# Complaints and Adverse Event Reporting for Medical Devices

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# Outline

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- ISO 13485 Variants
- Complaint Definition
- ISO 13485:2016 Complaint Management
- US Complaint Management
- EU Complaint Management
- Adverse Event Definition
- US Adverse Event Reporting
- EU Adverse Event Reporting
- US vs. EU Comparison
- Questions

# Overview

# Overview

- Focus on the US and EU for simplicity
- Medical device manufacturers ensure their devices are safe and effective
  - For most devices, another organization checks the documentation
- Medical device manufacturers collect safety information from device use
  - In some cases, the manufacturer reports the information to the regulator

# Overview


Complaint Received
Adverse Event?
Report to US
Report to EU
Correction
Corrective Action
Update Risk Management

# Regulatory Regions

# Regulatory Regions

**US**

**Complaint: QMSR, the US modification of ISO 13485:2016**

**EU**

**Complaint: EN ISO 13485:2016/A11:2021, the EU modification of ISO 13485:2016**

# Regulatory Regions

**US**

**Adverse Event:**
**21 CFR Part 803**
**Medical Device**
**Reporting**

**EU**

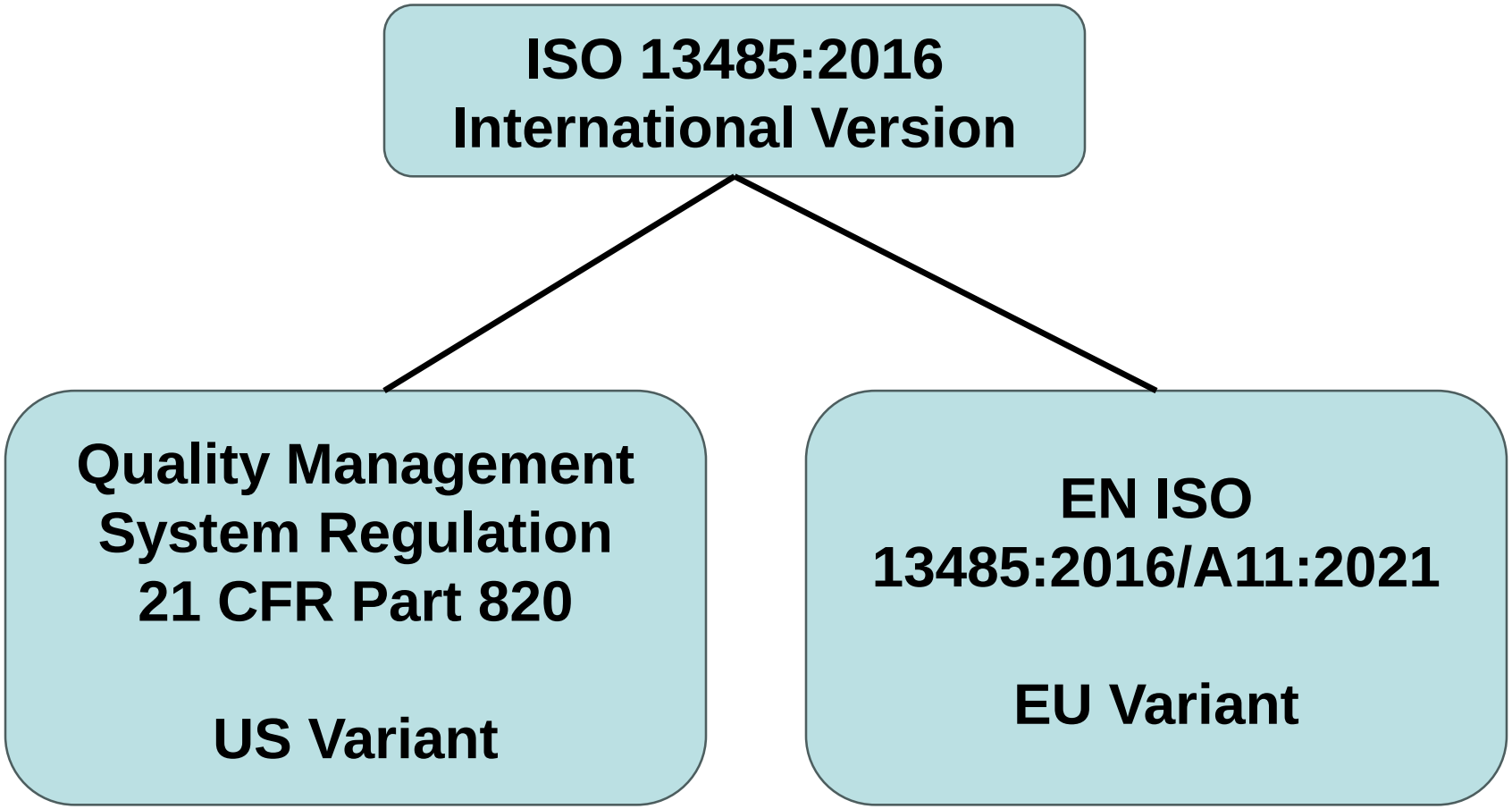
**Adverse Event:**
**EU-MDR Article 87**
**Reporting Of Serious**
**Incidents And Field**
**Safety Corrective**
**Actions**

