

Different government regulatory agencies

Regulatory agencies in the
USA and EU



17.2.1 List different government regulatory agencies and describe them

Unit C 17.2 Intro to Medical Equipment Regulation

Module 279-17-C Regulations, Standards and Ethics

Government tasks (?)

Collect Taxes

- income tax
- property tax
- inheritance tax
- sales tax
-

Provide Subsidies

- Fuel
- Maize
-

Establish Laws & Regulations

- fair competition

Provide Public Safety

- police, army
- food regulations
- **medical equipment safety**

Provide Public Utilities

- water
- electricity
- sewage
- **telephone**

Provide Public Transport

- bus
- train
- **airplane**

Provide Public Infrastructure

- roads
- government buildings

Education

- primary schools
- secondary schools
- colleges
- universities

Healthcare

- hospitals
- health programs

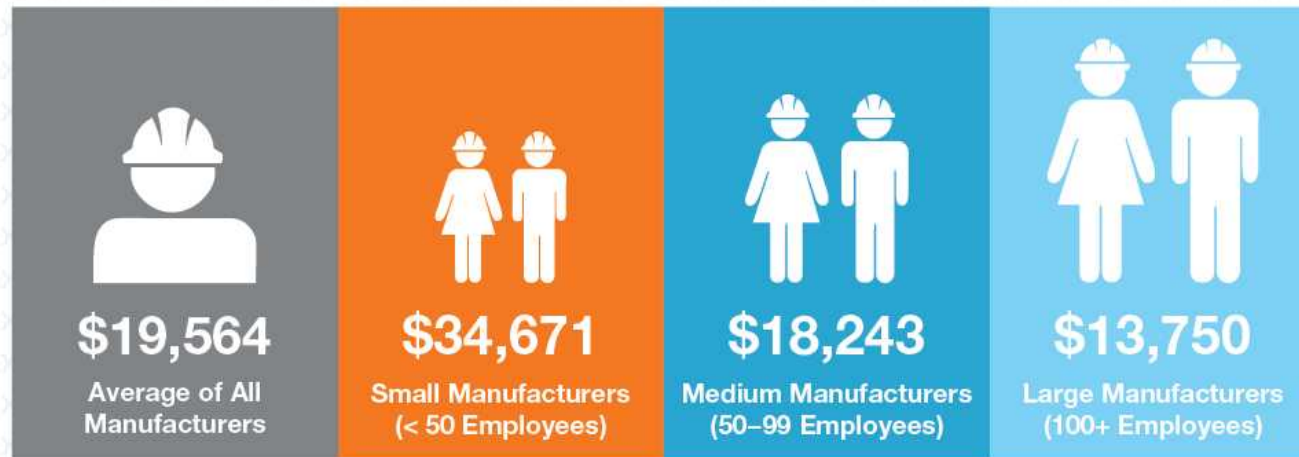
Businesses

- copper mines
- hydro dams
- maize seeds
& sales

Cost of Regulations

All regulations impose a cost on society (manufacturers, vendors, users, public, government) to establish and maintain such regulations.

Regulatory Compliance Costs per Employee per Year for Manufacturers, 2012 (in 2014 Dollars)



It is important that the cost of regulations is

- not higher than necessary and
- justified by the (public) benefits

FDA / USA



FDA: the Food and Drug Administration

The Food and Drug Administration (FDA) is a **federal** agency of the United States **Department of Health and Human Services**. The FDA is responsible for protecting and promoting public health through the regulation and supervision of:

- food safety, tobacco products, dietary supplements, prescription and over-the-counter pharmaceutical drugs (medications), vaccines, biopharmaceuticals, blood transfusions, **medical devices**, electromagnetic radiation emitting devices (ERED), cosmetics, animal foods & feed and veterinary products.

The agency has 223 field offices and 13 laboratories located throughout the United States.

In 2008, the FDA began to post employees to foreign countries, including China, India, Costa Rica, Chile, Belgium, and the United Kingdom.

