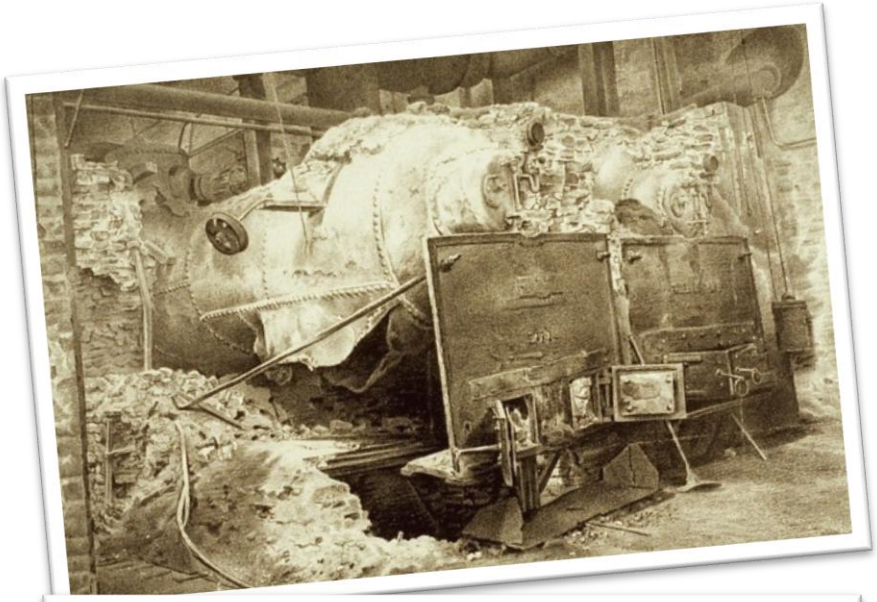
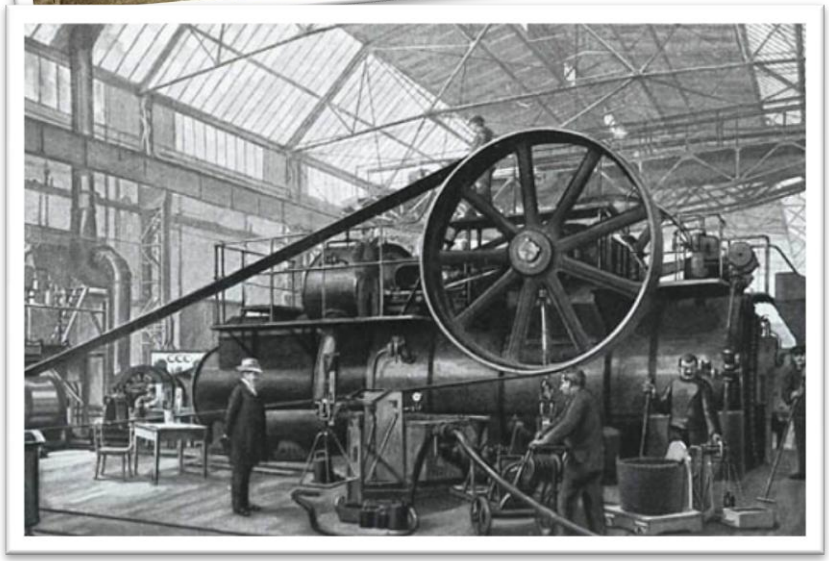
Choose certainty.
Add value.

Design Requirements of Wearable Medical Device Based on Regulations

Vivian Li
2015.03

Our heritage: 148 years of business success





1866 Establishment of a Mannheim-based steam boiler inspection association by 21 operators and owners of steam boilers, with the objective of protecting man, the environment and property against the risk emanating from a new and largely unknown form of technology

1910 First vehicle periodic technical inspection (PTI)

1926 Introduction of the “TÜV mark / stamp” in Germany

1958 Development of a Bavaria-wide network of vehicle inspection centres in the late 1950s

1990s Conglomeration of TÜVs from the southern part of Germany to form TÜV SÜD and the expansion of business operations into Asia

2006 Expansion of services in ASEAN by acquiring Singapore-based PSB Group

2009 Launch of Turkey-wide vehicle inspection by TÜVTURK

Today TÜV SÜD continues to pursue a strategy of internationalisation and growth

Choose certainty. Add value.

TÜV SÜD in numbers: Growing from strength to strength

1	One-stop technical solution provider
150	years of experience
800	locations worldwide
1,900	million Euro in sales revenue 2013
20,200	employees worldwide

Note: Figures have been rounded off.

Technical expertise & broad industry knowledge

Testing & product certification

Chemical, physical, mechanical, electrical and environmental testing and product certification.