# ISO 13485 Variants

# ISO 13485:2016

- The quality management standard for medical devices
- Originally derived from an earlier version of ISO 9001
- It is a stand-alone standard with its own update path
  - It does not use the current ISO 9001 structure
- It is the standard across the globe except:
  - US
  - EU

# ISO 13485:2016 Variants



# Complaint Definition

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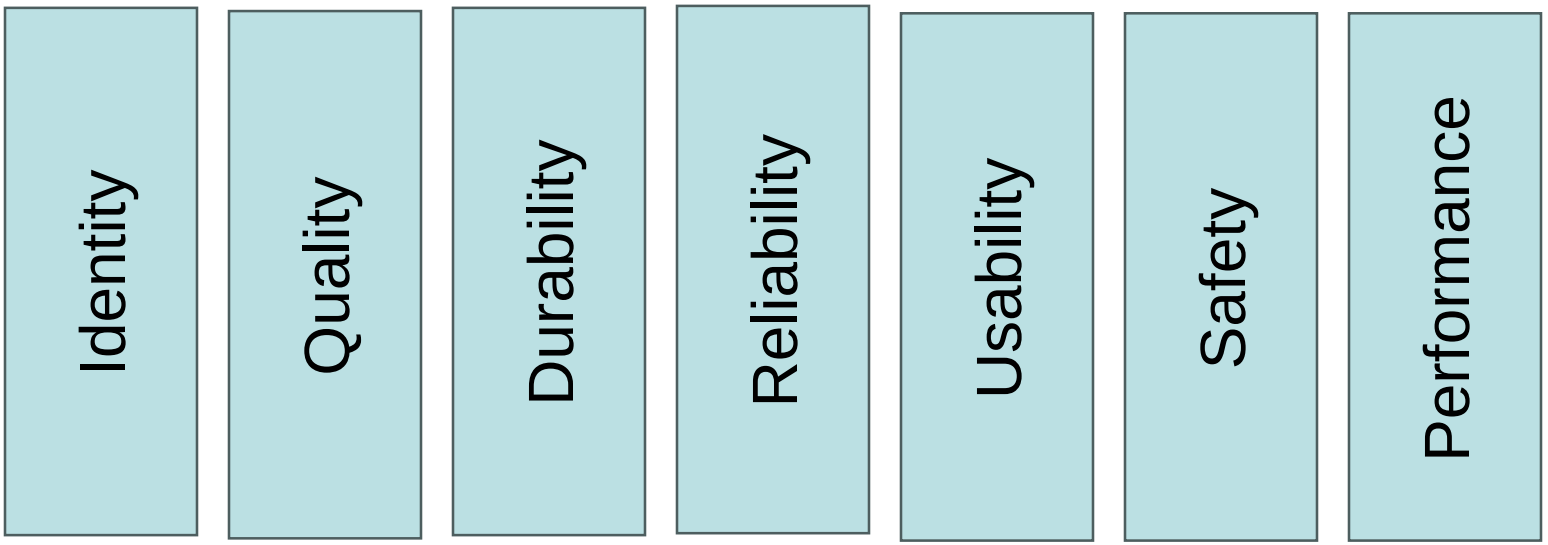
Any written, electronic, or oral communication that alleges deficiencies related to




