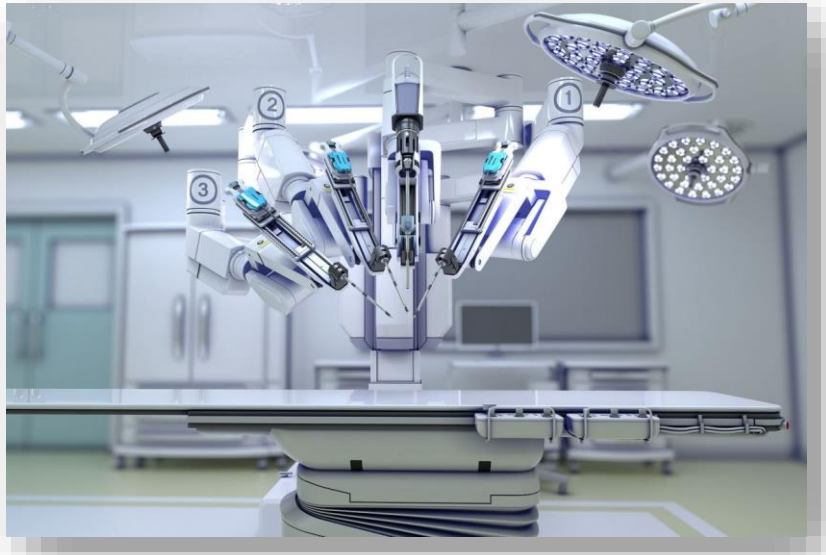
Healthcare Technology Management Professionals: Partnering with FDA for Patient Safety



Presenters

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Outreach and Partnerships Team 2

Division of Clinical Science and Quality

Office of Clinical Evidence and Analysis

Center for Devices and Radiological Health (CDRH)

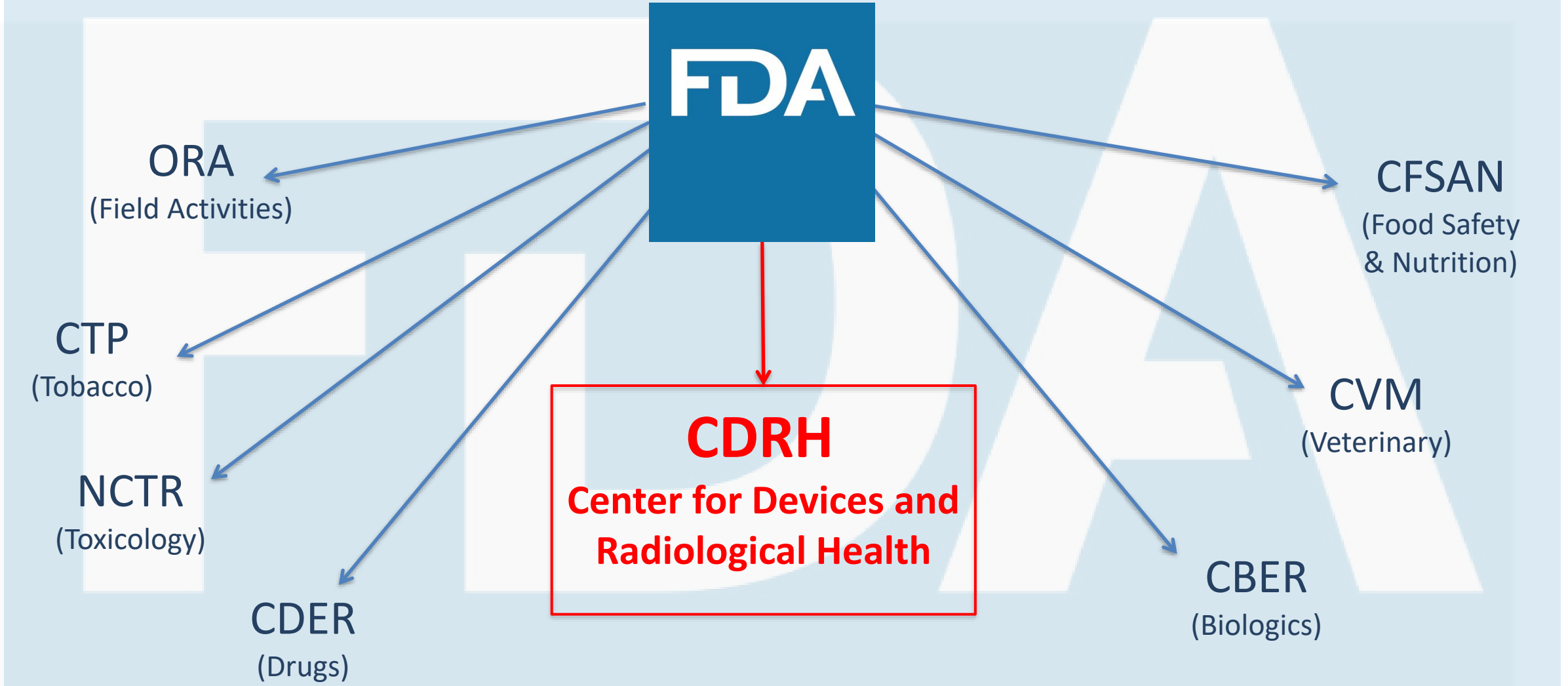
U.S Food and Drug Administration (FDA)

