The Role of Regulatory Authorities in Ensuring Medical Devices

Safety, Effectiveness, Quality and Performance.

Dr. Saleh Al Tayyar
Director General
Medical Devices Sector
Saudi Food & Drug Authority

الهيئة العامة للغذاء والدواء
Saudi Food & Drug Authority

This Presentation is of two parts:

- **Part 1**

  SFDA in brief

- **Part 2**

  The Role of Regulatory Authorities in Ensuring Medical Devices Safety, Effectiveness, Quality and Performance.

الهيئة العامة للغذاء والدواء
Saudi Food & Drug Authority

Part 1

الهيئة العامة للغذاء والدواء
Saudi Food & Drug Authority
SFDA

In brief

Introduction

- The Saudi Food & Drug Authority (SFDA) was established on 7/1/1424.
- It is an independent body with an independent budget.
- It reports directly to the premier of the council of ministers.

الهيئة العامة للغذاء والدواء
Saudi Food & Drug Authority

Introduction(cont)

It has a board of director consisting of 14 members headed by /

HRH Prince Sultan bin Abdulaziz,

Crown Prince, Second Deputy Premier, Minister of Defense, Aviation and the Inspector General

الهيئة العامة للغذاء والدواء
Saudi Food & Drug Authority

Vision

To be the leading regional regulatory authority for Food, Drug, and Medical Devices with professional and excellent services that contributes to the protection and advancement of the health in Saudi Arabia.

الهيئة العامة للغذاء والدواء
Saudi Food & Drug Authority

Mission

To ensure the safety of Food; the safety, quality and efficacy of Drug; and the safety and effectiveness of Medical Devices, by developing and enforcing an appropriate regulatory system.

Objectives

The SFDA has 8 main objectives

These objectives are summarized as follows:

الهيئة العامة للغذاء والدواء
Saudi Food & Drug Authority

Objectives (cont)

To insure the safety of electronic products on public health.

Objectives (cont)

Insure high standards of medical devices & in vitro diagnostic

Objectives (cont)

Establish well defined policies and procedures for
Food, Drug, and Medical Devices
And make the Necessary plans to achieve these policies objectives.

الهيئة العامة للغذاء والدواء
Saudi Food & Drug Authority

Objectives (cont)

Perform research and studies to highlight the health problems and their causes.

Objectives (cont)

Monitor the rules and regulations pertaining to Food, Drug, and Medical Devices.

Objectives (cont)

Establish a good communication and cooperation with various agencies both locally and internationally, and establish a data base for Food, Drug, and Medical Devices.

Tasks

Legislative Tasks.

- **Review all the current rules and regulation pertaining to Food, Drug, and Medical Devices and make the necessary improvement and updates.**

- **Approve the Food, Drug, and Medical Devices policies in Saudi Arabia.**

الهيئة العامة للغذاء والدواء
Saudi Food & Drug Authority

Tasks (cont)

Executive Tasks.

- **Testing, Analysis and Inspection of all food products, drug, cosmetics, medical devices & in vitro diagnostic, pesticides, and water, for both locally produced and imported.**

Tasks (cont)

Regulatory Tasks.

- Inspection services of all food related premises.
- Regulation of all drug and related products.
- Regulation of all electronics and medical devices.

الهيئة العامة للغذاء والدواء
Saudi Food & Drug Authority

Implementation Phases

The SFDA is going to assume its tasks at two phases:

Phase I

The duration of this phase will extend for 5 years.

During which the SFDA will assume legislative, regulatory, and auditing tasks over the existing regulations related to Food, Drug, & Medical Devices performed by various government agencies.

الهيئة العامة للغذاء والدواء
Saudi Food & Drug Authority

Implementation Phases (con)

Phase II

This phase will start at the end of the fifth year. The SFDA will fully assume all its tasks.