Inspection

Product, system, building, plant and infrastructure inspection.

Auditing & system certification

Audits system certification in a variety of fields including quality, safety, energy, IT security, social compliance and environment.

Knowledge services

Safety, quality, risk, environmental protection and regulatory advisory.

Training

Training in work safety, technical skills, management systems and executive programs.

Tangible economic benefits for your business

Increase

Market access

Productivity & profits

Brand reputation

Decrease

Costs & inefficiencies

Time to market

Business risks

01 Development of Wearable Medical Device

02 Design Challenges of Wearable Medical Device

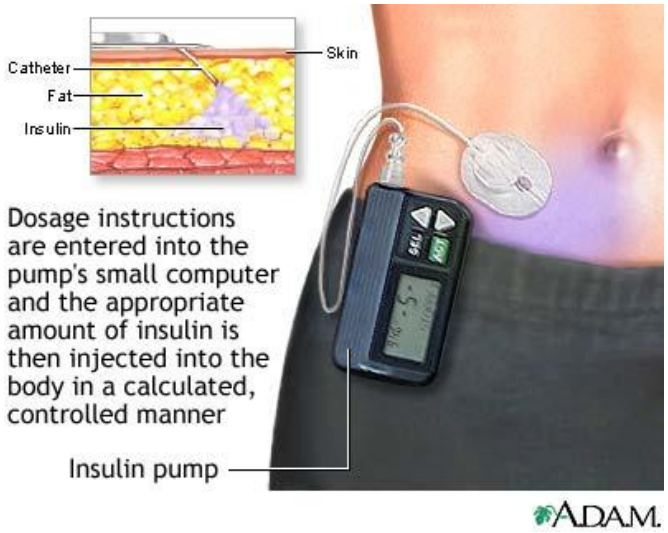
03 Design Requirements Based on Regulations

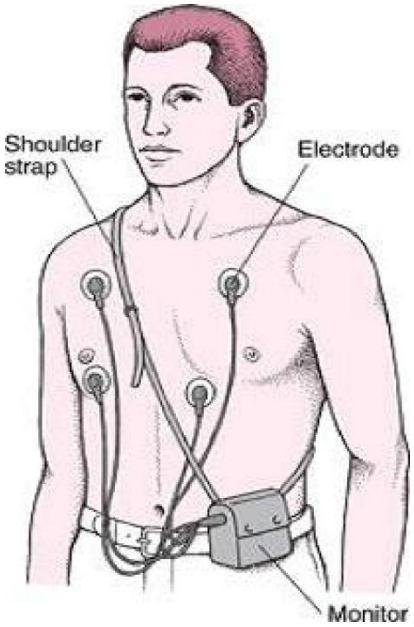
01 **Development of Wearable Medical Device**

