Post-Marketing Alert System
(ANNEX 5 ASEAN Medical Device Directive)

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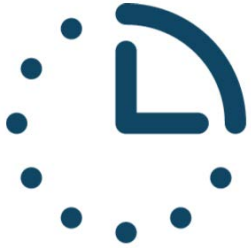
SEE BRILLIANTLY

Reminders

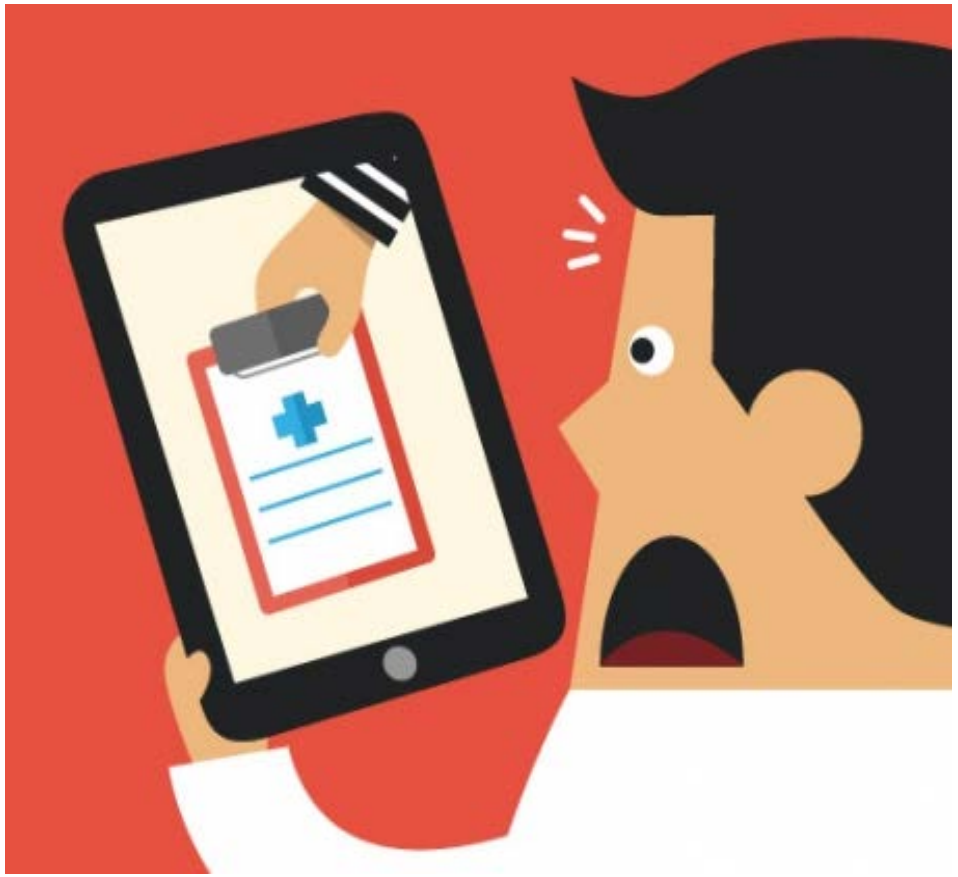


This technical training will last for **45 minutes**.

Turn off your video and microphone

If you have any questions during the session, please use the **chat panel.**
Any opinion or recommendations by the resource speaker does not in any way represent the views or policies of the company he is associated with.

AGENDA



- Introduction
- Definitions
- PMAS Process Flow
  - Documentation Management
  - Complaints / Distribution Records
  - Adverse Events
  - Field Safety Corrective Actions
- *Key Take Away*

Introduction

Design & Development

Clinical Trials and Validation

Product Lifecycle Management

Manufacture

Testing

Distribution

Post-Marketing Surveillance

R.A. No. 3720 (as amended by RA No. 9711):

