Background and Discussion

Case Study Background: *Handout*

Scenario

- Your company has a product on the market that has been approved for the general population (ages 13-85).
- The "Product" is an integrated auto-injected type delivery system. At the subsystem level, the delivery system is comprised of a drug product solution contained in a glass syringe, an injector, and a needle.
- This is a life-saving product that treats an acute/emergency health risk.
- The therapeutic is first in class hence there is no other product approved for this medical condition.

Case Study Background: *Handout*

Scenario (cont'd)

- The system is provided as a reusable medical device (cleared 510K and CE marked) or disposable (single use) combination product (approved by CDER). The disposable system was previously approved in Japan in January 2016.

- Distribution in the US began in mid- February 2016. To date, 2000 single use (Lot A) and 25,000 reusable units (Lot B) have been distributed.

- The company, founded in 1875, is multinational with its headquarters in the US and has affiliates of various sizes throughout Europe as well as a large affiliate in Japan. The company has 75,000 employees worldwide and is the fifth largest (by sales) healthcare company in the world.

Case Study Background: *Handout*

Problem

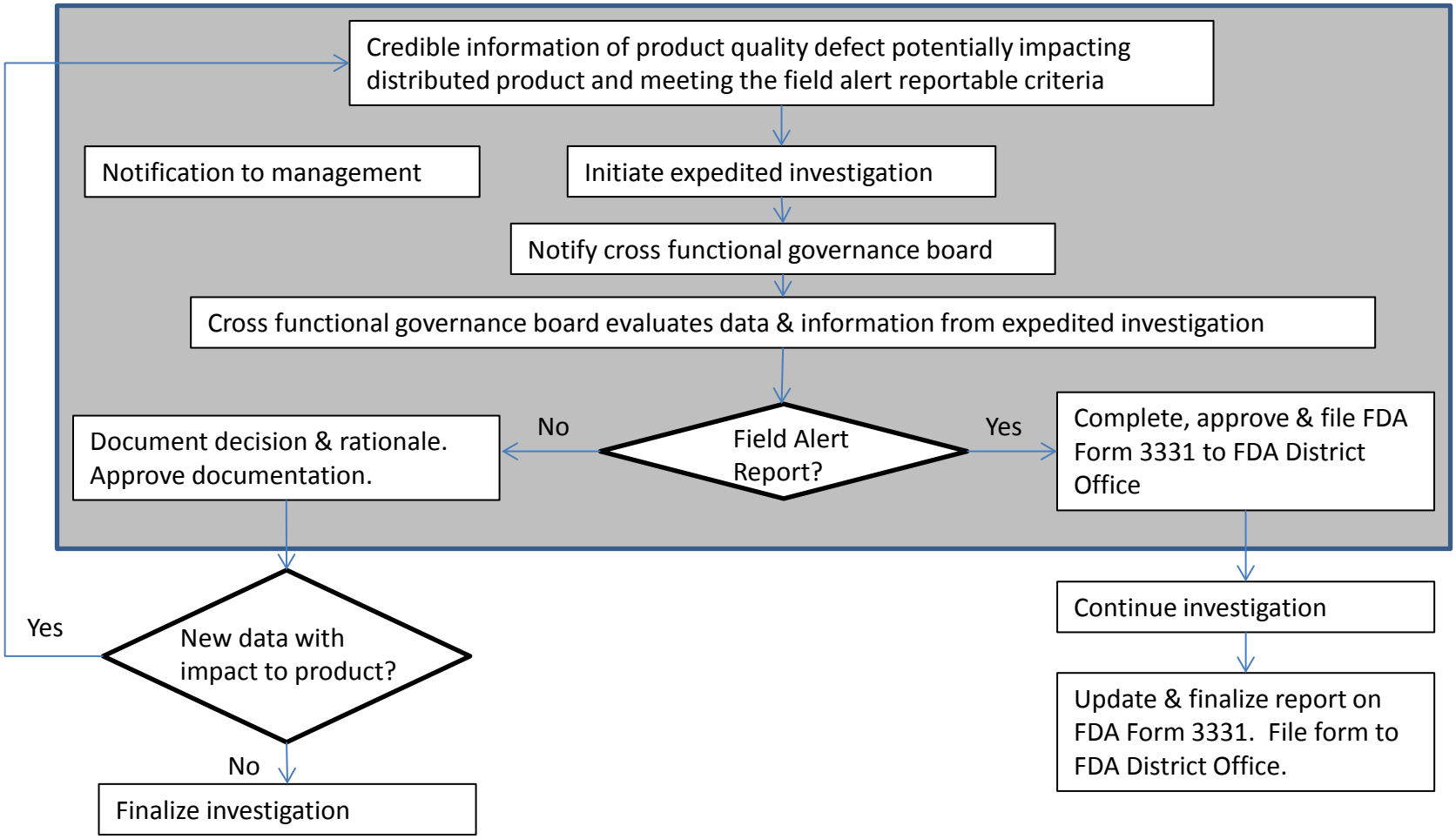
On March 30, 2016, the spouse of a 75 year old male (non-health care professional) called to report that upon use of your product the day prior, her husband had major complications. Caller believes that he did everything correctly, but the product did not work and her husband began convulsing (serious spontaneous adverse event) and was hospitalized. The caller stated that the device may have "felt funny" during administration, but she really couldn't remember and was unwilling to troubleshoot. A request for the complaint sample to be returned has been rejected by the patient's family.