Learning Objectives

1. Overview of CDRH and the benefit of identifying and reporting medical device issues to FDA to improve patient safety

2. Goals of CDRH's Medical Product Safety Network (MedSun)

3. Examples of how HTM professionals can partner with FDA to resolve device issues


FDA
ORA
(Field Activities)
CTP
(Tobacco)
NCTR
(Toxicology)
CDER
(Drugs)
CDRH
Center for Devices and
Radiological Health
CFSAN
(Food Safety
& Nutrition)
CVM
(Veterinary)
CBER
(Biologics)

CDRH's Mission

To *protect and promote public health* by getting safe and effective medical devices to market as quickly as possible…

…while ensuring that devices on the market remain **safe and effective** (postmarket surveillance)

The voice of the clinical community is paramount to FDA's holistic understanding of medical device safety and performance.

Critical Insights of HTM Professionals

THROUGH ROUTINE ACTIVITIES:

- Scheduled maintenance and repairs
- Incident documentation and investigations
- Corrective maintenance
- Interoperability topics
- Human factors topics
- “Use error” topics

THROUGH INTERACTIONS AND VISIBILITY:

- Crosscutting work - many hospital departments
- Interactions with patients, regulatory agencies, clinical teams, vendors, manufacturers

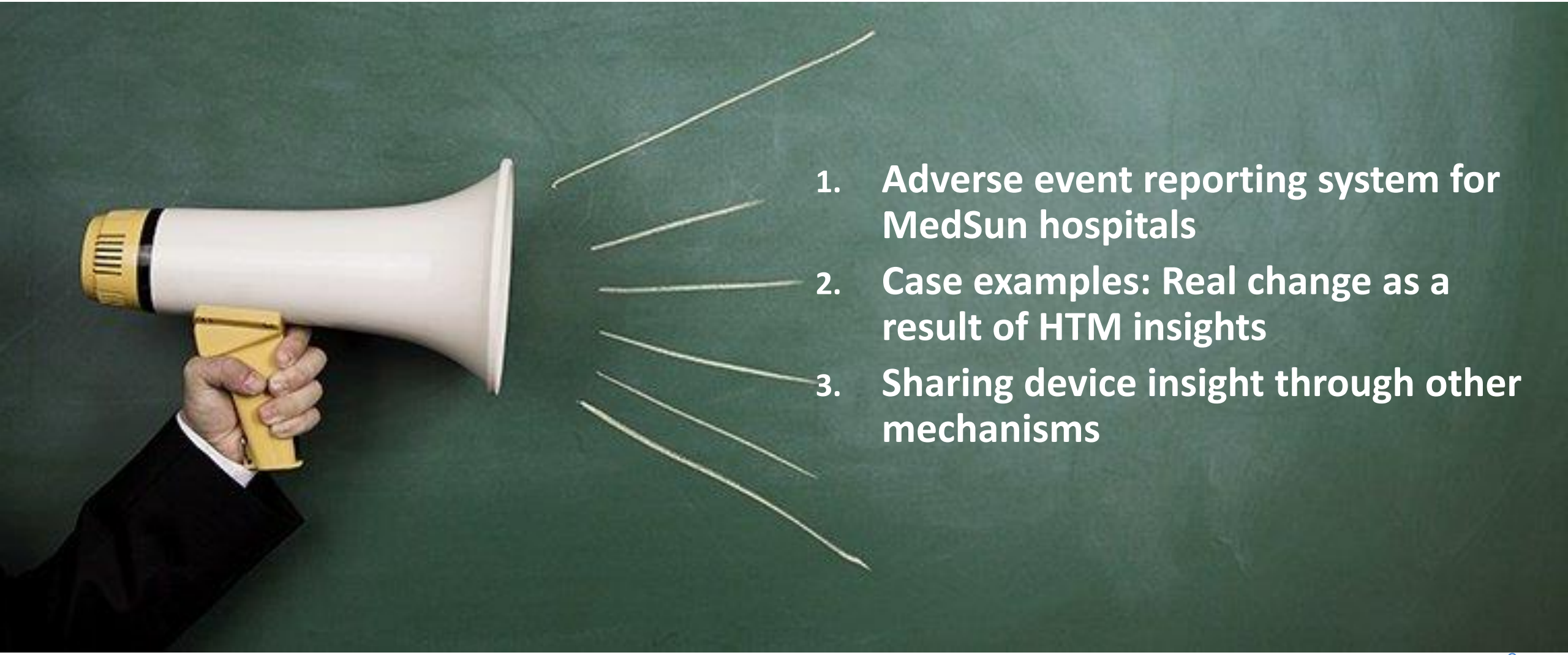
The HTM's point of view is critical to improve the safety and performance of medical devices.

HTM Professionals are key to improving patient safety.

FDA

- **Network of 300+ hospitals nationwide**

- **Dedicated to developing a relationship with the clinical community to:**
  - Understand problems with the use of medical devices