In 2010, the FDA had **15,100 employees**.



FDA: the Food and Drug Administration

The FDA regulates more than **US\$1 trillion** worth of consumer goods, about **25% of consumer expenditures** in the United States. This includes \$466 billion in food sales, \$275 billion in drugs, \$60 billion in cosmetics and \$18 billion in vitamin supplements. Much of these expenditures are for goods imported into the United States; **the FDA is responsible for monitoring imports.**

The FDA's federal budget request for fiscal year (FY) 2012 totalled **\$4.4 billion**. About \$2 billion of this budget is generated by user fees. Pharmaceutical firms pay the majority of these fees, which are used to expedite drug reviews.



FDA: the Center for Devices and Radiological Health

The **Center for Devices and Radiological Health (CDRH)** is the branch of the FDA responsible for

- regulating firms who manufacture, repackage, relabel, and/or import **medical devices** sold in the United States.
- the **pre-market approval** of all medical devices, as well as overseeing the **manufacturing, performance and safety** of these devices. In addition, CDRH regulates radiation-emitting electronic products (medical and non-medical) such as lasers, x-ray systems, ultrasound equipment, microwave ovens and color televisions.

CDRH regulatory powers include the **authority:**

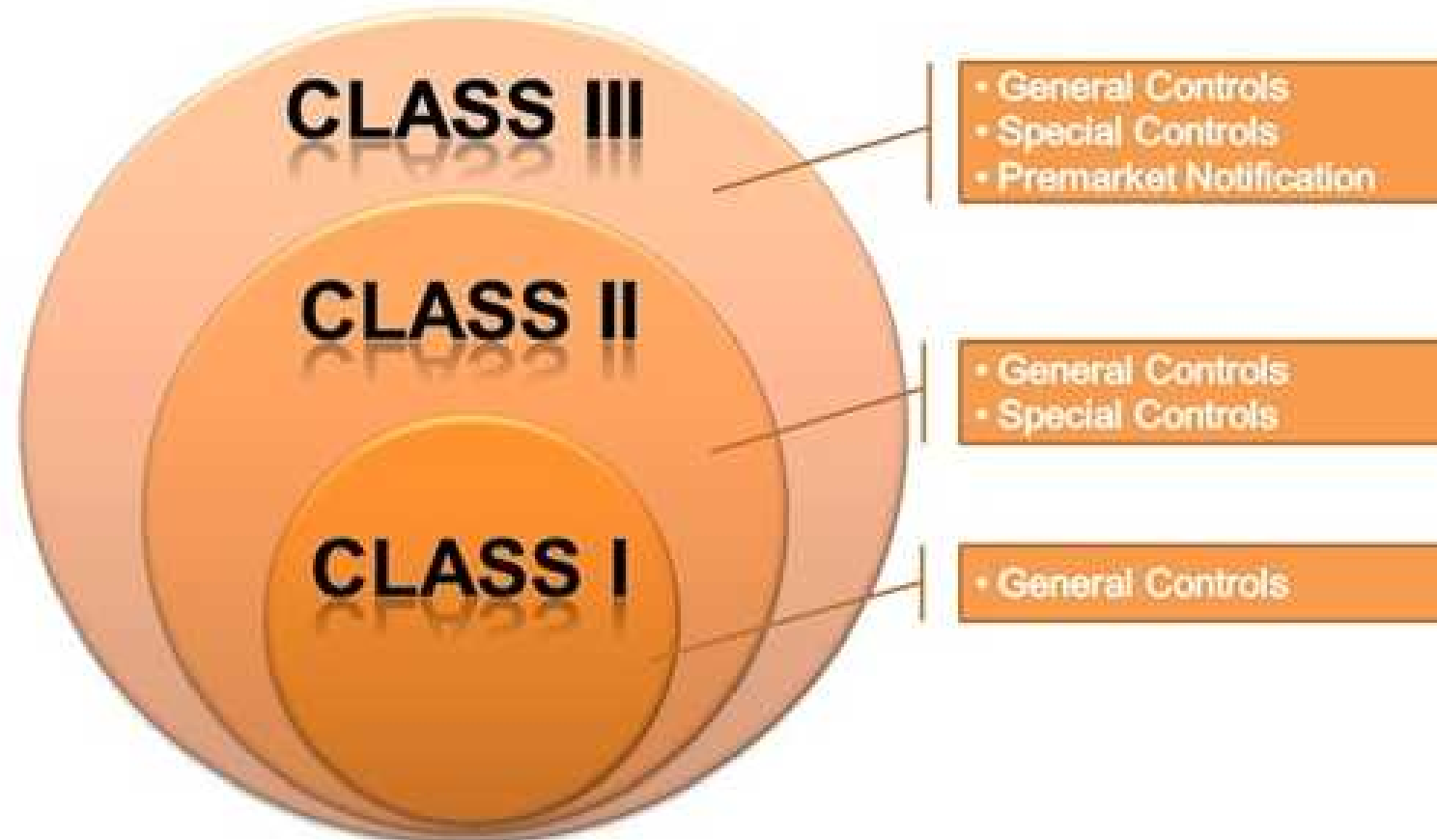
- to **require certain technical reports** from the manufacturers or importers of regulated products,
- to **declare regulated products defective**, and
- to order the **recall of defective or noncompliant products**.