of a medical device that has been released from the organization's control

# Communication

| | |
|---|---|
| **Written** | A letter to the manufacturer<br>A lawsuit claiming patient harm |
| **Electronic** | An e-mail to the manufacturer<br>A user describes a problem on Facebook |
| **Oral** | A nurse tells the service engineer<br>A doctor tells the sales representative |

# Alleged Deficiency

| | |
|---|---|
| **Deficiency** | The communication claims a problem with the device |
| **Is** | Identity, quality, durability, reliability, usability, safety, or performance |
| **Is Not** | Late delivery<br>Poor customer service |

# Production Process

| | |
|---|---|
| **Is** | If the problem occurs after delivery, it is a complaint |
| **Is Not** | If the problem occurs before delivery, it is **not** a complaint |

The standard has a clause for non-conforming product before delivery and a clause for after delivery

# Example

- A customer complained that the device arrived two weeks after the promised delivery date.
- This is **not** a complaint, because it doesn't allege a deficiency in one of the –ilities.
- However, there is an unhappy customer – some companies distinguish between a regulatory complaint and a customer satisfaction complaint.
  - A complaint could be both.

# Example

- A doctor’s office orders a box of 50 each of size 12 French needles. The box label says 12 French, but the needles inside were 15 French.
- This is a complaint because it alleges a deficiency in identity. The box was incorrectly labeled.
- This is also an unhappy customer.

# Example

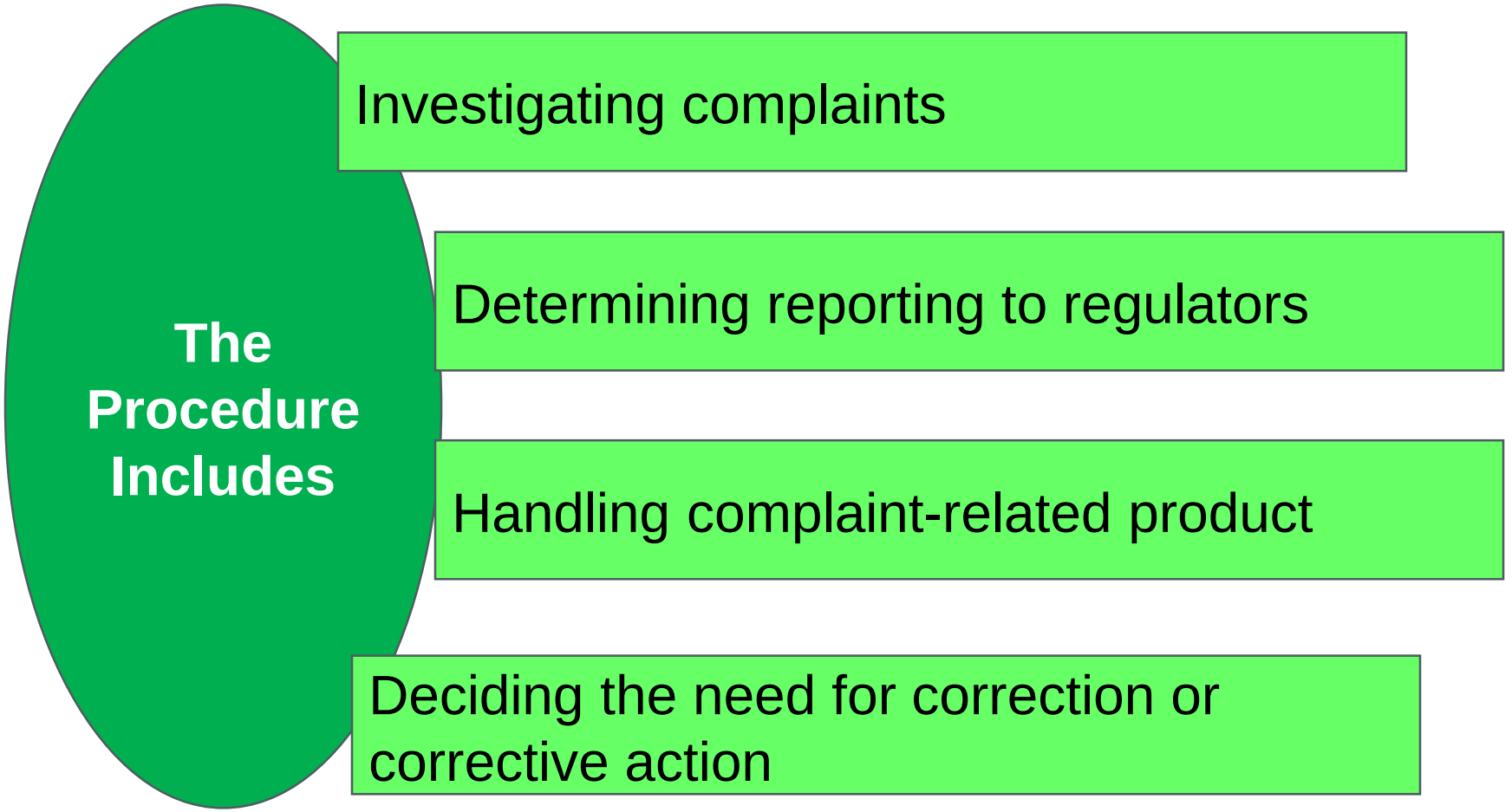
- A customer purchased a home use blood pressure machine and used it for about a week. One day she accidently knocked it off the table and it didn’t work.

