The Lifecycle of a Medical Device

and

The Controls

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Agenda:

1. What is a Medical Device
2. Key Measures of a Medical Device
3. Life Cycle of a Medical Device
4. Controls in Each Phase of Medical Device
5. New Standards and Regulations

What Is a Medical Device? --- FDA definition

defined within the Food Drug & Cosmetic Act as

A medical device is defined within the Food Drug & 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 other animals, or
- intended to affect the structure or any function of the body of human or other animals,

and which does not achieve any of it's primary intended purposes through chemical action within or on the body of human or other animals and which is not dependent upon being metabolized for the achievement of any of its primary intended purposes."

FDA对医疗器械有明确和严格的定义，其定义如下：“所谓医疗器械是指符合以下条件之仪器、装置、工具、机械、器具、插入管、体外试剂及其它相关物品，包括组件、零件或附件：明确列于National Formulary或the Unite States Pharmacopeia或前述两者的附录中者；

- **预期使用于动物或人类疾病，或其它身体状况之诊断，或用于疾病之治愈、减缓与治疗者；**
- **预期影响动物或人体身体功能或结构，**

但不经由新陈代谢来达到其主要目的者”。

What Is a Medical Device? --- EU definition

The MDD (article 1.2a) define a Medical Device as:

'Any instrument, apparatus, appliance, material or other article, whether used alone or in combination, including software necessary for its proper application 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, alleviation of or compensation for an injury or disability;
- Investigation, replacement or modification of the anatomy or of a physiological process;
- Control of conception.

and which does not achieve its principal intended action in or on the human body by pharmacological, immunological or metabolic means, but which may be assisted in its function by such means.

医疗器械是指直接或者间接用于人体的仪器、设备、器具，体外诊断试剂及校准物、材料以及其他类似或者相关的物品，包括所需要的计算机软件。

效用主要通过物理等方式获得，不是通过药理学、免疫学或者代谢的方式获得，或者虽然有这些方式参与但是只起辅助作用。目的是：

- **疾病的诊断、预防、监护、治疗或者缓解；**
- **损伤的诊断、监护、治疗、缓解或者功能补偿；**
- **生理结构或者生理过程的检验、替代、调节或者支持；**
- **生命的支持或者维持；**
- **妊娠控制**

Key Measures of a Medical Device

How do we know if a Medical Device is a good device?

- Safety
- Efficacy (Performance)

What if a Medical Device is not perfectly Safe or effective?

- Risk Assessment

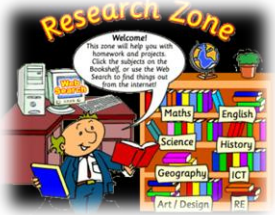
What if risk is not acceptable?

- Risk Benefit Analysis
- Labeling

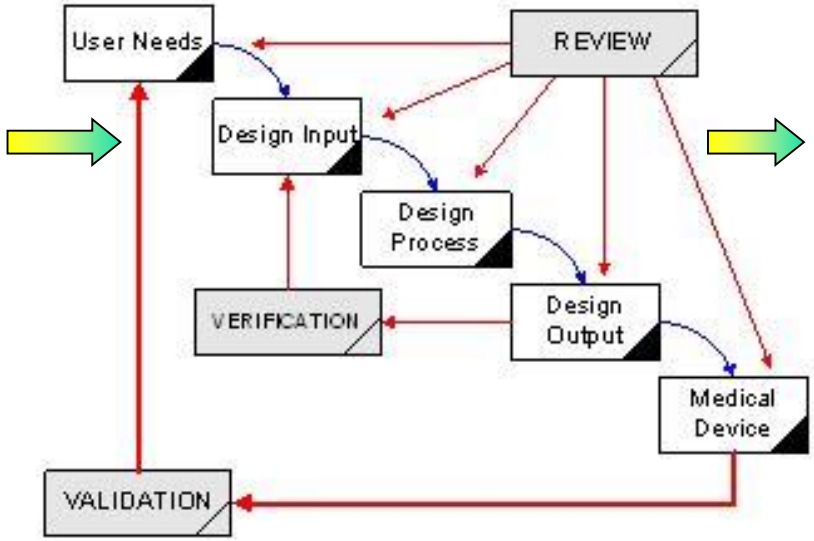
FDA Oversight in a Medical Device LifeCycle