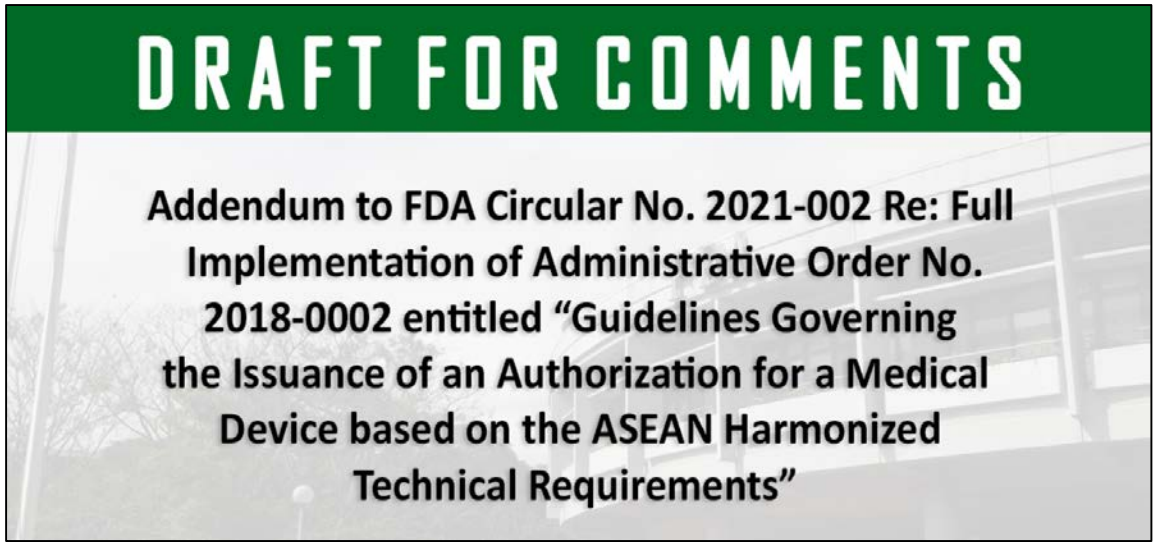
- ***Ensure safety, efficacy and quality of health products (including medical devices)***
- ***Enacted to protect and promote the right to health of the Filipino people***

Introduction

FDA Food and Drug Administration PHILIPPINES

Home About FDA Transparency Issuances

Draft for Comments of Adoption of the Post Marketing Alert System (PMAS) Requirements, Annex 5 of the ASEAN Medical Device Directive (AMDD)



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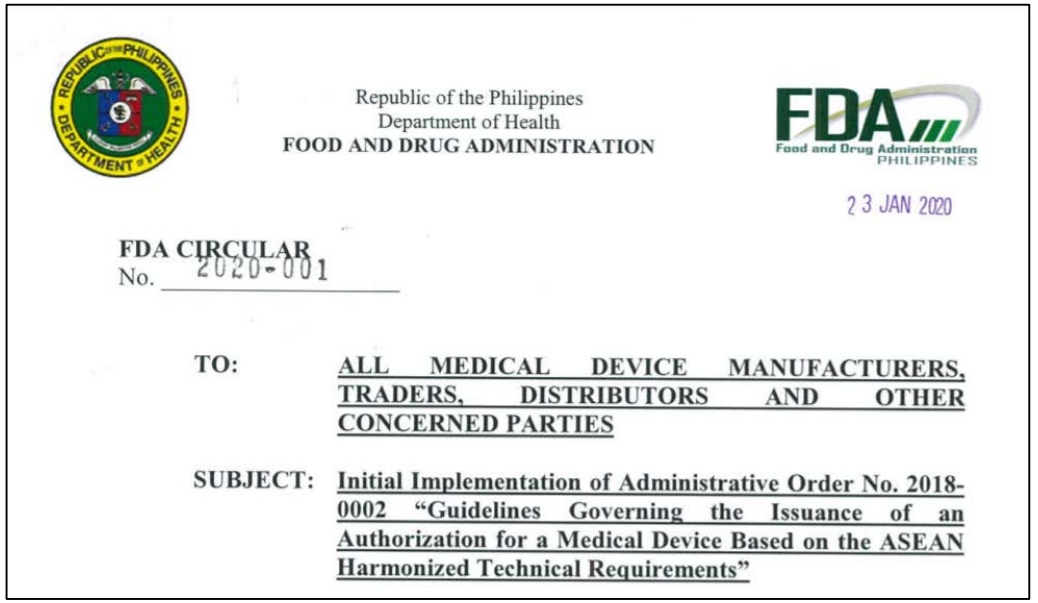


