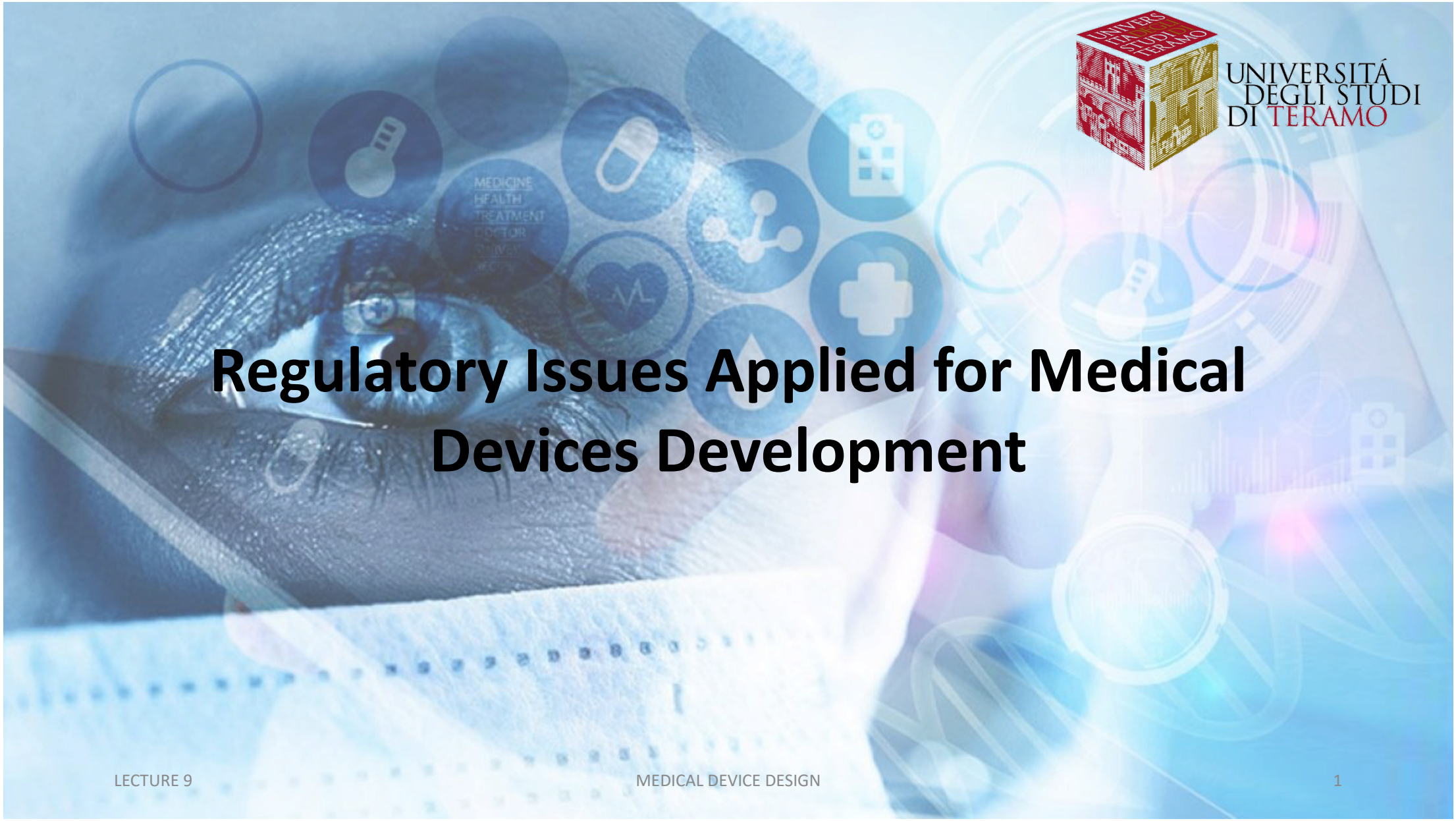


Regulatory Issues Applied for Medical Devices Development

UNIVERSITÁ DEGLI STUDI DI TERAMO

A medical device is defined within the Food, Drug, and Cosmetic Act as:

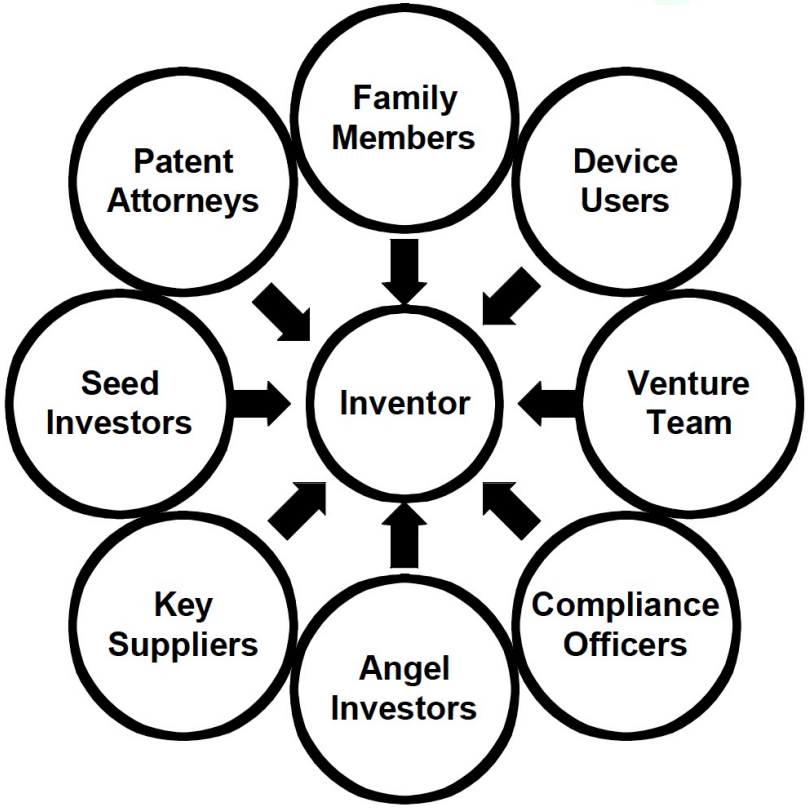
- "...**an instrument, apparatus, implement, machine, contrivance, implant, in vitro reagent**, or other similar or related article, including a component part, or accessory which is:
  - recognized in the official National Formulary, or the United States Pharmacopoeia, or any supplement to them,
  - intended for use in the **diagnosis** of **disease** or **other conditions**, or in the **cure, mitigation, treatment, or prevention** of **disease**, in human or animals,
  - or intended to **affect the structure or any function of the body** of human or animals,
  - and does not achieve any of its primary intended purposes through **chemical action** within or on the body of man or other animals and which is not dependent upon being **metabolized** for the achievement of any of its primary intended purposes. "**is not a drug**"