  - Work with the clinical community and manufacturers to solve these problems
  - Provide timely feedback to healthcare professionals to improve patient safety


1. Adverse event reporting system for MedSun hospitals
2. Case examples: Real change as a result of HTM insights
3. Sharing device insight through other mechanisms

Medical Device Reporting from Hospitals is Critical

Why is Reporting from Hospitals Important?

- **Not all devices require clinical studies before they are marketed:**
  - 47% of devices are low risk and thus are “pre-market exempt”
    - tongue depressors, gauze, sponges, etc.
  - 43% must be shown to be similar to another marketed device (rarely requires clinical data)
    - ventilators, infusion pumps, oxygenators, by-pass machines, etc.
  - **Only 10% require clinical studies prior to being approved for marketing**
    - **new, high risk devices, most implantable devices**

Safe Medical Devices Act (SMDA) Mandatory Reporting for Devices

- Mandatory requirements pertain to events where a medical device may have caused or may have contributed to a patient death or serious injury.

- A "serious injury" means an injury or illness that:
  - is life-threatening;
  - results in permanent impairment of a body function or permanent damage to a body structure; or
  - necessitates medical or surgical intervention to preclude permanent impairment.

What is Voluntary Reporting?

- Events where a medical device may have caused or contributed to minor harm to a patient or caregiver, or has the potential to cause harm.

- Additionally, events that may not cause harm, but would improve the performance of the device if addressed.