Republic of the Philippines
Department of Health
FOOD AND DRUG ADMINISTRATION

FDA Food and Drug Administration PHILIPPINES

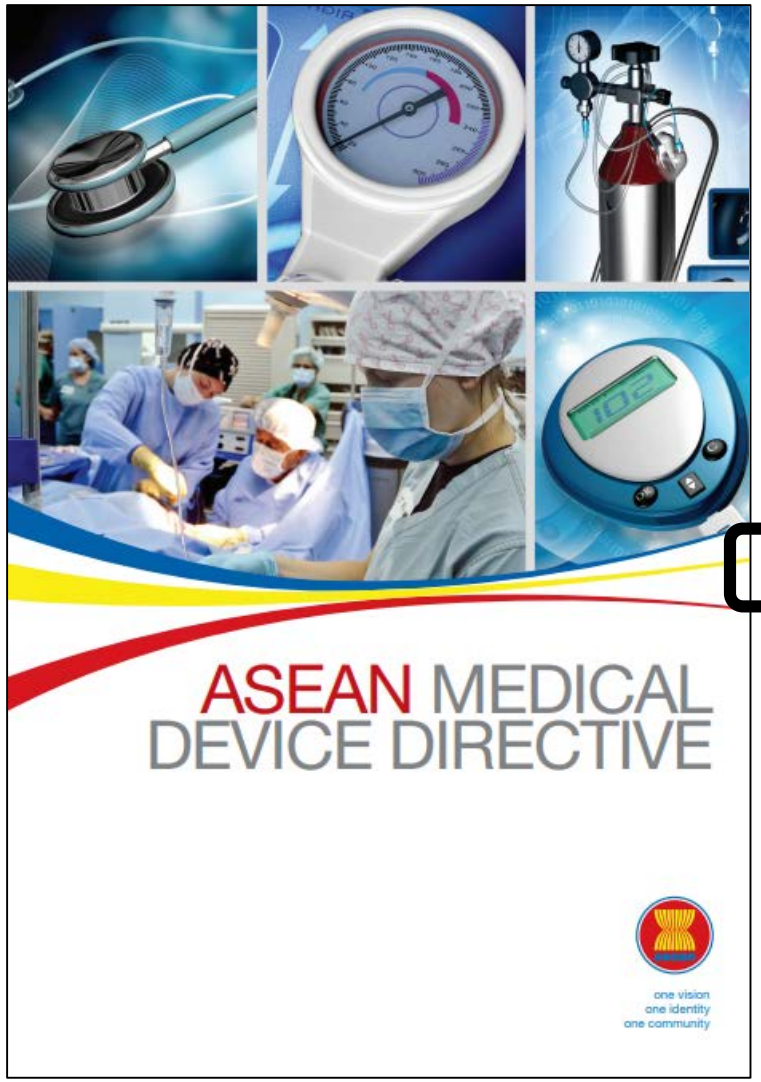
23 JAN 2020

FDA CIRCULAR
No. 2020-001

TO: ALL MEDICAL DEVICE MANUFACTURERS, TRADERS, DISTRIBUTORS AND OTHER CONCERNED PARTIES

SUBJECT: Initial Implementation of Administrative Order No. 2018-0002 "Guidelines Governing the Issuance of an Authorization for a Medical Device Based on the ASEAN Harmonized Technical Requirements"

The ASEAN Medical Device Directive (AMDD)



- Article 1: General Provisions
- Article 2: Definitions and Scope
- Article 3: Essential Principles of Safety & Performance
- Article 4: Classification of Medical Devices
- Article 5: Conformity of Assessment of Medical Device
- Article 6: Registration & Placement on the Market
- Article 7: Licensing of Person Responsible for Placing Medical Devices on the Market
- Article 8: Technical Documents for Medical Devices
- Article 9: References to Technical Standards
- Article 10: Labelling
- Article 11: Medical Device Claims
- **ARTICLE 12: Post-Marketing Alert System; Annex 5: PMAS Requirements**
- Article 13: Clinical Investigation
- Article 14: Institutional Arrangements
- Article 15: Safeguard Clauses
- Article 16: Confidentiality
- Article 17: Special Cases
- Article 18: Implementation
- Article 19: Revisions, Modifications and Amendments
- Article 20: Dispute Settlement
- Article 21: Reservations
- Article 22: Entry into Force
- Article 23: Annexes
- Article 24: Depository