Part 2

The Role of Regulatory Authorities in Ensuring Medical Devices Safety, Effectiveness, Quality and Performance

الهيئة العامة للغذاء والدواء
Saudi Food & Drug Authority

Dr. Saleh Al Tayyar

Medical Device Definition

According to WHO/GHTF definition of medical Devices

A medical Device is:

Any instrument, apparatus, appliance, material or other, article, whether used alone or in combination, together with any accessories including the software necessary for its proper application and functioning, intended by the manufacturer to be used for human beings for the purpose of :- Diagnosis, prevention, monitoring, treatment or alleviation of disease- Diagnosis, monitoring, treatment or alleviation of compensation for any injury or handicap- Investigation, replacement or modification of the anatomy or of a physiological process- Control of conception. AS Active medical device- -Active implantable medical device -Custom-made device -Device intended for clinical investigation -Device for self-testing And which dose not achieve its principal intended action in or on the human body by:- -Pharmacological -Immunological -metabolic means. But which may be assisted in its function by such means.

In summary:

Medical Devices cover every thing from

tongue depressor

to

heart rate regulator

الهيئة العامة للغذاء والدواء
Saudi Food & Drug Authority

Terms and definitions

Safety	**Quality**
Effectiveness	**Performance**

الهيئة العامة للغذاء والدواء
Saudi Food & Drug Authority

Medical Devices Classification

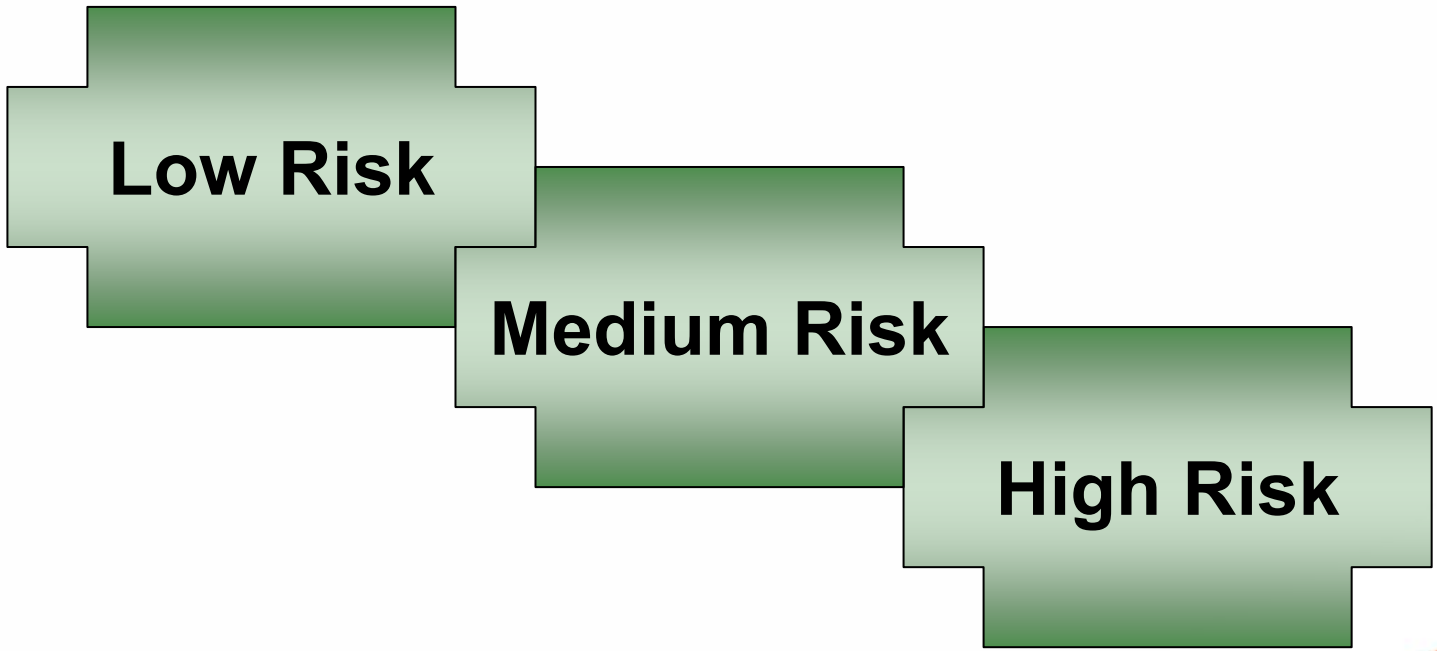
Medical devices are classified according to their risk