- This is a complaint because it alleges a deficiency in durability. The manufacturer should expect it to be dropped, especially a home-use device and design it for durability.

- This is also an unhappy customer.

# ISO 13485:2016
# Complaint Management

# Required Procedure



# US Complaint Management

# QMSR

- On February 2, 2026, FDA's Quality Management System Regulation, QMSR, went into effect.
- The QMSR concept uses ISO 13485:2016 with modifications to meet US statutory requirements.
- Complaint management is one of the areas modified.

# QMSR Modifications

If there is a failure of a device, labeling, or packaging to meets specs, then maintain records of the review, evaluation, and investigation

If there was an investigation of a similar complaint, then another investigation is not necessary – document the justification

Keep records of complaints reportable as an adverse event and any complaint investigated – QMSR prescribes the minimum content of the records

# EU Complaint Management

# EU System

- The concept is to use ISO 13485:2016 with some modifications to meet EU regulations (MDR & IVDR).

- Complaint management is **not** one of the areas modified.

# Adverse Event

# Adverse Event

- There are international definitions of adverse events.
- World health Organization (WHO) – A problem that can or does result in permanent impairment, injury, or death to the patient or the user.

# Example

- A manufacturer releases a batch of out-of-specification blood glucose test strips. A patient uses the strips according to the instructions, but they create incorrect readings leading to incorrect insulin dosage, resulting in hypoglycemic shock and hospitalization.

- This problem resulted in injury to a patient.

# Examples

- An infusion pump stopped, due to a malfunction, but failed to give an alarm. The patient received under-infusion of needed fluids and required extra days in the hospital.

- This problem resulted in injury to a patient.

