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# Issues: Regulatory Obligations Post-marketing Adverse Event Reporting; MDRs and Safety Reports

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# Topics for today

- Post-approval requirements devices
  - Regulatory Submissions
  - Adverse Events
  - Other Post-Marketing Reports
  - Medical Device Reports
  - Safety Reports

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# Adverse Device Effects

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# User Reports

- Users (healthcare professionals, consumers, etc.) may also file reports (MedWatch)
- If sponsor is notified by FDA and sent a copy of the User Report, the sponsor does not file a separate report (to avoid duplication at the FDA), but does report on follow-up research and activities.

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# Adverse Device Effects

- **Medical Device Effects 21 CFR 803**
  - medical device has/may have caused/contributed to a death or serious injury
  - device has malfunctioned/failed and that malfunction/failure has or may have caused or contributed to a death or serious injury
  - other causes of MDE may be improper or inadequate design, problems in manufacturing, labeling or user error
  - source of reports may be manufacturer, distributor, importer, user, healthcare professional or other semi-professionals

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# Problems Unique to Medical Device Reporting

- Lack of standard nomenclature for devices
- These events represent numerators, usually with no clear denominator available
- Operator involvement and human factors issues inherent in virtually every event
- Complex multi-device situations are common, leading to complex evaluation

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# Device problems - continued

- Information in reports is often limited
- MDR may not be able to detect increases in rates of known events
- Specific disincentives to reporting, e.g., user error
- MDR not a good method for certain types of products, e.g., IVDs
- New technology and the learning curve; adequacy of training

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# Medical Device Reports

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MedWatch

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# FDA's MedWatch Program

- **Mandatory Reporting**
  - Manufacturers (bylaw) report deaths and serious injuries or malfunctions (near incidents) if a medical device may have caused or contributed to the event
  - All user facilities (hospitals, nursing homes, etc.) must report deaths to FDA and serious injuries to manufacturers
- **Voluntary reports encouraged from health professionals**



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# Medical Device Reports

- Complete a MedWatch form (Form 3500A)
- Timing of reports
  - User facility: within 10 days of becoming aware of the event
  - Importers : within 30 days
  - Manufacturers
    - within 30 days for an individual event
    - within 5 days if remedial action is needed to prevent unreasonable risk of substantial harm to the public

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# Contents of Form 3500A

[www.fda.gov/opacom/morechoices/fdaforms/fdaforms.html](http://www.fda.gov/opacom/morechoices/fdaforms/fdaforms.html)

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# Complaints

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21 CFR 820.198

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# Complaint Regulations

- NOTE: MDRs are a subset of complaints
- Need SOPs: receiving, reviewing, evaluating complaints...by a formally designated unit
- Complaints must be:
  - presented in a uniform and timely manner
  - documented upon receipt (oral or written)
  - evaluated to see if it meets criteria for an MDR (21CFR 803)

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# Complaint regulations - cont'd

- Complaints must be evaluated to see if an investigation is needed; if not, document reason
- Review, evaluate, investigate involving the failure of a device, labeling or packaging to meet any of its specifications
- If it is reportable as an MDR, the report must be maintained separately, or clearly identified

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# Complaint Regulations - cont'd

- Definition: any expression (written, oral or implied) of dissatisfaction regarding a failure of a product to meet performance specifications or customer expectations
- Complaints must be reviewed, investigated and documented

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# Remember...

- For all AE reports, the time begins when any team member\* becomes aware of the information
- \* regulatory, clinical, sales, marketing, etc.

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# Medical Product Safety Information

## ■ FDA Database

- Safety Alerts for Drugs, Biologics, Devices and Dietary Supplements

[www.fda.gov/medwatch/safety.htm](http://www.fda.gov/medwatch/safety.htm)

## ■ Searchable FDA Safety Databases

- Vaccine Adverse Event Reporting System (VAERS)
- Special Nutritional AE Monitoring System
- Manufacturer and User Facility Device Experience Database (MAUDE)