MEDICAL DEVICE DEVELOPMENT

WHAT KEEPS THE INVENTOR UP AT NIGHT?

Know your product

- What is the **intended use** of the product?
- How does your product **function**?
- What **claim** do you intend to make?



1.‘**active medical device**’ means any medical device relying for its functioning on a source of electrical energy or any source of power other than that directly generated by the human body or gravity;

2.‘**active implantable medical device**’ means any active medical device which is intended to be totally or partially introduced, surgically or medically, into the human body or by medical intervention into a natural orifice, and which is intended to remain after the procedure

FDA Classification

I

Lowest risk classification. FDA Review is not typically required. Usually 510(k) exempt.

- Bandages
- Many surgical tools

II

FDA clearance is typically needed via FDA 510(k) process. Applicant must show "Substantial Equivalence" to a previously cleared "Predicate Device"

- Intravascular guide wires
- X-ray machines

III

Highest risk classification. Approval is usually obtained through FDA's Premarket Approval (PMA) process

- Pacemakers
- Heart valves

Classification - Medical Devices EU

Class I

- Wheelchairs
- Walking aids
- Stethoscopes
- Incision drapes
- Dental patient chairs

Class IIa

- Hearing aids
- Tubing intended for use with infusion pump
- Devices for storage of organs for transplantation
- Tracheal tubes
- Dental aspirator tips
- TENS devices
- Software apps

Class IIb

- Lung ventilators
- Dressings for severe wounds
- Urethral stents
- Urinary catheters for long term use
- Stents
- Peripheral vascular catheters

Class III

- Breast implants
- Intra-aortic balloon pumps
- Spinal stents
- Prosthetic heart valves
- Central vascular catheters

Categorization of medical devices

Medical devices shall be categorized according to the nature of body contact.

Non-contacting medical devices

These include medical devices (or components) that have neither direct nor indirect contact with the body and where biocompatibility information would not be necessary.
Diagnostic software, an in vitro diagnostic device and a blood-collection tube are examples of non contact devices.

Surface-contacting medical devices

a) Skin: Medical devices that contact intact skin surfaces only.
b) Mucosal membranes: Medical devices that contact intact mucosal membranes.
prostheses and orthodontic devices.
c) Breached or compromised surfaces: Medical devices that contact breached or otherwise compromised body surfaces.

Categorization of medical devices

Medical devices shall be categorized according to the nature of body contact.

Externally communicating medical devices

a) Blood path, indirect: Medical devices or components that do not necessarily directly contact the blood path directly but serve as conduits to deliver fluids into the vascular system.
b) Tissue/bone/dentin:

- Medical devices that contact tissue, bone or pulp/dentin systems.
- Medical devices or components that do not necessarily directly contact tissue or bone but serve as conduits to delivery fluids to the tissue or bone.

c) Circulating blood: Medical devices that contact circulating blood.

Implant medical devices

a) Tissue/bone:

- Medical devices principally contacting bone.
- Medical devices principally contacting tissue and tissue fluid.

b) Blood: Medical devices principally contacting circulating blood in the cardiovascular system.

Categorization of medical devices

Medical devices shall be categorized according to the duration of body contact.

5.3.1 Contact duration categories

a) Limited exposure (A) – medical devices whose cumulative sum of single, multiple or repeated duration of contact is up to 24 h.

b) Prolonged exposure (B) – medical devices whose cumulative sum of single, multiple or repeated contact time is likely to exceed 24 h but not exceed 30 d.

c) Long-term exposure (C) – medical devices whose cumulative sum of single, multiple or repeated contact time exceeds 30 d.

EU Medical Device Directives

Medical devices for sale in Europe are regulated by "device directives"

- Medical Device Directive (MDD 93/42/EEC)
- Active Implantable Medical Device Directive (AIMDD 90/385/EEC)
- In Vitro Diagnostic Directive (IVDD 98/79/EEC).

EU Medical Device Directives

Each directive includes a list of "Essential Requirements" (ERs) that must be satisfied before a device can be brought to market.

One method of demonstrating conformity with the ERs is to use "Harmonized Standards", which give the presumption of conformity with the ERs.

EU Harmonized Standards

Examples

ISO 13485 (QMS)

EN 980 (Labelling)

EN 10993 (Biological compatibility)

EN 11607 (Packaging)

EN 14155 (Clinical Evaluation)

ISO 14971 (Risk management)

EN 60601 (Medical electrical equipment)