24 Articles

8 Annexes

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DEFINITIONS

AMDD Post-Marketing Alert System (PMAS)

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INCIDENTS

Recording and Evaluation

1. Malfunction/deterioration in characteristics or performance
2. Inadequacy in labelling or instructions for use (IFU)

Technical / medical reason in relation to the characteristics or performance of the medical device

CUSTOMER COMPLAINT

Communication (Written, Electronic or Oral)

that *alleges* deficiencies related to the

1. Identity
2. **Quality**
3. Durability
4. **Reliability**
5. Safety
6. **Performance**

of a medical device *placed in the market*

ADVERSE EVENT

A malfunction OR a deterioration
in the characteristics or performance
OR a use error

which *could have caused* or has caused
1. Injury to health OR
2. Contributed to the death

of patients or other persons

Field Safety Corrective Action (FSCA)

Action taken by the *product owner*
to REDUCE a risk of death
OR serious deterioration in state of health
associated with the use of a medical device

1. **RETURNS**
2. **MODIFICATIONS (Retrofits, Labelling/IFU changes, Software upgrades, Px clinical mgmt)**
3. **EXCHANGES**
4. **DESTRUCTION**
5. **ADVICE given re: use of device**

Field Safety Notice (FSN)

A communication sent out by product owner or its representative to the medical device users in relation to a FSCA

PROCESS FLOW

AMDD Post-Marketing Alert System (PMAS)

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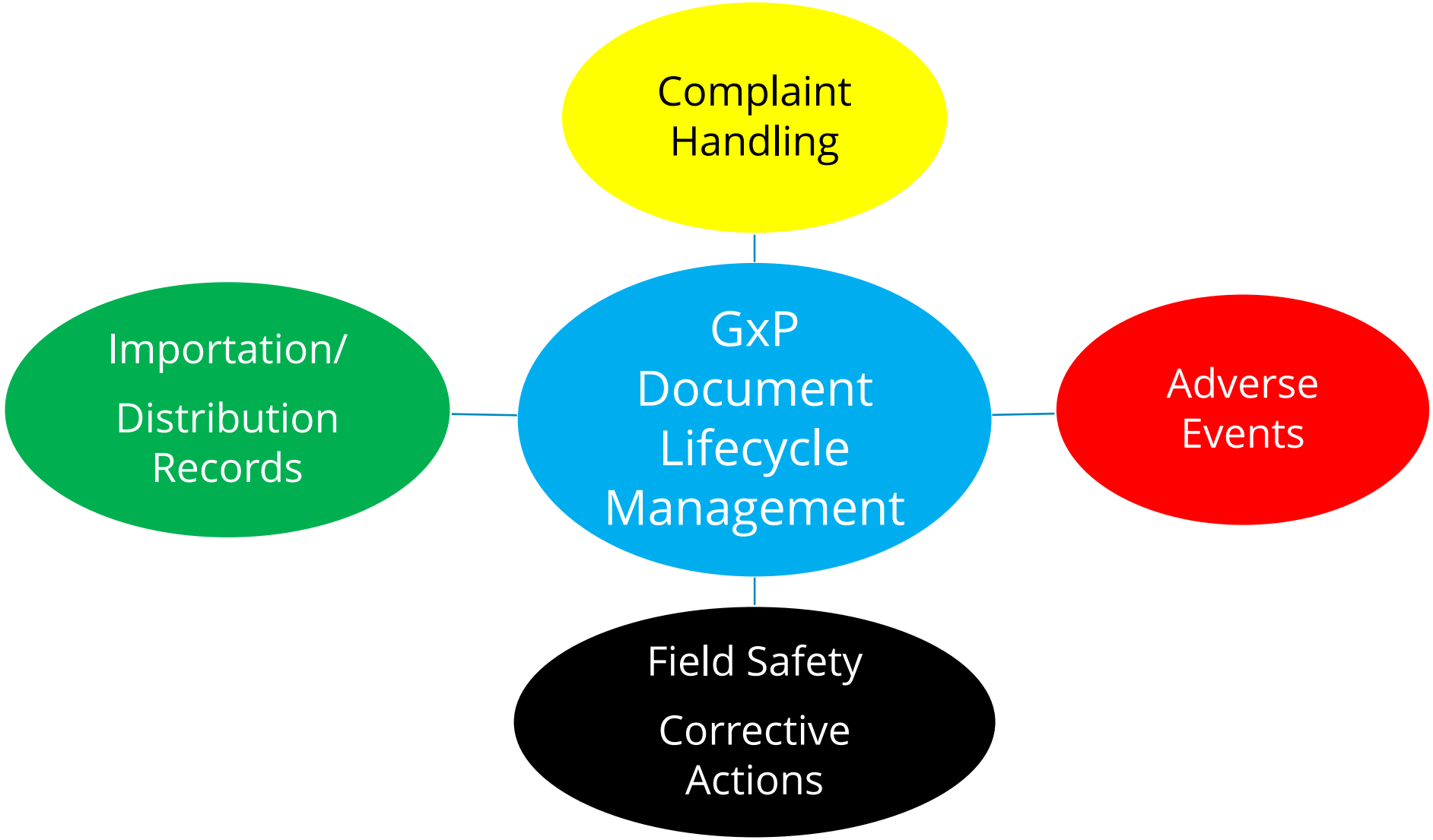
The Post-Marketing Alert System



