Stryker Medical Device Recall process

PEAC

Ommeed Shahrokh, Director Regulatory Compliance and QMS Integration

stryker

Mission

Together with our customers, we are driven to make healthcare better.

Values

Integrity
We do what's right

Accountability
We do what we say

People
We grow talent

Performance
We deliver

Agenda

- Product Field Actions (Recalls)
- Post Market Surveillance
- PFA Assessment
- PFA Execution
- Effectivity Monitoring

Reports of Corrections and Removals (806)

- Recall is method of removing or correcting consumer products that are in violation of laws administered by the Food and Drug Administration.
  - Correction means repair, modification, adjustment, relabeling, destruction, or inspection (including patient monitoring) of a product without its physical removal to some other location.

- Recall is a *voluntary action* that takes place when manufacturers (and/or distributors) actively protect the public health from products that present a risk of injury or are otherwise defective.

Production and Post Market Monitoring

1. Nonconformance (NC)
2. Complaints
3. Adverse Event Reporting
4. Product Field Action
5. Service
6. Product change control
7. New threat sources, threat events, vulnerabilities
8. Review of usage trends for the medical device (e.g., sales data)
9. Review of new or revised standards and regulations
10. Review of publicly available information about similar medical devices on the market (e.g., MAUDE database)
11. Review of technological trends relevant to the medical device.

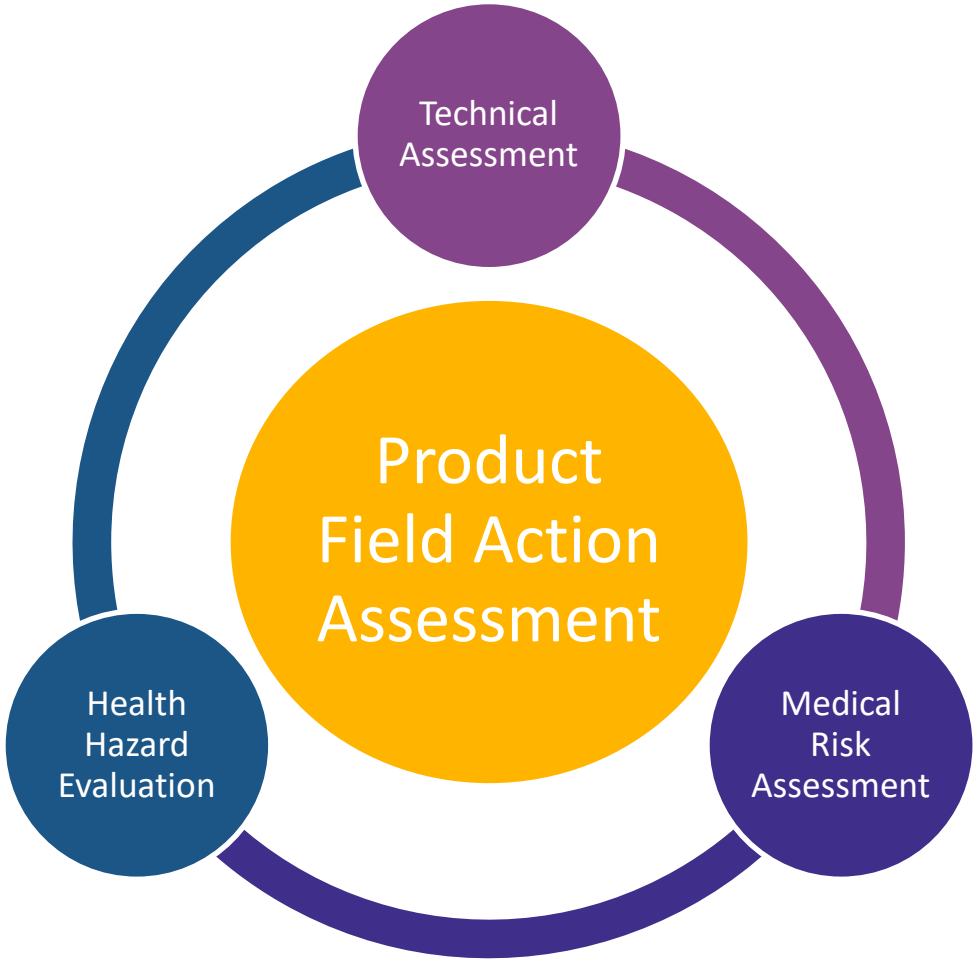
Non-conforming faucet

Product Field Action assessment

A Product Field Action assessment is performed to determine whether to initiate a recall on product. It is a vital aspect of post market surveillance activities.

Stryker utilizes three main inputs within this process: the **technical assessment**, the **medical risk assessment** and a **health hazard evaluation.**

These three main inputs are then used to determine whether a recall will be initiated.



Technical and Medical Assessment

Hazard/Harm Identification

Technical Assessment: identifies potential Hazards associated with a non-conforming device:

- **Hazard**: Potential source of harm
- **Hazardous situation:** last observable set of conditions prior to **Harm.** Circumstance in which people, property, or the environment are exposed to one or more hazard(s). Hazardous situations usually include the elements of exposure necessary for **Harm** to be possible.

e.g., potential hazard that can occur due to the non-conforming faucet is a leak, which can lead to the hazardous situation (hazardous situation) of standing water on the floor.

Hazard

Technical and Medical Assessment

Hazard/Harm Identification

Medical Assessment (performed by Health Care Provider skilled in the field): identifies potential patient harms based upon hazards and the use of the non-conforming device

- **Harm:** Physical injury or damage to health of people, or damage to property or the environment.

e.g., hazard of slipping on a wet floor can result in the potential harm of fractured bone.

Non-conforming faucet

Hazard

Harm

How are Recalls used?

To reduce the risk to health posed by the device OR remedy the violation of the act caused by the device which may present a risk to health.

Removal -

- The physical removal of a device from its point of use to some other location for repair, modification, adjustment, relabeling, destruction, or inspection.

Correction –

- The Repair, modification, adjustment, relabeling, destruction or inspection of a device without physically removing it from its point of use to some other location.

e.g., A recall is issued notifying customers of the issue and actions to be taken. Any unused faucets are required to be returned to the manufacturer and faucets in the field will be corrected by installing the missing washer.

Recall Execution and Effectivity

Medical Device recalls are communicated via a Product Field Action Letter.

- Product Field Action Letter includes product description, affected catalog/lot numbers, description of issue, potential hazards and harms, risk mitigation, and actions required to be taken.
- Effectiveness checks are performed to verify that consignees have responded (Accountability/Acknowledgment form) to the Product Field Action notification.
- Follow up customer communications (i.e., letters, email, phone calls) are performed as part of the recall effectiveness check.

Questions