- MedSun **strongly encourages** reporting of these events. Reporting these types of events may help to mitigate or resolve device issues **before harm occurs.**

Timelines Associated with Mandatory and Voluntary Reports

- **Mandatory reports:**
  - User facilities: Submit reports no later than **10 work days** after the day of becoming aware of a mandatory event.
  - Manufacturers: Submit reports no later than **30 calendar days** after the day of becoming aware of a mandatory event.
- **Voluntary reports:**
  - Submit as soon as reasonably possible.

Reporting to FDA Through MedSun

- Interactions with FDA about reports as needed to ensure that reporter's perspective is relayed to FDA.
- MedSun reports receive individual review with expedited internal timelines.
- Satisfies mandatory reporting requirements for user facilities
- Feedback from reporting outcomes is shared back with reporting facilities.

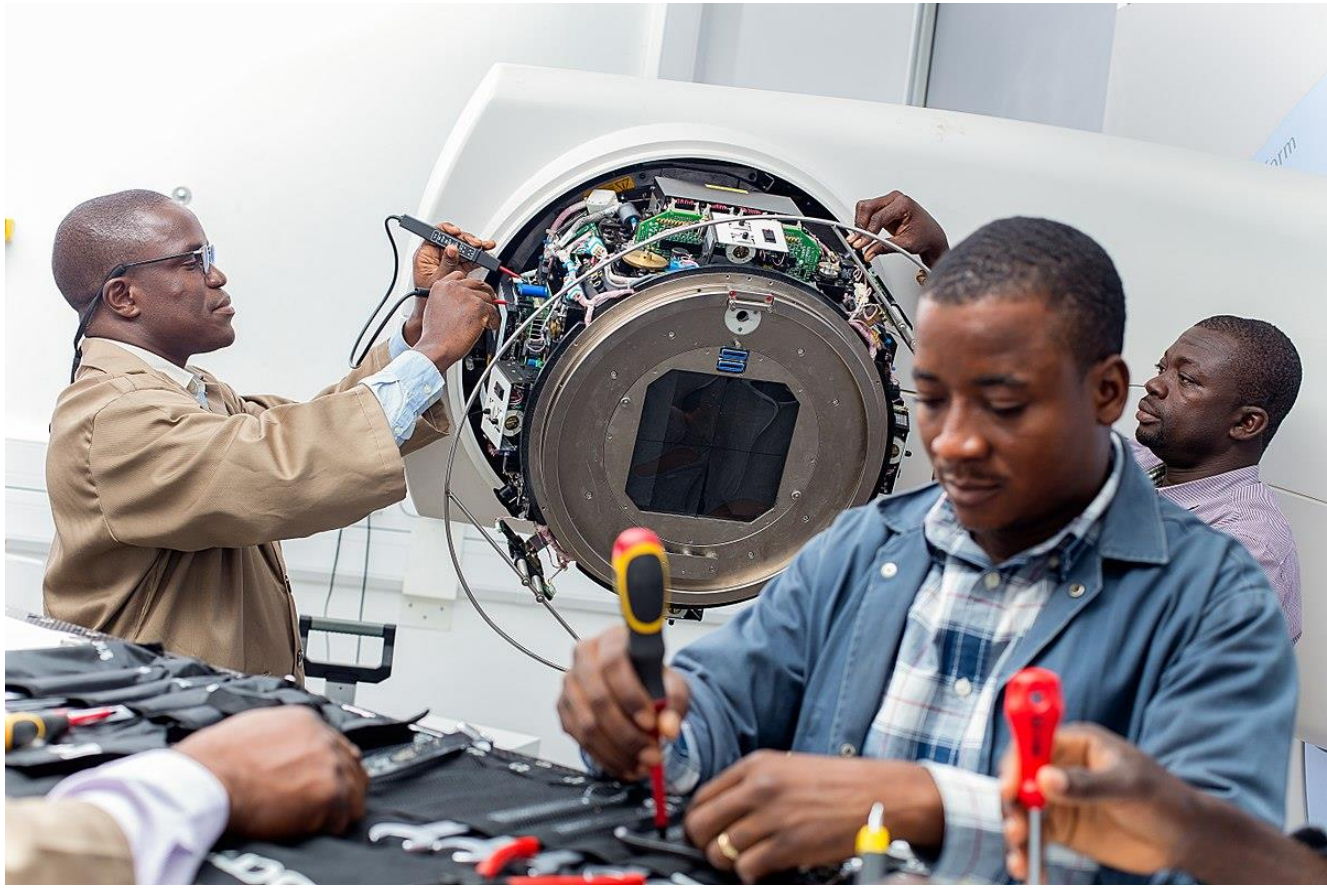
What Can HTMs Report?