Importation / Distribution Records

IMPORTANCE

Identify PRODUCT OWNER for each batch of medical device

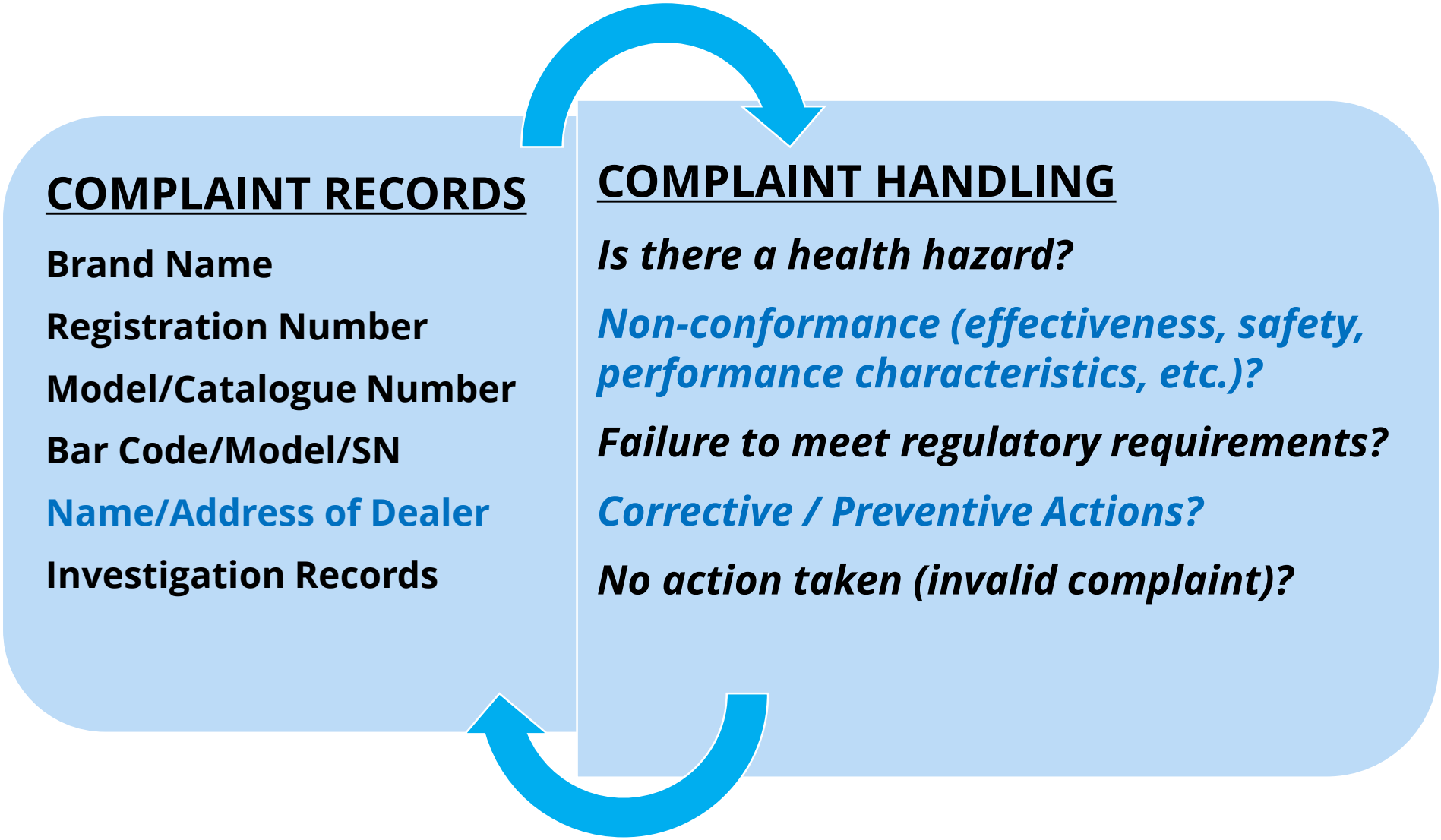
Identify where each batch of product is supplied