USA	CANADA	EU
Class I (low risk) **Class II** (med risk) **Class III** (high risk)	**Class I** (low risk) **Class II** } (med risk) **Class III** } **Class IV** (high risk)	**Class I** (low risk) **Class IIa** } (med risk) **Class IIb** } **Class III** (high risk)

الهيئة العامة للغذاء والدواء
Saudi Food & Drug Authority

Medical Devices regulation

Medical Devices regulation requirements stringency are risk based:

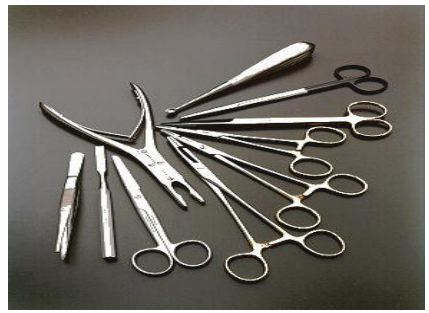


الهيئة العامة للغذاء والدواء
Saudi Food & Drug Authority

Medical Devices regulation (cont)

Low Risk

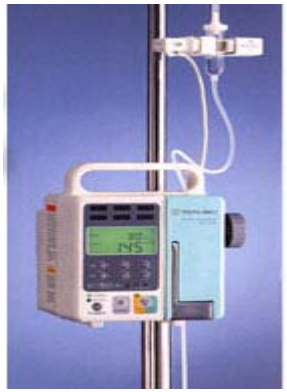
o subject to the least regulatory control.
o present minimal potential for harm to the user.
o simpler in design than Med Risk or High Risk devices.



Medical Devices regulation (cont)

Medium Risk

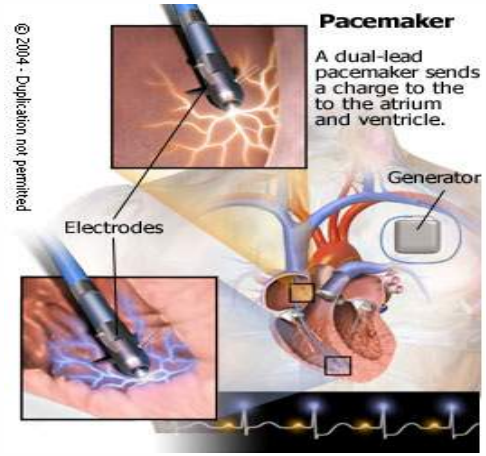
Medium Risk devices are those for which general controls alone are insufficient to assure safety and effectiveness, and existing methods are available to provide such assurances.



Medical Devices regulation (cont)

High Risk:

The most stringent regulatory category for devices.