HTMs can report device problems to FDA, like:

- New issues
- Recurrent issues that occur at increased frequencies or introduce new harm to patients
- Discrepancies/issues with the manufacturer or suppliers
- Devices that have required a work-around to operate
- Issues where the staff has trouble using the device, even if no mechanical/electrical problem is found

Which problems should be reported?

- Instructions, Labeling, Packaging
- Defects, malfunctions
- Software Problems
- Failure to Work as Intended
- Interactions with Other Devices
- Reprocessing problems
- Manufacturer promotion of off-label use
- Manufacturer removal of product
- Use Errors
  - Unsafe designs
  - User characteristics
  - Environmental problems



Your Medical Device Reports Can Lead To FDA or Manufacturer Actions

Investigation and/or CAPA (corrective action/preventative action) initiation leading to:

- Device correction
  - Design change and/or manufacturing process change
  - Correction leading to device recall
- Safety communication
- Postmarket study
- Improved labeling and/or Instructions for Use (IFU)
- Voluntary recalls

HTMs Making Change by Sharing Concerns

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HTM told us:

Unexpected ventilator shut down without alarm.
Possibly related to faulty printed circuit board (PCB)

Outcome:

Recall – Manufacturer to replace
power management PCB

Is the mitigation timely?

HTMs Making Change by Sharing Concerns

HTM told us:

Continuous Renal Replacement Therapy (CRRT) in progress. **Blood leaking – patient disconnected from CRRT machine**. **Patient expired.** The filter circuit on the patient return line found to be disconnected from the Tego connector, which was attached to the patient's catheter. The disconnection occurred between…the Prismaflex set and the yellow Tego connector.

CRRT default alarm parameters were not met, so this incident occurred without alarm. **HTM suggests** software enhancements for the manufacturer to explore: include incorporating rate/percentage based alarms for the return line.

Outcome:

Recall – Manufacturer to include safety communication in operator's manual

Is this mitigation adequate?

HTMs Making Change by Sharing Concerns

HTM told us:

Heart-lung machine console: Loud noises from roller head pumps. Multiple complaints by perfusion and biomed to manufacturer. Functionality was not affected but load noises caused perfusion and biomed to reach out to vendor and investigate. Upon investigation, bad bearings on pump roller head appeared to cause the issue.

Outcome:

Recall – Manufacturer to notify customers and schedule repairs to roller pumps.

Are there concerns with the repair being completed?

HTMs Making Change by Sharing Concerns

HTM told us:

Alarm and subsequent unanticipated shutoff of pump during use: When disconnected from wall outlet, battery low alarm sounding later than it should – when battery was very close to depletion. Machine alarmed its 20 minute alarm but powered off in less than 1 minute – posing potential for serious patient harm. No patient harm, but significant concern.

Outcome:

Recall – An internal device component was susceptible to vibration failure…. which may result in pump alarms and potential abrupt cessation of function or inability to start the IABP.

Recall Strategy for Hospitals:

- Short-term plan: Sequester devices, do not use for pt transport
- Long-term plan: Manufacturer conducting inspections, corrections on devices, using updated component.

HTM Feedback to FDA's Questions

HTM Feedback to FDA's Questions

- What impact would your facility experience if your current fleet of AEDs became unsupported by the device manufacturer?
- What are the common problems you encounter with ventilators?
- Is this recommendation easy to understand and implement (pre-publication)?
- Would you be able to implement this recall at your facility? What resources would be involved to carry out this work?

