Clinical Engineering

Introduction to Clinical Engineering

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Outline

- Medical Device – Definition
- Life Cycle of a Medical Device
- Life cycle of a Medical Devices in Healthcare Facilities
- Difference between Clinical Engineering and Biomedical Engineering
- Interactions of a clinical engineer

Medical Device - Definition

(GHTF/SG1/N29R16:2005)

any instrument, apparatus, implement, machine, appliance, implant, in vitro reagent or calibrator, software, material or other similar or related article, intended by manufacturer to be used, alone or in combination, for human beings, with some kinds of purpose (diagnosis, prevention, monitoring, treatment, etc)

Example

Suture

Pacemaker

Lung ventilator

X-ray films

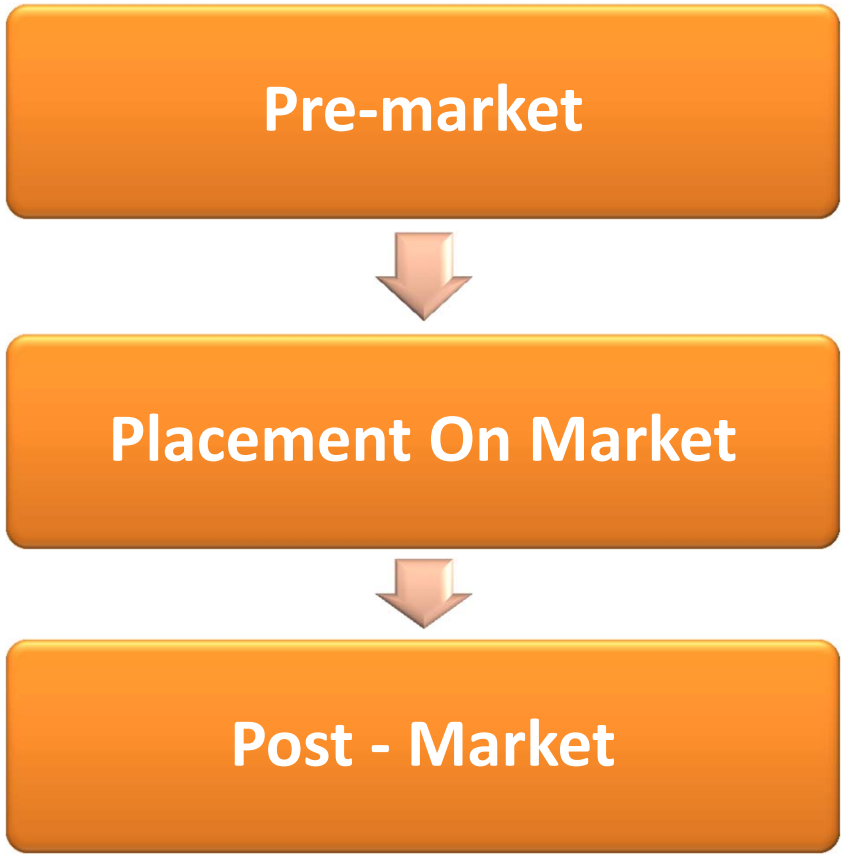
contact lens disinfecting

condom

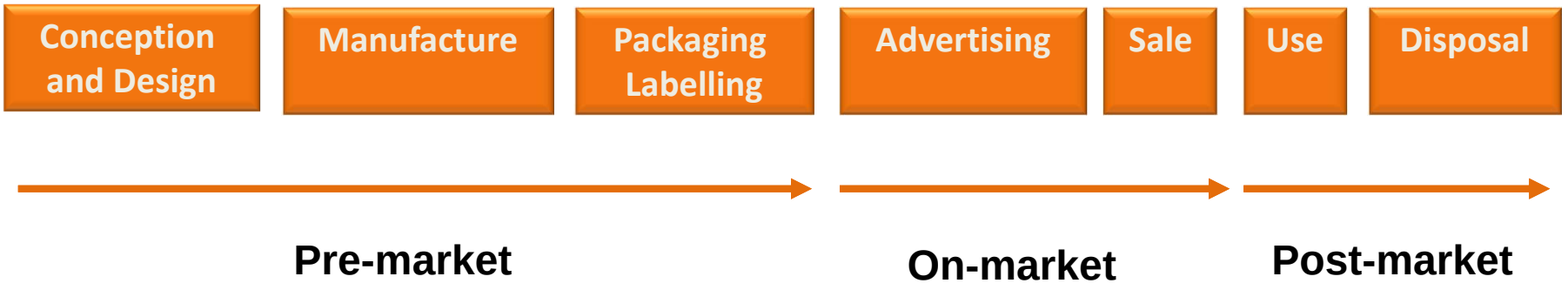
Thermometer

No **Yes**

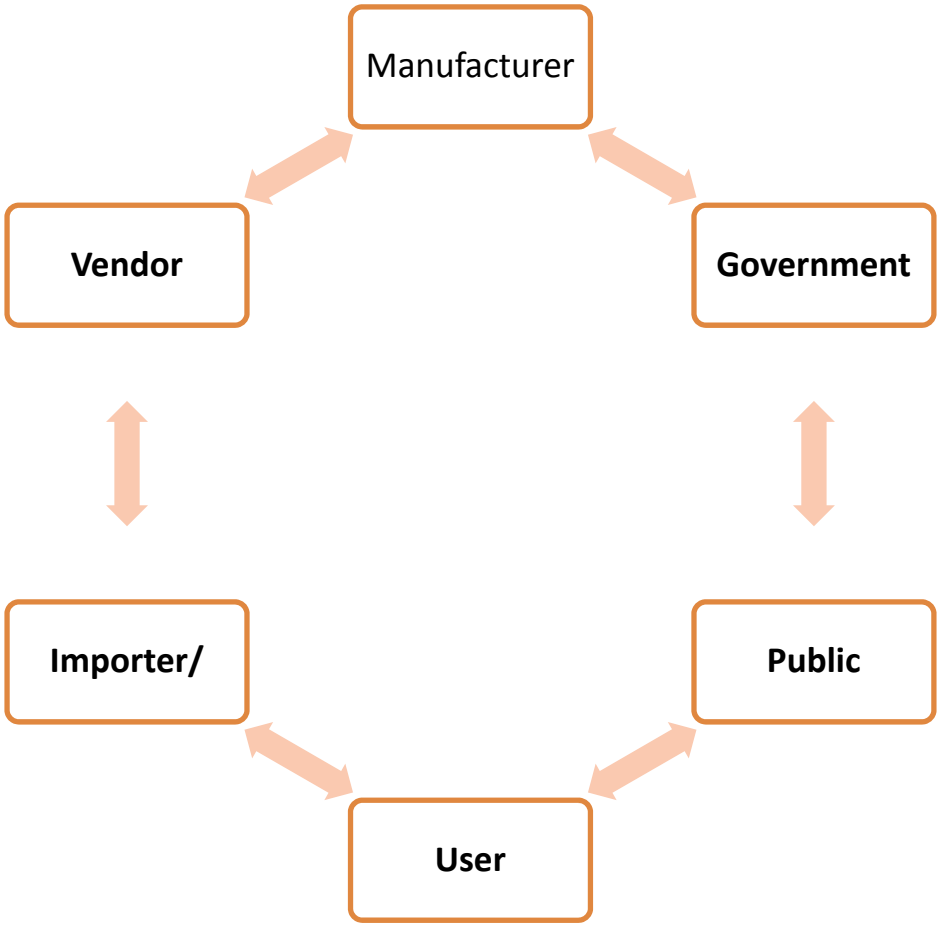
MEDICAL DEVICES REGULATORY ACTIVITIES



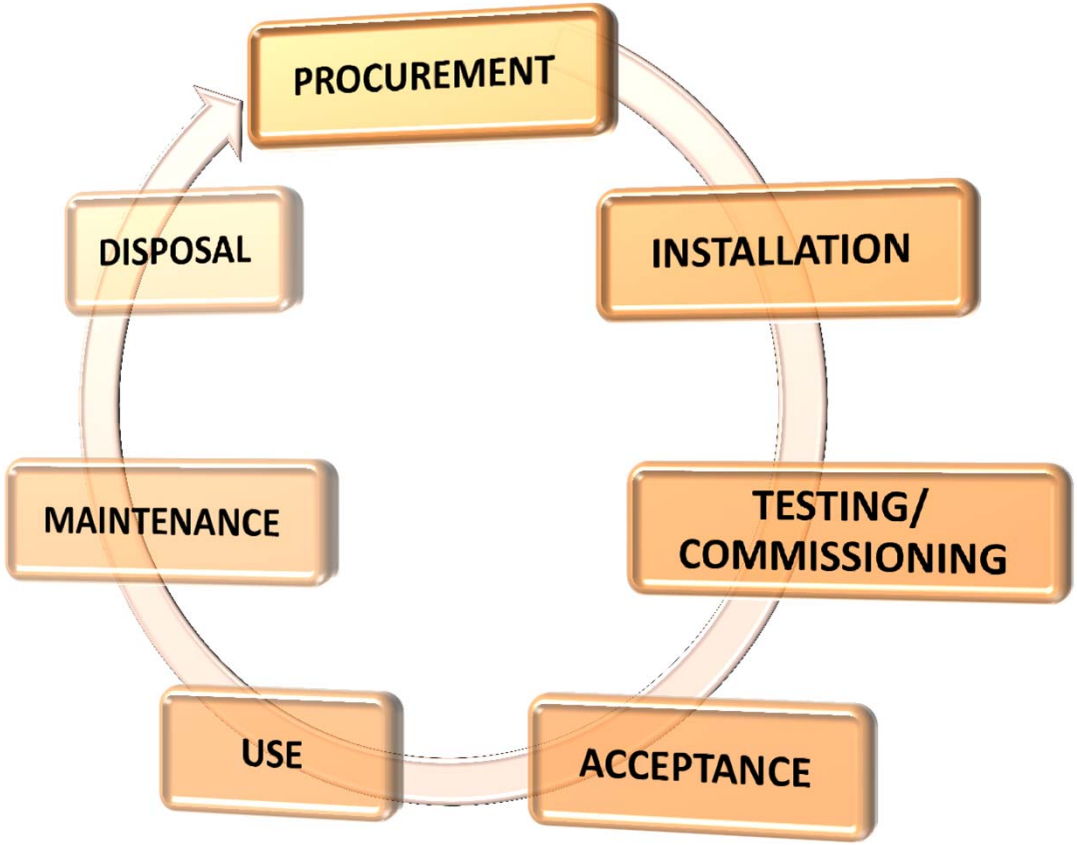
Life Cycle of a Medical Device



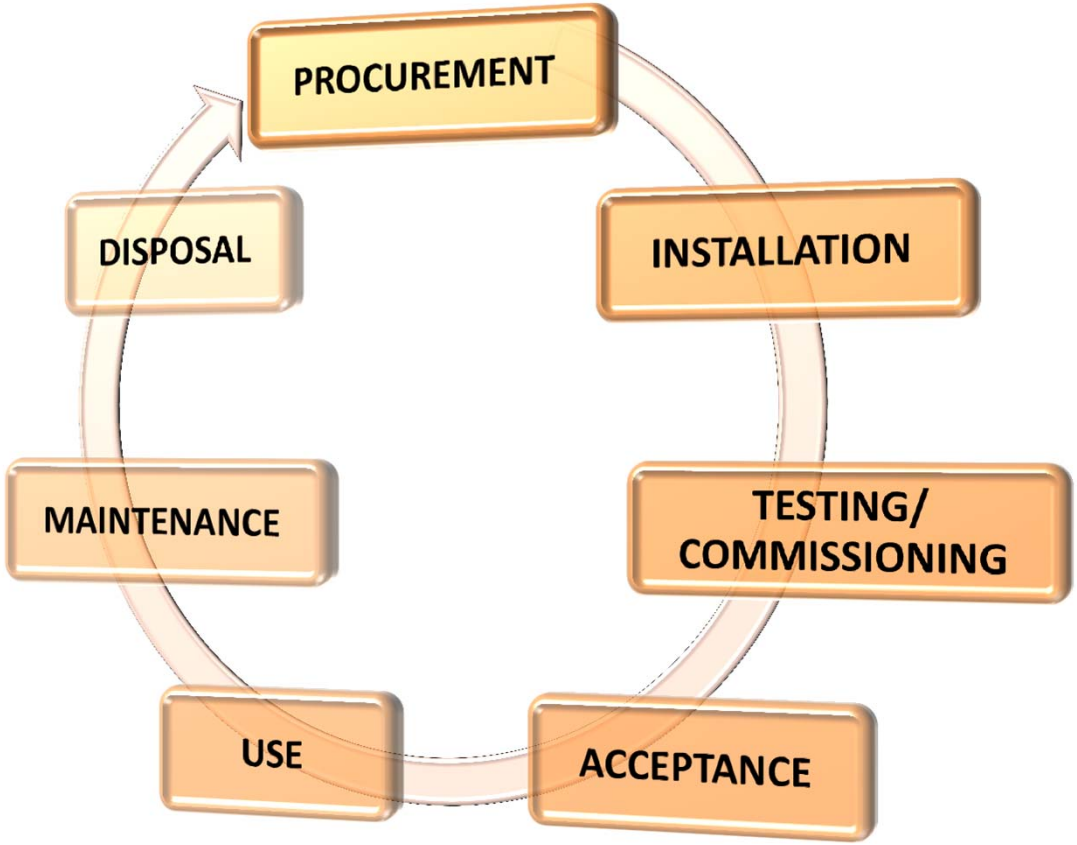
The role of each participant/stakeholder