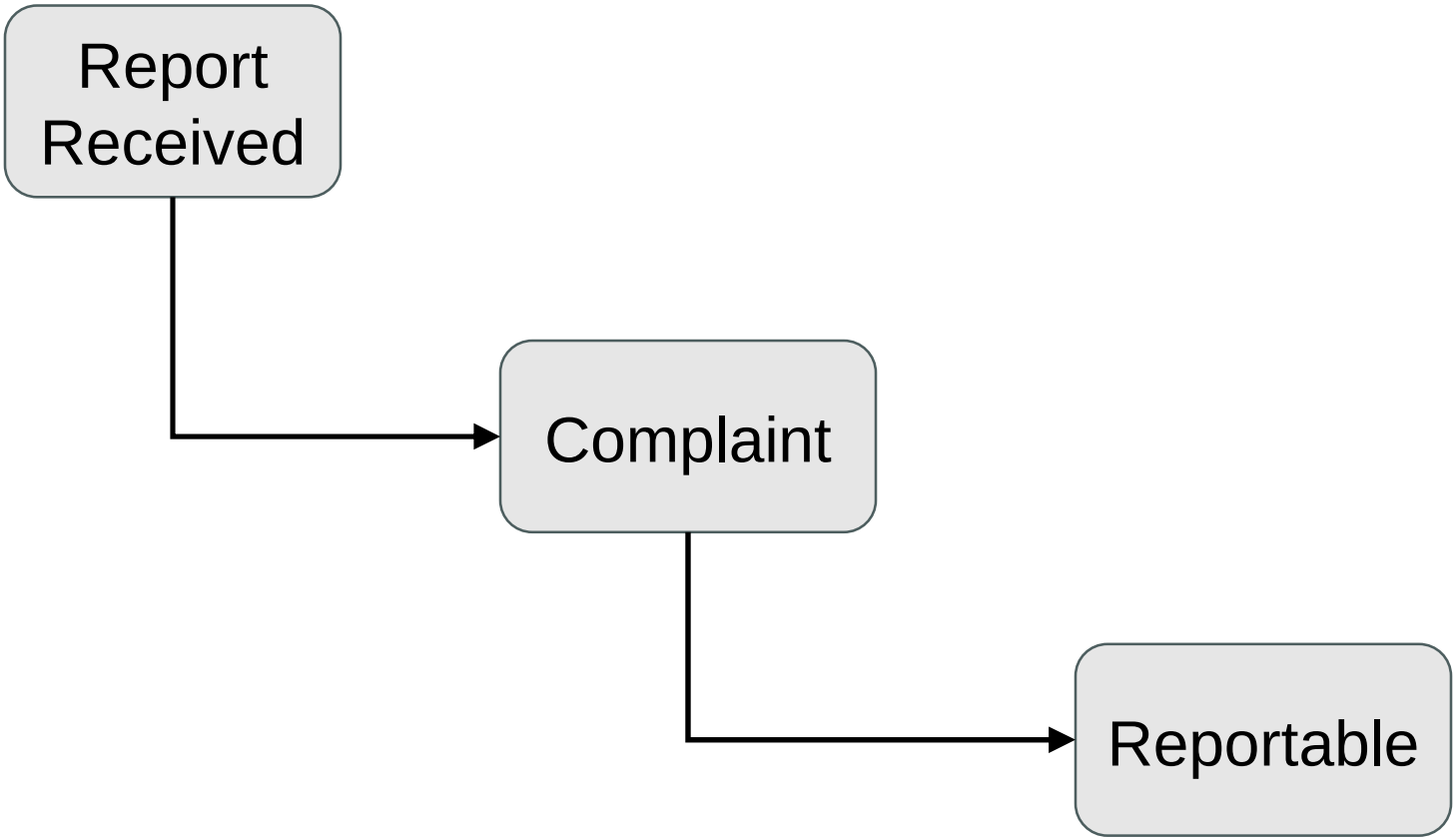
# Examples

- A monitor suspension system fell from the ceiling when the bolts holding the swivel joint broke. The system was installed, maintained, and used according to the manufacturer's instructions. Nobody in the surgical theater was injured.

- This problem could result in permanent impairment, injury, or death to a patient or user.

