Post-market and Compliance

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Outline

• Postmarket Surveillance
  – Medical Device Reports (MDR)
  – Accidental Radiation Occurrences (ARO)
• Recalls
  – Medical Device (806) Corrections and Removals
  – Rad Health (EPRC) Defects and Failures to Comply
• Manufacturer Establishment Inspections
• Trade Complaints

https://goo.gl/eg9hRv
Postmarket Surveillance

- Individual adverse event reports
- Reviewed by limited staff for trending and follow-up
- Can be used to influence premarket questions and decisions

Medical Device Reports (MDR)

- User facilities report to manufacturers:
  - Deaths
  - Serious injuries
- User facilities report to FDA:
  - Deaths
  - Serious injuries when manufacturer is unknown
- Manufacturers report to FDA:
  - Deaths, serious injuries, malfunctions

Serious injury: Life-threatening, results in permanent impairment or damage, or necessitated medical intervention

Publically Available

Accidental Radiation Occurrence (ARO)

- Manufacturers report to FDA:
  - Injurious or potentially injurious exposure to electronic product radiation
- Examples (x-ray):
  - Unexpected exposure
  - Intentional exposure but higher dose than expected
  - Accidental exposure at no fault of the machine

MDR and ARO Reporting Criteria

- MDR Event
  - One (or more) events
  - Involving anyone
  - Not limited to radiation exposure
  - Involving a medical device
  - Which may have contributed to death or serious injury (or could if recurred)
  - Reported by a user facility or manufacturer
- Accidental Radiation Occurrence
  - One or more events
  - Involving anyone at any time
  - Resulting from machine produced radiation
  - Not limited to medical devices
  - Which is injurious or potentially injurious
  - Reported by manufacturers
  - Not required if the event meets reporting criteria for MDR

FDA/CDRH’s MedSun Program

- Network of 250 hospitals nationwide
- Provides CDRH direct communication with the reporting hospital
- Provides opportunities to obtain experience and expertise of both clinicians and technical staff
Post-Market Information Follow-up

- There are several possible actions resulting from post-market information review:
  - MDR or ARO additional information letter
  - Requests clarification of submitted information
  - Initiate a recall
  - Asking questions in a premarket review
  - Broader discussion with industry

Recalls

- Reported to FDA if done to reduce risk or to correct a violation of the FD&C Act
- FDA evaluates risk and ensures that corrections were implemented
- Voluntary
- Information is publically available

Corrections & Removals (806)

- Reported to FDA if done to reduce risk or to correct a violation of the FD&C Act
- FDA evaluates risk and ensures that corrections were implemented
- Voluntary
- Information is publically available
Defect/Failure to Comply (1003)

- Corrections related to Electronic Product Radiation emission and/or Performance Standards
- Corrective actions must be reviewed and approved by FDA
- Corrections made at no charge
Inspections

- Field investigators perform site inspections
- Reports of findings are reviewed and corrections are enforced
- Evaluates the design and manufacturing process
  - Largely a visual and paperwork review
  - Little, if any, device testing is performed by investigators
- Significant enforcements are publically available
  [Link](http://www.fda.gov/ICECI/EnforcementActions/WarningLetters/)

Trade Complaints

- Can come from anyone, even ourselves
  [Link](http://www.fda.gov/ForConsumers/ConsumerUpdates/ucm095859.htm)
- Followed up on an individual basis
- Can result in:
  - Product recalls
  - Simple questions to a manufacturer
  - Letters to industry
  [Link](http://www.fda.gov/MedicalDevices/ResourcesforYou/industry/ucm111104.htm)

What can you do?

- Send complaints to the manufacturer
- Identify safety problems with quality MDR reporting
  - Providing detailed device information
  - Detailed event description
- Identify safety signals to ensure safe and effective devices are on the market (trade complaints)
References

- 21 Code of Federal Regulations
  http://www.ecfr.gov/cgi-bin/text-idx?SID=30f6447420c11e3a4b37caf5c1aa9a12&mc=true&tpl=/ecfrbrowse/Title21/21cfrv8_02.tpl#0

- Medical Device Reporting (MDR):
  - Manufacturer and User Facility Device Experience (MAUDE)
    http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfmaude/search.cfm
  - MedSun Program
    http://medsun.fda.gov/medsun/

- ARO Reporting

https://goo.gl/eg9hRv

References

- Corrections and Removals

- Defects/Failures to Comply

- Enforcement Actions (Warning Letters)
  http://www.fda.gov/ICECI/EnforcementActions/WarningLetters/

- Letters to Industry
  http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/ucm111104.htm

- Submitting Trade Complaints
  http://www.fda.gov/ForConsumers/ConsumerUpdates/ucm095859.htm

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Questions?

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