Medical Devices Regulatory Model

	"Command and Control" (e.g., Japan)	"Oversee and Verify" (e.g., Canada)	"Monitor and Moderate" (e.g., Germany)
Licensing & Standards	• Government enforcement of strict initial licensing / approval processes and ongoing audit / inspection processes	• Government enforcement of moderate initial licensing / approval processes • Establishment-based or outsourced ongoing inspections, but with oversight • Harmonized mandatory and voluntary standards	• Government enforcement of equivalency and notification-style processes • Establishment-based self regulation, with basic government oversight
Risk	• Country-specific, mandatory standards • Strict import controls • Heavy submission documentation requirements • Long decision time (i.e. reviews, approvals, amendments, etc.) • All medical devices and establishments are subjected to government control, regardless of risk implications	• Relaxed import controls; reliance on unilateral and mutual recognition • Submission documentation proportional to implied risk level • Short decision times • Government control of products and establishments proportional to implied risk	• Harmonized voluntary standards • Heavy reliance on mutual recognition • Submission documentation required only for high-risk devices
Fees & Systems	• High charges applied to customers as a result of full cost recovery systems • Dedicated laboratory for pre-market and post-market verifications and inspections • Relief responsibilities for adverse events	• Moderate charges; full or partial cost-recovery • Medical device laboratory shared with drugs; outsourced to private sector; concerned with adverse event research	• Few charges; no cost-recovery consideration • No local medical device laboratory; use global or local private sector when needed

الهيئة العامة للغذاء والدواء
Saudi Food & Drug Authority

Stages of regulatory control

A medical device is regulated throughout its life cycle i.e. conception and development to retirement and disposal.

Pre Market

Placing On Market

Post Market

الهيئة العامة للغذاء والدواء
Saudi Food & Drug Authority

Pre-market:

to ensure that the product to be placed on market complies with regulatory requirements.

Products of all classes should have the following (Technical Information).

- Intended use.
- Classification
- Instructions for use
- Product Description
- labeling
- Packaging unit
- Manufacturer.
- Risk analysis.
- Safety
- Row material.

الهيئة العامة للغذاء والدواء
Saudi Food & Drug Authority

Pre-market *(cont)*

In addition; High classes (> class I) may require the following depending on their risk:

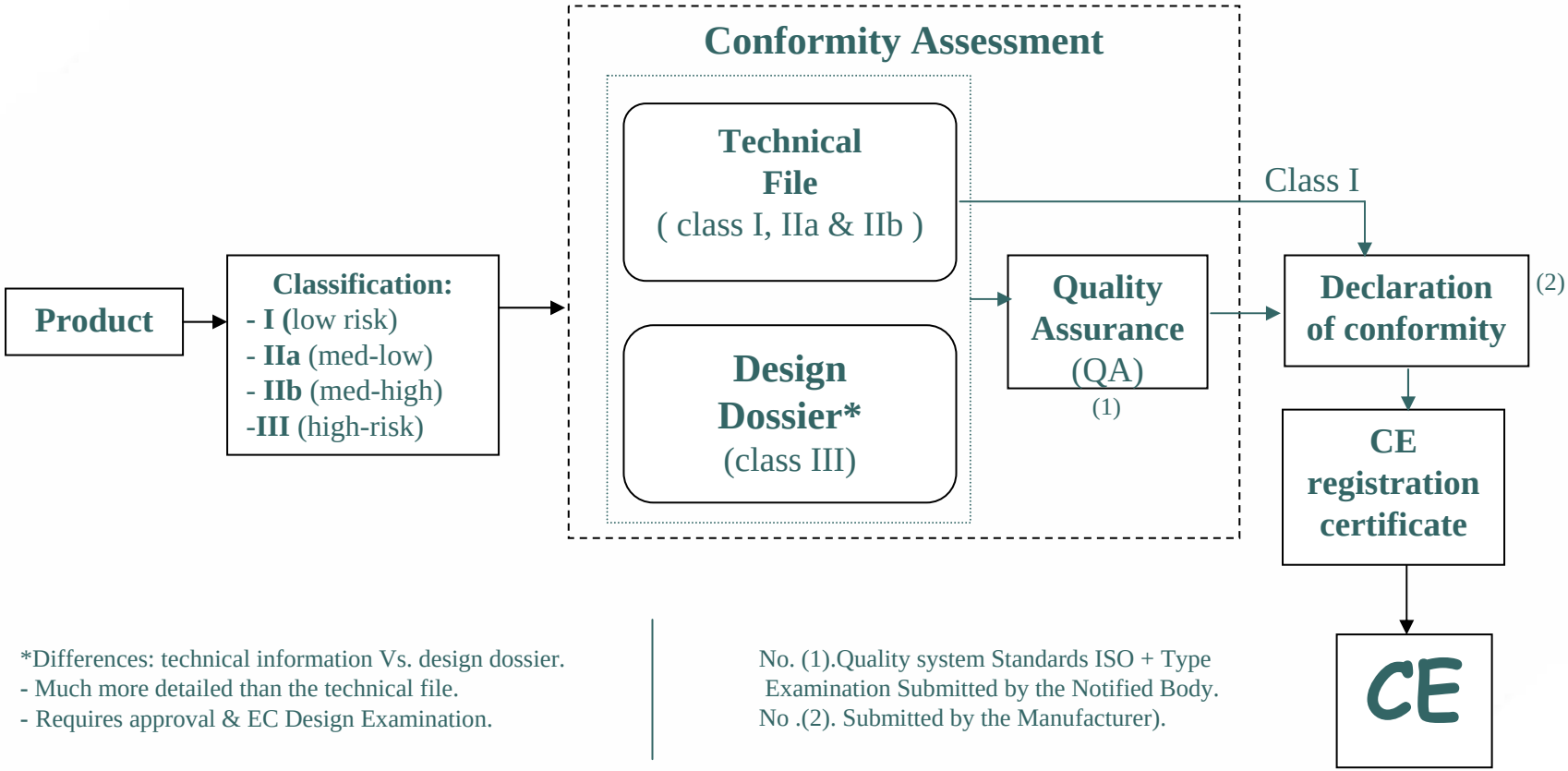
- Electrical safety.
- Clinical trials.
- Performance tests.