# US Adverse Event Reporting

# US Flow



# Reporting

- The US regulation is in 21 CFR Part 803 Medical Device Reporting

- A manufacturer reports information that reasonably suggests the device:
  - May have caused or contributed to a death or serious injury
  - Has malfunctioned and this device or a similar device that you market would be likely to cause or contribute to a death or serious injury, if the malfunction were to recur

# Reporting Timelines

- File an initial report within 30 calendar days after receiving the information

- File an initial report within 5 work days if the event necessitates remedial action to prevent an unreasonable risk of substantial harm to the public health
- File an initial report within 5 work days if FDA sent a letter requiring 5 day reports

- File a follow-up report within 30 calendar days of receiving additional information

# Reporting Format

- Report using FDA Form 3500A
- FDA provides free software, eSubmitter, to prepare the 3500A
  - The software produces a PDF
  - The software generates an HL7 Individual Case Safety Report, ICSR
- The manufacturer submits an encrypted version of the HL7 ICSR to FDA

# Records

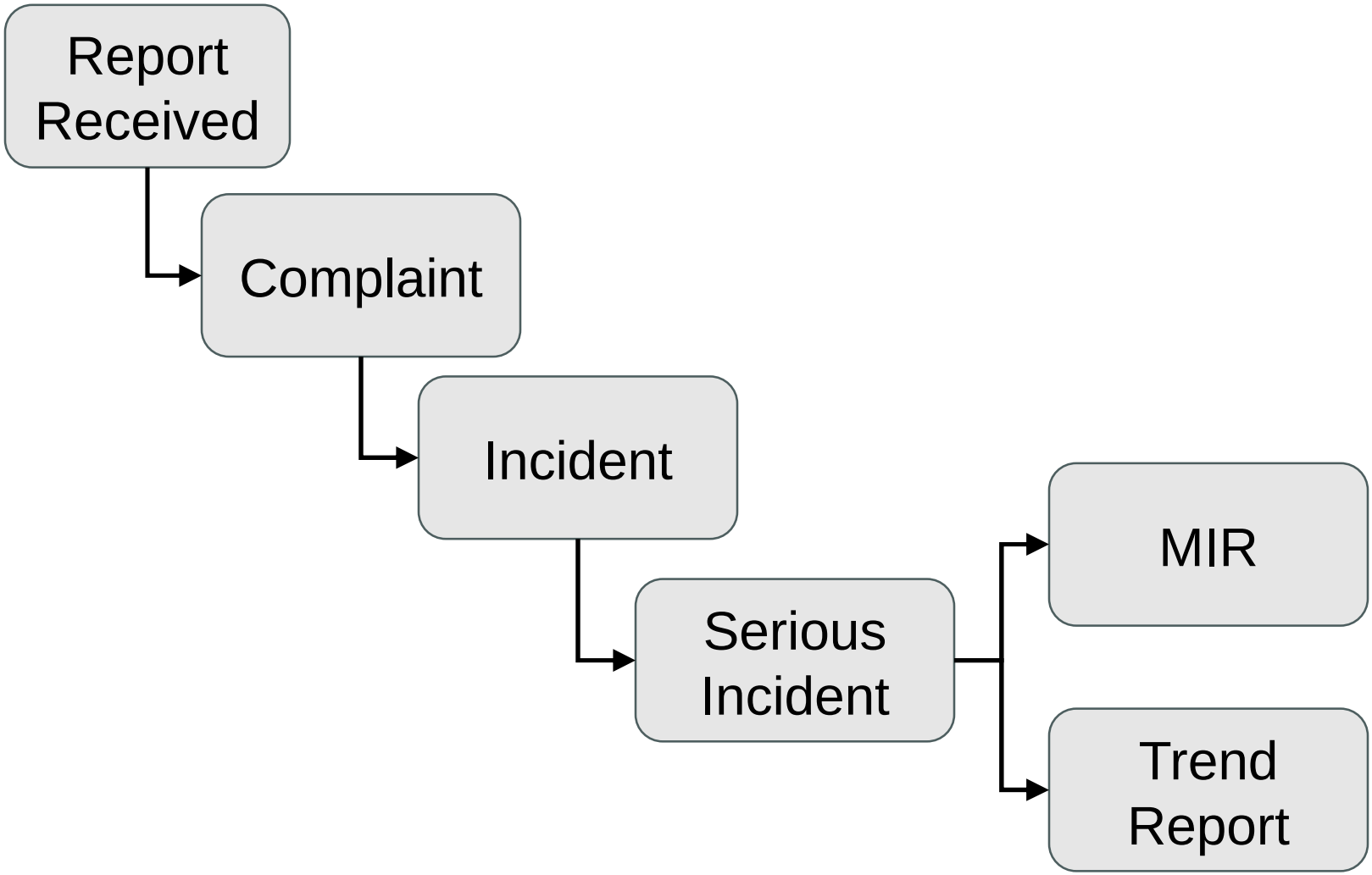
- Software at FDA checks each submission at three process steps and returns acknowledgements to the manufacturer.
- Each acknowledgement either says the step is successful or points out errors.
- The manufacturer keeps a copy of the MDR and the three successful acknowledgements.