Case Study Discussion #1: *Handout*

At Your Table

With no other information: compare and contrast your company's processes (e.g. product complaint, adverse event or pharmacovigilance surveillance/ medical assessment) for handling a situation like this.

Management Notification Example



The process steps in the shaded area must take place within three (3) working days.

Adverse Event System

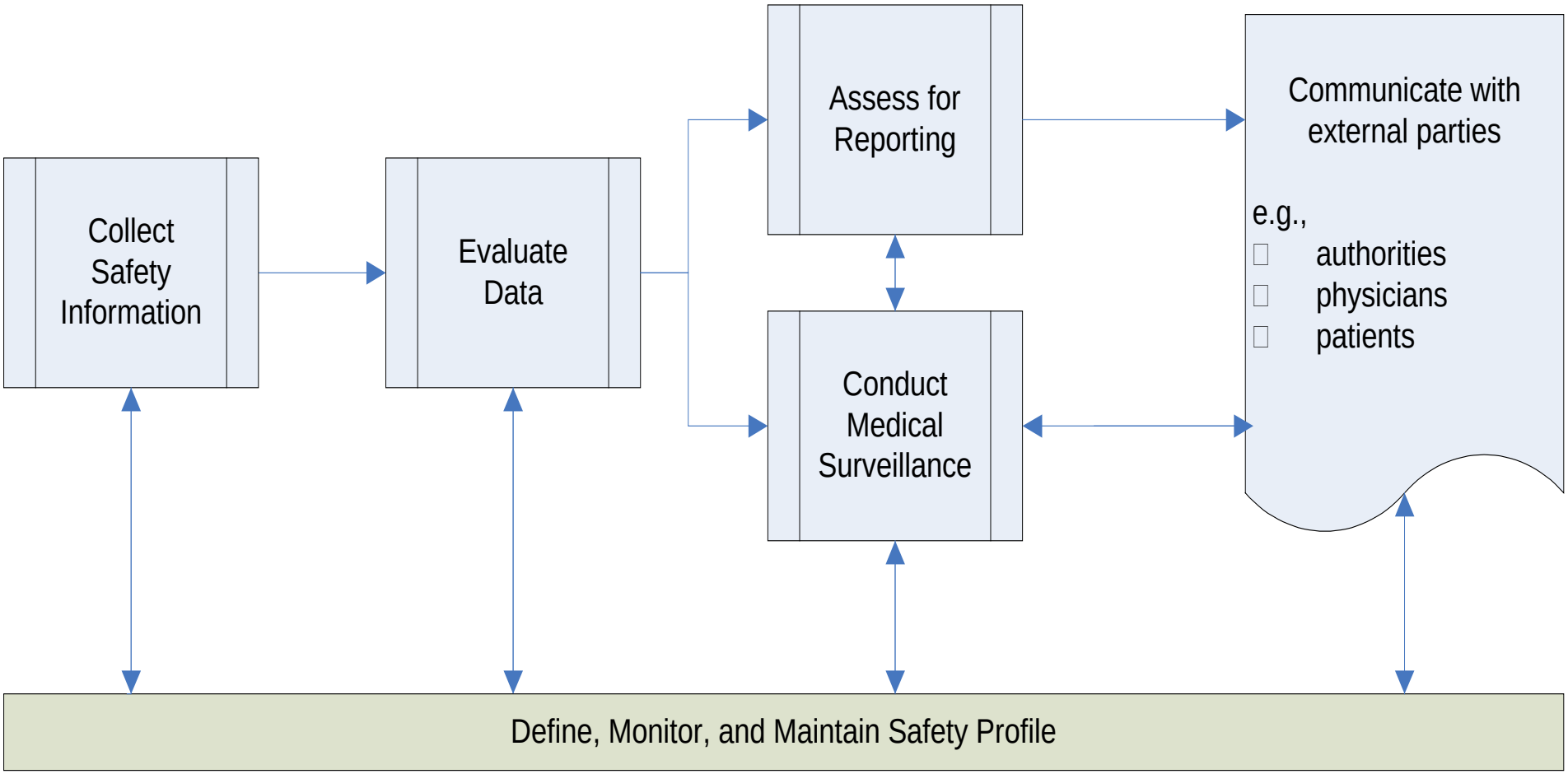
The following guidance may be used regarding requirements for expedited submission of individual device safety reports for cleared/approved devices, CE-Marked device, and investigational devices, if they meet certain criteria.

Decisions on whether or not to submit individual device safety reports are based on the requirement of local law.

In general, the thresholds for reporting are:

- Serious injury or death with alleged malfunction,
- Serious injury or death involving use error, and/or
- Company identified reportable malfunction with or without actual injury.

Adverse Event Program Example



AE/PC Integrated Assessment Example