We also want to hear…

- Usability or other human factors issues
- Software or cybersecurity concerns
- Impact of proposed regulatory action
- Clarity and usefulness of communications
- Difficulty resolving problem with manufacturer
- Workarounds
- Results of in-house troubleshooting
- Other HTM insights that could impact FDA's regulatory decisions

Currently Seeking HTM Feedback on…

- **COVID-19: Current and anticipated device supply disruptions**
  - **There are many scenarios where FDA can help mitigate a supply disruption so that important equipment is available for patients and staff who need it most.**
    - **Modify approach to recall**
    - **Authorize product to remain on market under certain conditions**
    - **Issue EUA if needed**
    - **Modify timing of regulatory action**
  - **Ventilators, dialysis machines, pulse oximeters, accessories, ECMO devices**
    - **How do you typically procure this device, and what roadblocks are you encountering?**

Other Areas for Collaboration

- CMMS Analytics Project
- Insights to device problems from FDA databases
- Education to/from FDA and HTMs

What can I do?

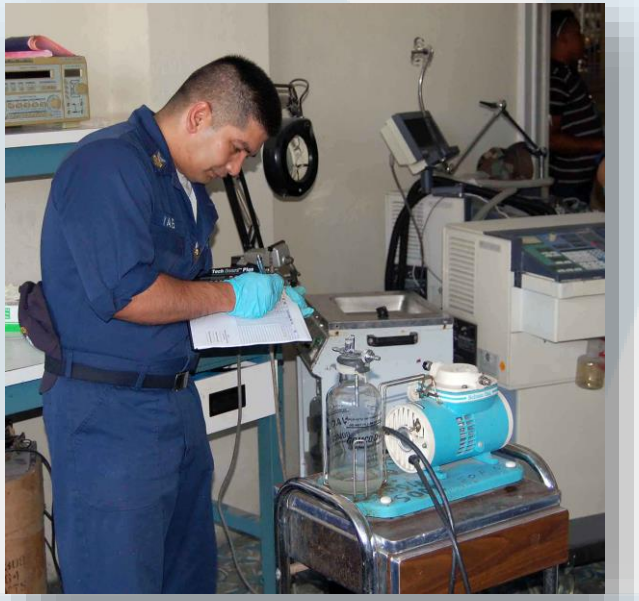
- Find out if your hospital is a MedSun partner.
- Join your hospital's reporting team
- Consider partnering with MedSun as a reporting hospital
- Share feedback through MedSun surveys
- Contact MedSun to share device concerns with FDA

HTM Professionals as Key Stakeholders

FDA Resources for HTMs

- FDA Emergency Use Authorizations related to COVID-19
- COVID-19-Related Guidance Documents for Industry, FDA Staff, and Other Stakeholders
- FDA Medical Device Safety – Includes safety communications, letters to Health Care Providers, banned products, etc.
- 510(k) database: Most Class II (moderate risk) devices require 510(k) clearance from the FDA before they may be legally marketed. This database includes releasable 510(k) information.
- PMA database: Most Class III (high risk) devices require Premarket Approval (PMA) before they may be legally marketed. This database includes devices with Premarket Approval, and includes the approval order, Summary of Safety and Effectiveness, and labeling for the approved device (original PMAs and panel-track supplements).
- Manufacturer and User Facility Device Experience (MAUDE) - medical device reports submitted to the FDA by mandatory reporters (manufacturers, importers and device user facilities) and voluntary reporters such as health care professionals, patients and consumers
- Recalls - Medical Device Recalls classified since November 2002
- MDDS Requirements for Health Care Facilities and Manufacturers
- Code of Federal Regulations - Parts 800-1299 apply to medical devices
- FDA Guidance Documents – Guidance documents represent FDA's current thinking on a topic but the recommendations are not binding if an alternative approach satisfies the requirements of the applicable statutes and regulations.

Thank You!



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