LIFE CYCLE OF DEVICES IN HEALTHCARE FACILITIES



LIFE CYCLE OF DEVICES IN HEALTHCARE FACILITIES



Discipline of Biomedical Engineering

Biomedical Engineer

VS

Clinical Engineer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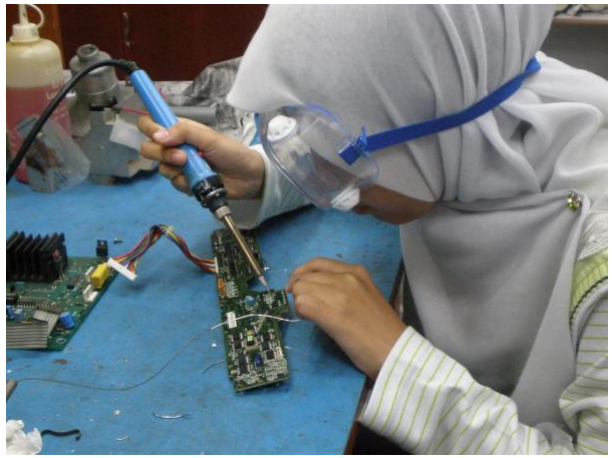


Ed. Joseph D. Bronzino define biomedical engineering as:

"A Biomedical Engineer uses traditional engineering expertise to analyze and solve problems in biology and medicine, providing an overall enhancement of health care. "

"Biomedical engineers are involved in many medical ventures. They are involved in the design, development and utilization of materials, devices and techniques for clinical research and use; and serve as members of the health care delivery team seeking new solutions for difficult heath care problems confronting our society."

"A Clinical Engineer is a professional who supports and advances patient care by applying engineering and managerial skills to healthcare technology."

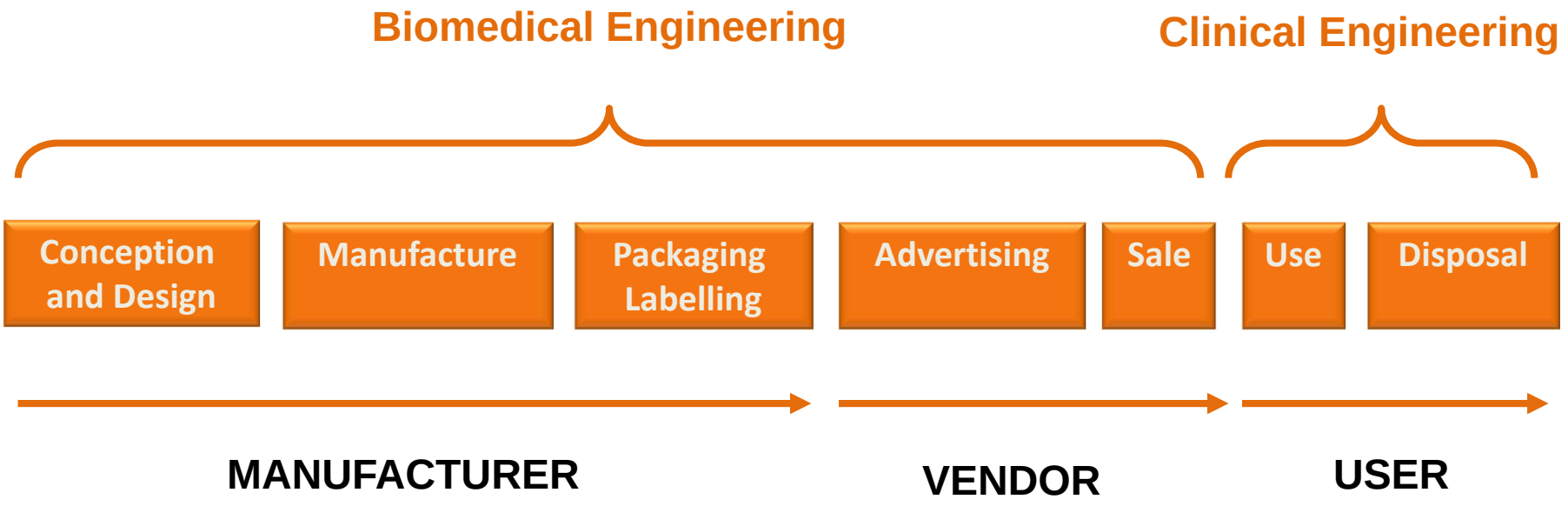
ACCE Definition, 1992

ACCE – American College of Clinical Engineering

Difference between CE and BE

- Biomedical engineers (BE) is generally thought to be more all-encompassing, including engineers who work directly in the design of medical devices for manufacturers
- Clinical engineers (CE) generally work in hospitals solving problems that are very close to where equipment is actually used in a patient care setting

Life Cycle of a Medical Device



Interactions of a clinical engineer