Design and Development

Research



- Ideas,
- Concepts,
- Feasibilities



FDA review

- 510(k) Clearance
- Investigational Devices Exemptions (IDE's)
- PMA

Design Controls

Manufacture and Service

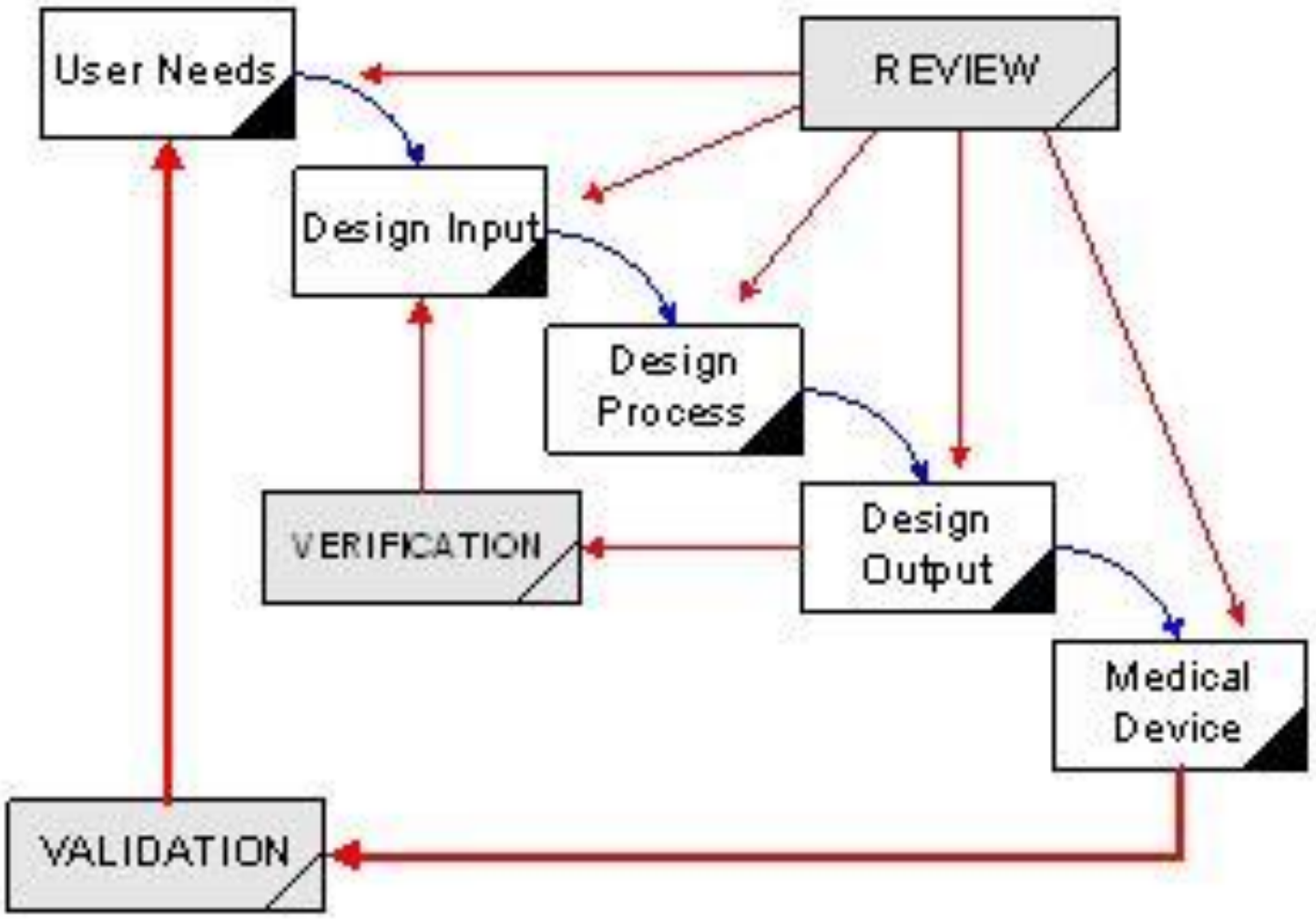
- Design Transfer
- Process Control
- Labeling Controls
- Design controls

- Recalls
- Complaints
- Medical Device Reporting

Obsolescence

Record Retention

Controls in Design Phase



Design Control Elements

- Design Planning
- Design Input (Requirements)
- Design Output (Specifications)
- Design Reviews
- Design Verification (Meets Input)
- Design Validation (Meets clinical needs)
- Design Transfer (Moves from Design to Manufacturing)
- Design Changes
- Design History File (DHF)

Production Control

Each Manufacturer shall develop, conduct, control, and monitor production processes to ensure that a device conforms to its specifications.

- Documented process instructions
- Purchasing Control
- Validated manufacturing processes test methods
- Controlled environment
- Personnel
- Contamination Control
- Building and equipment
- Maintenance and calibration
- Inspection
- Identification and Traceability
- Nonconforming Material Control
- Corrective and Preventive Action

Post Production Control

- Distributor Control
- Customer Feedback and Customer Complaints
- Adverse Event Report
- Product Recall

How do we know if the controls are being effective?

- Internal Audits
- Management Reviews
- Routine Performance Monitoring
- External Audits
- Field issues

New Standard, Regulations and Programs

- ISO 13485 :2016 (Previous version 2003)
  - Mandatory March 2019
  - Risk Based Approach to Quality Management System Processes
- MDR Medical Device Regulation 2017/745
  - Expected to come into effect May 2020
  - Lifecycle approach
  - Post Market Surveillance and Post Market Clinical Follow Up
  - UDI (Unique Device Identification)
  - Control of Notified Bodies
- MDSAP (Medical Device Single Audit Program)
  - Become permanent as of January 1st 2017
  - The current participating regulatory authorities : USA, Canada, Brazil, Australia and Japan

Thank You ！

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