CDRH also conducts limited amounts of direct product testing.



FDA: General Controls

General controls are the minimum regulations that apply to all FDA regulated medical devices.



FDA: General Controls

General controls include the next five elements:

1. **establishment registration** — for e.g. manufacturers, distributors and foreign firms
2. **device listing** — listing with FDA of all devices to be marketed;
3. **good manufacturing practices (GMP)**— manufacturing of devices in accordance with the Quality Systems Regulation (QSR)
4. **labelling** — labelling of devices or in vitro diagnostic products;
5. **premarket notification** — submission to FDA of a premarket notification 510(k).

EU



EU Legal Framework

The EU aims to remove technical barriers to trade and dispel the consequent uncertainty for economic operators, to facilitate free movement of goods inside the EU.

The core legal framework related to medical devices consists of three directives:













- Directive 90/385/EEC regarding active implantable medical devices
- **Directive 93/42/EEC regarding medical devices**
- Directive 98/79/EC regarding in vitro diagnostic medical devices

The Medical Device Directive 93/42/EEC of 14 June 1993 concerning medical devices, is intended to **harmonise the laws relating to medical devices within the European Union**.

The Directive was most recently reviewed and amended by the 2007/47/EC and a number of changes were made. Compliance with the revised directive became **mandatory** on March 21, 2010

There are a lot of Regulations in the EU ...

Major Regulations

| Document | Language | Number | Published |
|---|---|------------|-----------|
|  European Active Implantable Medical Devices Directive (AIMDD) |  | 90/385/EEC | 06/1990 |
|  European Cosmetic Products Directive |  | 76/768/EEC | 07/1976 |
|  European In-Vitro Diagnostic Devices Directive (IVDD) |  | 98/79/EC | 10/1998 |
|  European Medical Devices Directive (MDD) |  | 93/42/EEC | 06/1993 |
|  European Personal Protective Equipment Directive |  | 89/686/EEC | 12/1989 |
|  Regulation amending the European MDD 93/42/EEC and others |  | 2007/47/EC | 9/2007 |



EU: Competent Authority

The government of each Member State must appoint a **competent authority (CA)** responsible for medical devices.

The competent authority is a body with authority to act on behalf of the member state to ensure that member state government transposes requirements of medical device directives into national law and applies them. The CA reports to the minister of health in the member state.

In the UK, for example, the **Medicines and Healthcare products Regulatory Agency (MHRA)** acts as a CA

The Regulatory Agencies of the EU countries all have to comply with EU Directives...