Full information about reports and investigations of the adverse events.

Certified quality in the design and manufacture process.

Pre-market (cont)

Regulatory process (EU)

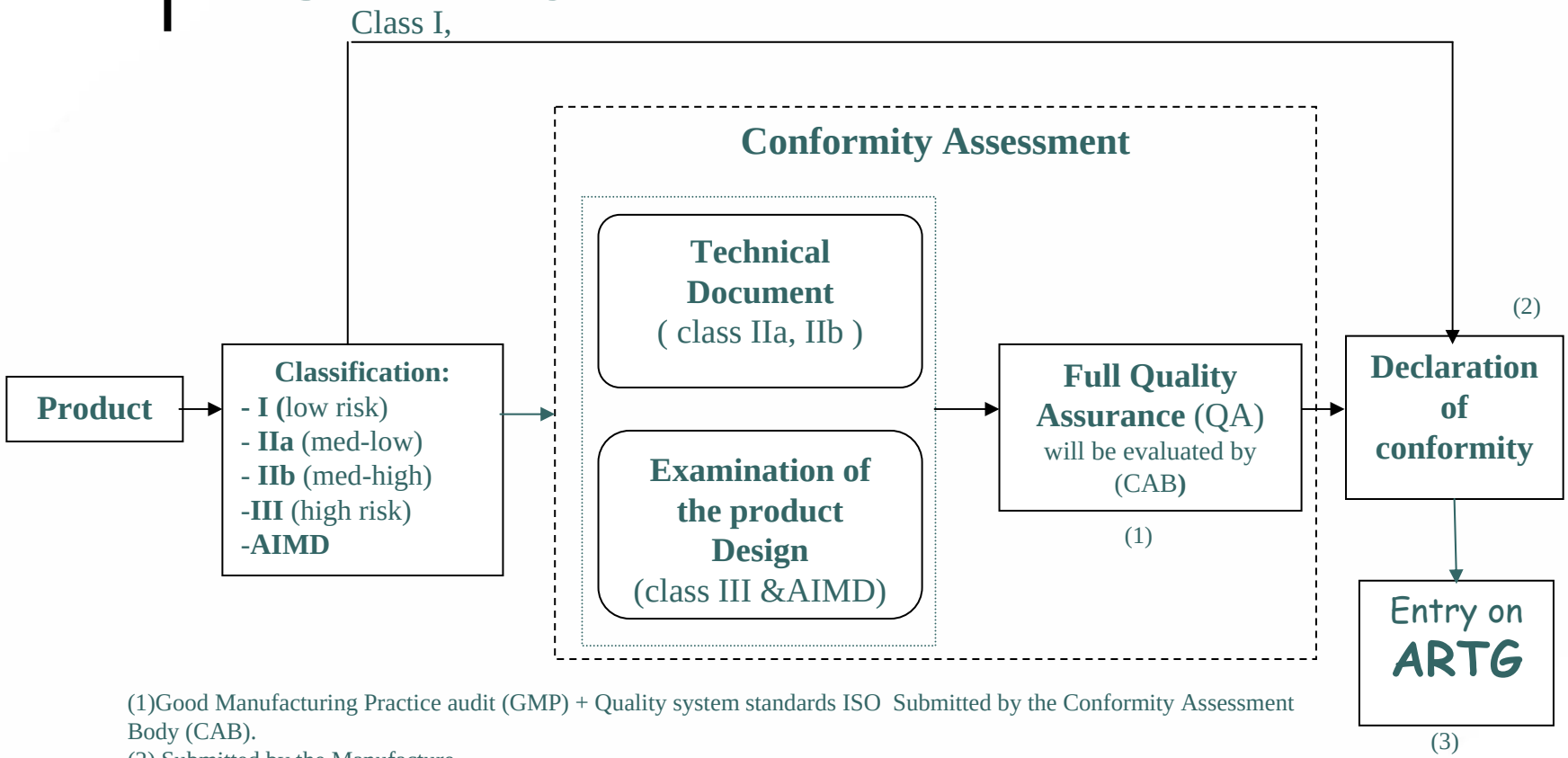


*Differences: technical information Vs. design dossier.
- Much more detailed than the technical file.
- Requires approval & EC Design Examination.

No. (1).Quality system Standards ISO + Type Examination Submitted by the Notified Body.
No .(2). Submitted by the Manufacturer).

Pre-market (cont)

Regulatory process Australia



(1)Good Manufacturing Practice audit (GMP) + Quality system standards ISO Submitted by the Conformity Assessment Body (CAB).
(2) Submitted by the Manufacture.
(3) ARTG: (Austalian register of therapeutic goods) is the register of information about therapeutic goods for human use that may be imported , supplied in, or exported from australia . ARTG issues an ARTG number to devices cleared for the market.

Pre-market (cont) (Registration)

Benefits

Assisting in the assessment of the medical devices market.

Identifying products not registered and competing illegally.

Providing consumers with increased confidence about quality and safety of medical devices.

Protecting hospitals from equipment with poor standards.

Helping trace and recall product.

Placing-on-market

assures establishment registration, device listing and after-sale obligations.

It is a sale control (sale monitor), with the vendor being responsible for this action. It is mainly to ensure that the product is:

Accurately labeled

- Is crucial in identifying the medical device and specifying instructions for it is proper use.

Accurately advertised

- Misleading and fraudulent advertising of medical devices may increase sales.
- Has the potential to create expectation and powerfully influence belief in a medical device's capabilities.
- Medical device marketing and advertising are regulated to prevent misrepresentation of a medical device and its performance.

الهيئة العامة للغذاء والدواء
Saudi Food & Drug Authority

Post-market

It is a broad term that covers all monitoring activities of medical devices in use. Such as:

1) The manufacturer's post-market surveillance system

- Implement corrective action, Proportional with the nature and risks involved with the medical device.
- Experiences gained after supply.
- Notify the sponsors of adverse events.

Post-market (cont)

2) Post-market monitoring of market compliance

- Inspections of manufacturer's or sponsor's records and documentations.
- On-site tests or taking samples for off-site testing.
- Audits of technical and clinical information.
- Audits of distribution records.