# Public Information

- After a successful submission, the report becomes public.
- It is in the Manufacturers and Users Device Experience, MAUDE, database.
- Anybody can search the database and download the report.

# EU Adverse Event Reporting

# EU Flow


Report Received
Complaint
Incident
Serious Incident
MIR
Trend Report

# Reporting

- The requirement is in the EU-MDR Article 87(1)(a)

- A manufacturer reports any incident that led or might lead to:
  - the death of a patient, user, or other person,
  - serious deterioration of a patient's or user's state of health,
  - a serious public health threat

- Other incidents are trended, but not reported unless they reach defined thresholds

# Reporting Timelines

- For a serious public health threat, file an initial report within 2 days.
- For a death or an unanticipated serious deterioration in a person's state of health, file an initial report within 10 days.
- For other incidents, file an initial report within 15 days.

# Reporting Format

- Report using the Manufacturer's Incident Report, MIR, template.
  - The template is a PDF form.
- Complete the template and run the built-in error check.
- The template can generate a PDF file and an XML file which the manufacturer submits to the Competent Authority by e-mail.

# EUDAMED

- The EU is building a massive database to contain the information about medical devices.
- When complete, it will have six modules, only four of which (highlighted below) are live:
  - **Actor registration**
  - **Device registration and unique device identification**
  - **Notified bodies and certificates**
  - Clinical investigations and performance studies
  - Vigilance and post-market surveillance
  - **Market surveillance**

# Public Information

- The Competent Authority, CA, receives the MIR and loads it to the Vigilance and post-market surveillance module.

- Not all the MIR information is public. The EUDAMED module will have two access levels: public and regulator only.

# US vs. EU Comparison

# Event Types

| US | EU |
| --- | --- |
| • Caused or contributed to a death or serious injury<br>• Malfunctioned and a recurrence could cause a death or serious injury | • Death of a patient, user, or other person<br>• Serious deterioration of a patient's or user's health<br>• Serious public health threat |

# Event Timelines

| US | EU |
| --- | --- |
| • 30 days in general<br>• 5 days for remedial action of a public health threat | • 15 days in general<br>• 10 days for death or serious deterioration of health<br>• 2 days for a serious public health threat |

# Reporting Format

| US | EU |
| --- | --- |
| • Use eSubmitter to create a 3500A<br>• Convert it to an HL7 ICSR<br>• Send the encrypted file directly to FDA | • Use the MIR template<br>• Convert it to a PDF file or XML file<br>• E-mail to the CA<br>• Note: The process before EUDAMED |

# Public Access

| US | EU |
| --- | --- |
| • The report is publicly available through the MAUDE database | • Two tier system through EUDAMED<br>– One tier for the public<br>– One tier for the regulators |

# Summary

# Complaints

- The process starts with a complaint
  - The definition is now the same for both the US and the EU
  - The manufacturer needs to distinguish between regulatory complaints and customer satisfaction complaints

- Complaints need analysis to determine if they are reportable as adverse events

# Adverse Events

- While there is a WHO definition neither regulatory region uses it.

- The differences between the US and the EU include:
  - Different definitions
  - Different reporting forms with different information
  - Different submission methods
  - Different levels of public access

# QUESTIONS