EU: Declaration of Conformity

The authorization of medical devices is guaranteed by a **Declaration of Conformity**.

This declaration is **issued by the manufacturer** itself.

- Medical devices that fit in class I can be marketed purely by **self-certification**.
- For products in higher classes, it must be **verified by a Certificate of Conformity** issued by a **Notified Body**.

A Notified Body is a public or private organisation that has been **accredited** to validate the compliance of the device to the European Directive.

All certified medical devices should have the **CE mark** on the packaging, insert leaflets, etc.



The CE mark

The **CE mark** is a conformity mark which all European medical devices must have before they can be marketed. It is seen as **a declaration by the manufacturer** that the product meets all the appropriate provisions of the relevant legislation **including those related to safety** and, where required, has been **assessed** in accordance with these.

The CE marking of conformity must appear in a **visible, legible and indelible form** on the device or its sterile pack, where practicable and appropriate, and on the instructions for use. Where applicable, the CE marking must also appear on the sales packaging.

It shall be accompanied by the **identification number of the notified body** involved.

The initials “CE” do not stand for any specific words; it is a symbol that is seen as a declaration by the manufacturer that the product meets all the appropriate provisions of the relevant legislation.



EU: Essential Principles applicable to all Medical Devices

A1

Medical devices should be designed and manufactured in such a way that, when used **under the conditions and for the purposes intended** and, where applicable, by virtue of the technical knowledge, experience, education or training, and the medical and physical conditions of intended users, they will perform as intended by the manufacturer and **not compromise the clinical condition or the safety of patients, or the safety and health of users or, where applicable, other persons**, provided that any risks which may be associated with their use constitute **acceptable risks when weighed against the benefits to the patient** and are compatible with a high level of protection of health and safety.

EU: Essential Principles applicable to all Medical Devices

A2

The solutions adopted by the manufacturer for the design and manufacture of the devices should conform to safety principles, taking account of the **generally acknowledged state of the art**. When risk reduction is required, the manufacturer should control the risks so that the **residual risk associated with each hazard is judged acceptable**.

The manufacturer **should apply the following principles** in the priority order listed:

- **identify known or foreseeable hazards** and estimate the associated risks arising from the intended use and foreseeable misuse;
- **eliminate risks** as far as reasonably practicable through **inherently safe design and manufacture**;
- reduce as far as reasonably practicable the remaining risks by taking adequate **protection measures, including alarms**; and
- **inform users of any residual risks**.

EU: Essential Principles applicable to all Medical Devices

A3

Medical devices should **achieve the performance intended by the manufacturer** and be designed and manufactured in such a way that, during normal conditions of use, they are **suitable for their intended purpose**.

A4

The characteristics and performances referred to in Clauses A1, A2 and A3 should not be adversely affected to such a degree that the health or safety of the patient or the user and, where applicable, of other persons are compromised during the lifetime of the device, as indicated by the manufacturer, **when the device is subjected to the stresses which can occur during normal conditions of use and has been properly maintained** in accordance with the manufacturer's instructions.

EU: Essential Principles applicable to all Medical Devices

A5

Medical devices should be designed, manufactured and packaged in such a way that their characteristics and performances during their intended use will **not be adversely affected by transport and storage conditions** (for example, fluctuations of temperature and humidity) taking account of the instructions and information provided by the manufacturer

A6

All known and foreseeable risks, and any undesirable effects, should be minimised and be acceptable when weighed against the benefits of the intended performance of medical devices during normal conditions of use.

International Harmonization of Regulations

Medical devices are used worldwide. With the rapid growth in the global market for medical devices, there is a need to harmonize national standards in order to minimize regulatory barriers, facilitate trade and improve access to new technologies.

Harmonization also reduces the cost of implementing regulations for governments and local industry.

We will return to the topic of Harmonization in section 17.3

END

The creation of this presentation was supported by a grant from THET:
see <https://www.thet.org/>