Post-market (cont)

3) Vigilance programs

- Adverse events reporting
- Malfunctions
- Results of testing

Post-market (cont)

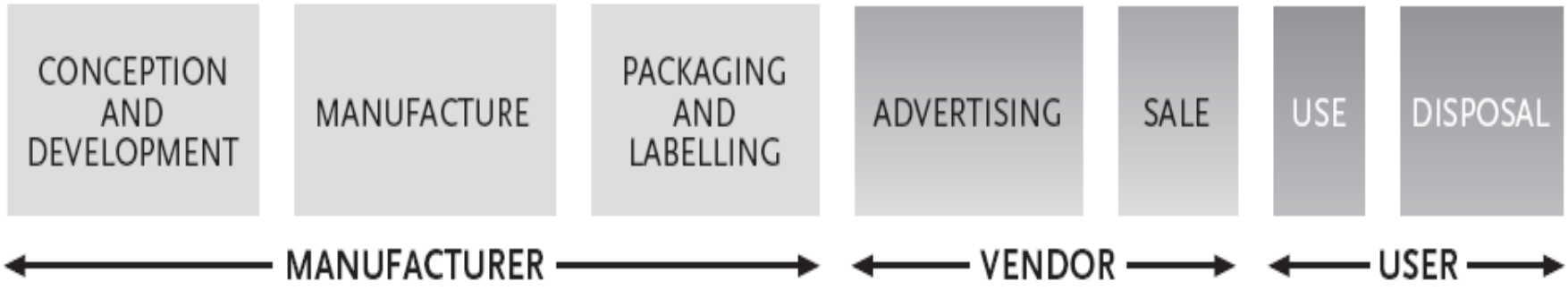
4) Recalls

A hazardous or potentially hazardous product.

Additional information are needed for the safe use of the product

Conception and development to disposal

A medical device should be regulated throughout its life cycle.



*According to

(medical device regulations global overview and guiding principles)

WHO

الهيئة العامة للغذاء والدواء
Saudi Food & Drug Authority

Conception and development to disposal (Cont)

Manufacturer

Must ensure that its device is manufactured to meet or exceed the required standards of safety and performance.

Conception and development to disposal (Cont)

Vendor

provides the interface between the product and the user. He/she should ensure that the products sold comply with regulatory requirements.

Conception and development to disposal (Cont)

User

User familiarity with the indications, contra-indications and operating procedures recommended by the manufacturer

user's qualifications and training in the proper use of the device

Important Notes

Regulatory Authorities are:

Concentrating more on Post Market

Moving Away from Pre-market Activities → Unilateral, bilateral, and/or mutual recognition

Manufacturer being responsible for their products

الهيئة العامة للغذاء والدواء
Saudi Food & Drug Authority

Important Notes (cont)

countries are working closely to Harmonize

- **Standards**
- **Conformity Requirements**
- **Approval; Certification Requirements**

GHTF

AHWP

Pan American Health Organization

الهيئة العامة للغذاء والدواء
Saudi Food & Drug Authority

Facts

- Health care in the middle east is growing very rapidly.

  increases the demand for medical devices.
- The Middle east market is very much open to all medical devices manufacturers
- Middle east medical devices market is huge and is growing tremendously.

الهيئة العامة للغذاء والدواء
Saudi Food & Drug Authority

Recommendations

- We need to ensure that the devices brought to our countries are safe, effective and do what they are intended for.
- We must not set up our regulations to drive manufacturers away.
- We must set up our regulations in coherence and harmony with the international community.

Conclusion

I strongly recommend that:

- The middle eastern countries join together in a harmonization working party similar to those of GHTF, AHWP…etc.
- Benefit from each other strength in various parts of regulatory activities without reinventing the wheel.
- Work on the basis of unilateral, Mutual recognition.

Thank you ....

الهيئة العامة للغذاء والدواء
Saudi Food & Drug Authority