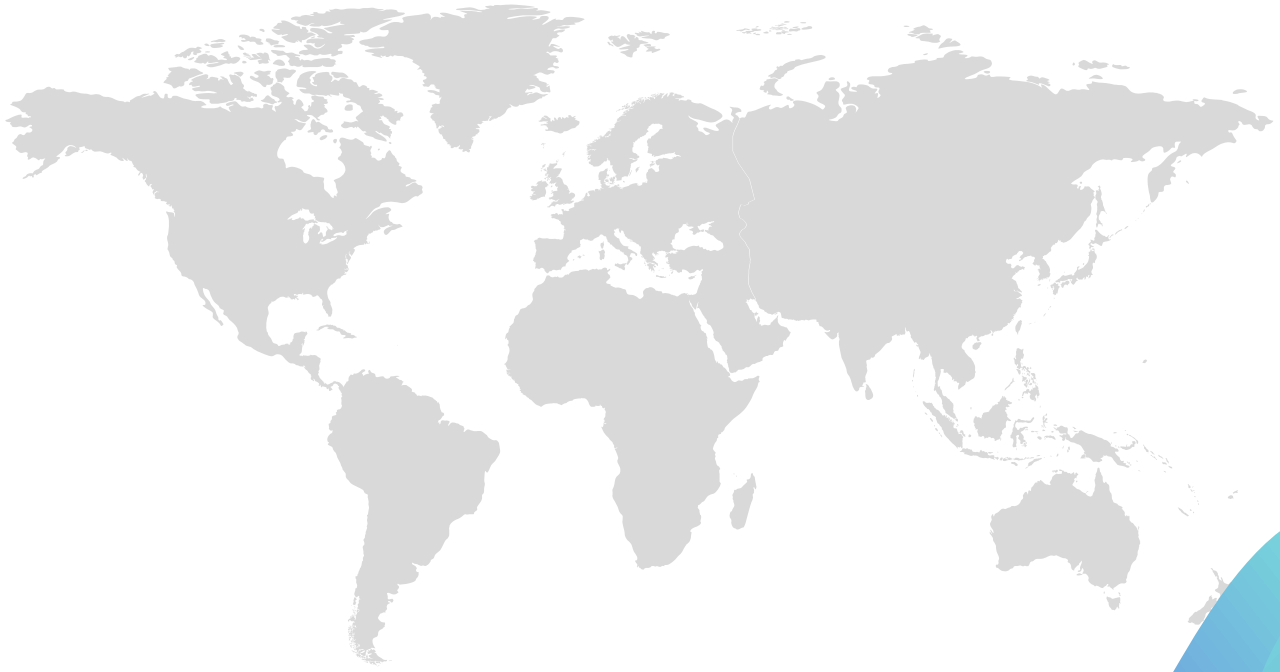
# Webinar Description

The US FDA receives over 100,000 reports a year of medical device adverse events including deaths, serious injuries, and malfunctions. Because of this high number of reports, the FDA sought ways to sort the data using hierarchical coding systems that included a device problems code; a manufacturer's evaluation fo the event: methods, result, and conclusion; and also information on the patient and the device component. Years ago, the Global Harmonization Task Force (GHTF) developed a "standard" international coding structure for device problem and conclusion. When the GHTF was retired, the IMDRF took the coding to the next level and developed a more detailed hierarchical coding structure with definitions of each term. The IMDRF continues to work on this process and will eventually develop coding structures for all terms used in adverse event reporting. The US FDA adopted the IMDRF coding and incorporated it into their reporting system. This webinar will assist anyone who is still mapping their company's coding and answer questions about global use.

New Requirements for Medical Device Manufacturers when reporting adverse events to the FDA were finalized in July 2018. Manufacturers must now use an international coding structure developed by the International Medical Device Regulator's Forum (IMDRF).

# Who Should Attend ?

*Regulatory staff required to submit adverse event reports to the US FDA*



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# Why Should Attend ?

*As part of the post-market monitoring for medical devices, manufacturers, device user facilities, and importers must report adverse events to the US FDA Center for Devices and Radiological Health (CDRH). Reports must be sent in electronically and the FDA relies on a system of codes to describe and categorize the events. The International Medical Device Regulator's Forum (IMDRF) published a hierarchical structure of codes that the FDA adopted and incorporated by regulation in July 2018. This new coding structure is mandatory for all reports sent to the FDA.*

*If you are unsure or need to verify, how to use the coding structure for adverse event reporting with medical devices, this course is for you. Learn how the codes are mapped to FDA codes and how you adapt to them in your facility.*

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