Expedite product batch recall

Importation / Distribution Records

- Name / Address of Initial Consignee
- Identity / quantity of imported / shipped products
- Date imported / shipped
- Control Numbers
  - Lot No.
  - Batch No.
  - Serial No.

Complaint Handling



Adverse Events (Reportability Criteria)

An Adverse Event has occurred

The Medical Device is associated with the AE

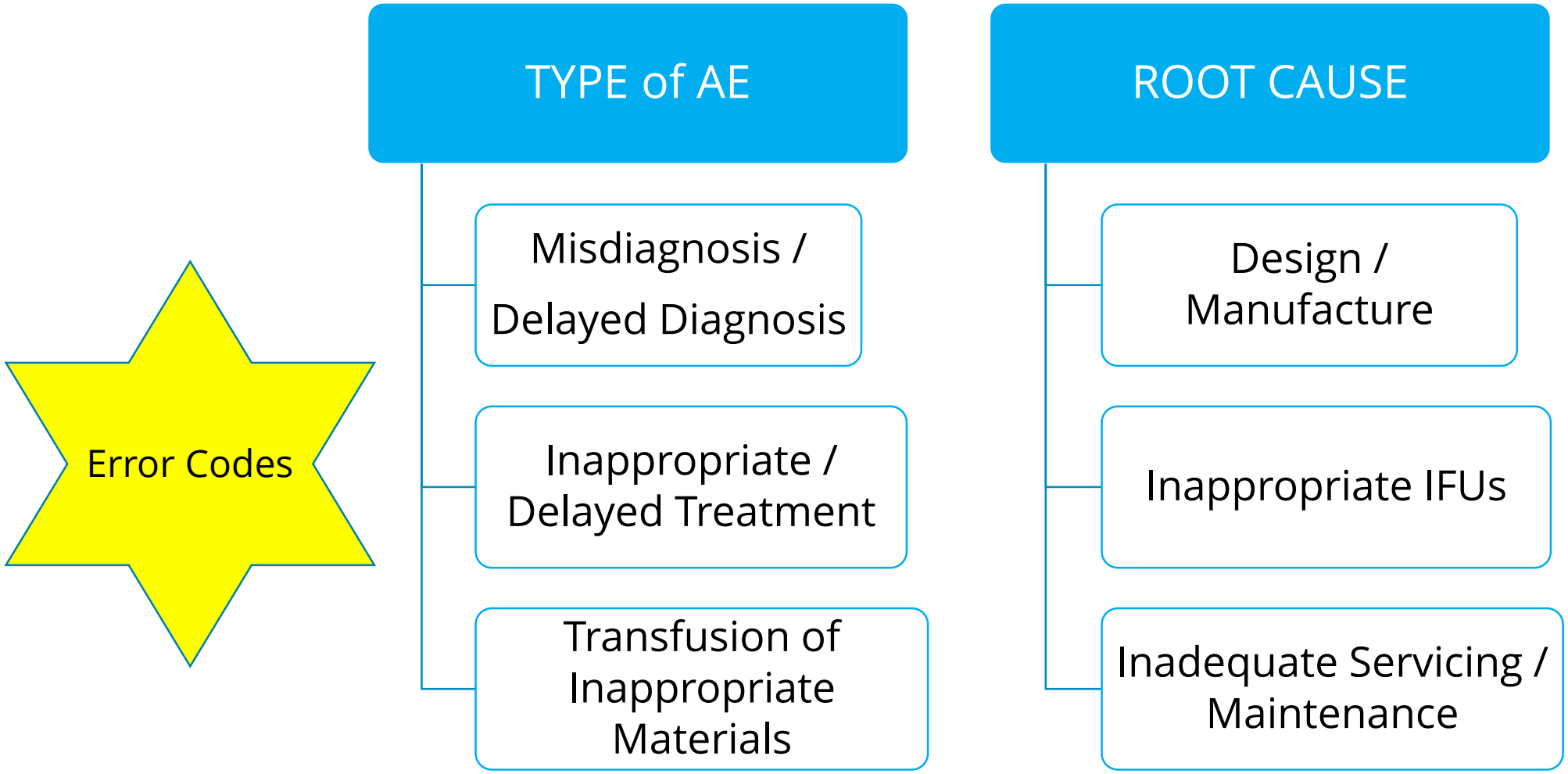
The AE led to any of the following outcomes:

1. DEATH
2. Serious threat to public health
3. Serious deterioration in the state of health
4. Event might lead to death or serious injury

Adverse Events

SERIOUS DETERIORATION in STATE of HEALTH

Adverse Events (IVD - Example)



Adverse Events (Reporting Timelines)

NLT 48 hours → **SERIOUS Threat to Public Health**

NLT 10 DAYS → **Patient/User DEATH OR Serious Deterioration in a state of health**

NLT 30 DAYS → **Recurrence of event MIGHT lead to Patient/User DEATH OR Serious Deterioration in a state of health**

Field Safety Corrective Actions (FSCA)

Determine need for FSCA

- Risk Assessment (ISO 13487)
- Additional Measures (HA-prescribed)

Notification Guidelines

- Notify HA of FSCA decision
- Time-frame / reports (HA-prescribed)

Closure of FSCA

- Provide details of proposed corrective actions
- Corrective actions completed (HA-approved)

Document Life Cycle Management (GxP)

Computerized System Validation

- Validated Database
- Automated Process
- Notifications/Alerts
- Electronic Records / Signatures

DATA Integrity

- ALCOA
- Audit Trail
- Metrics

Good Documentation Practices (GDP)

- Document Creation
- Archiving
- Document Retrieval

CONTRACTS / QUALITY AGREEMENTS

TRAINING MANAGEMENT

wipro

IQVIA

Lifecycle Safety-PSMF

Project Code: GZA99457

Marketing Authorization Holder: Alcon Laboratories Belgium B.V.B.A

EudraVigilance System Master File Number: MFL15399

EU QPPV Third Party Company Name: IQVIA Ltd.

KEY TAKE AWAYS

AMDD Post-Marketing Alert System (PMAS)

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WHY do we need PMAS?

Netflix
20.7M subscribers

SUBSCRIBE

What you don't know, can hurt you. From the Academy Award® nominated filmmakers Kirby Dick and Amy Ziering (The Invisible War, The Hunting Ground) comes a groundbreaking investigation into the crimes of Big Medical.

America has the most technologically advanced health care system in the world, yet medical interventions have become the third leading cause of death, and the overwhelming majority of high-risk implanted devices never require a single clinical trial.

Watch The Bleeding Edge on Netflix: https://www.netflix.com/in/title/8017...

SUBSCRIBE: http://bit.ly/29qBUt7

ASEAN PMAS: Partnership between regulators & MAH/Product Owners
to protect and promote Patient Safety


THANK YOU
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