02 **Design Challenges of Wearable Medical Device**

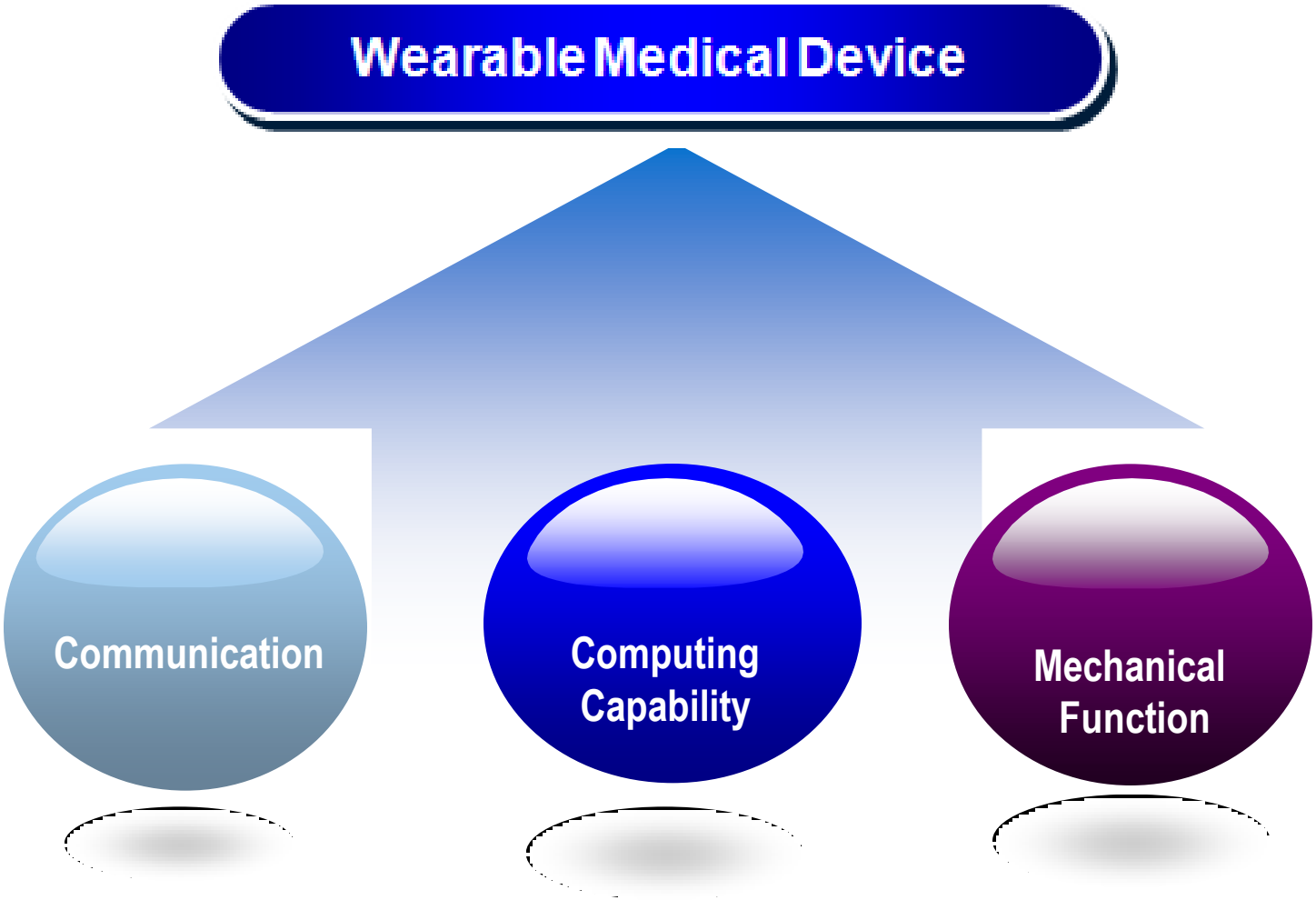
03 **Design Requirements Based on Regulations**

What is Wearable Medical Device?





Development of Wearable Medical Device



Application of Wearable Medical Device

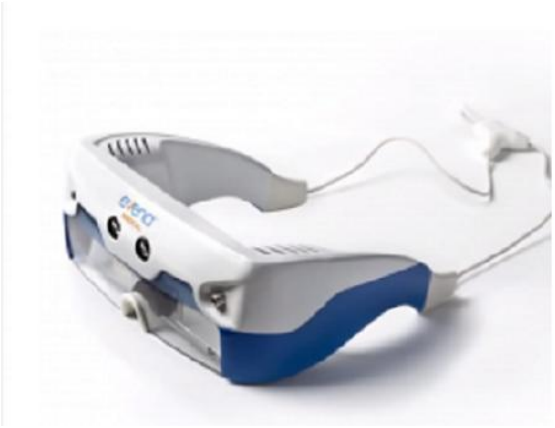
Wearable Monitoring Devices

- ECG
- Pulse rate
- Blood pressure
- Skin temperature
- Blood oxygen saturation
- Respiration

Wearable Rehabilitation Devices

- Controlling pain
- Functional electrical stimulation
- Accelerometric motion analysis

Wearable Medical Aids



- Assisting patients
- Assisting doctors and surgeons

01 Development of Wearable Medical Device

02 **Design Challenges of Wearable Medical Device**

03 Design Requirements Based on Regulations

Design Challenges of Wearable Medical Device

Design Challenges-Standards & Regulation

Is The Product A Medical Device?

Introduction

Determine if your product meets the Definition of a device. If it does, there are FDA requirements that apply. First, see the definition below.

Medical Device Definition

Medical devices range from simple tongue depressors and bedpans to complex programmable pacemakers with micro-chip technology and laser surgical devices. In addition, medical devices include in vitro diagnostic products, such as general purpose lab equipment, reagents, and test kits, which may include monoclonal antibody technology. Certain electronic radiation emitting products with medical application and claims meet the definition of medical device. Examples include diagnostic ultrasound products, x-ray machines and medical lasers. If a product is labeled, promoted or used in a manner that meets the following definition in section 201(h) of the Federal Food Drug & Cosmetic (FD&C) Act it will be regulated by the Food and Drug Administration (FDA) as a medical device and is subject to premarketing and postmarketing regulatory controls. A device is:

Key Words: **Intended Use** / **Diagnosis, Prevention, Monitoring, Treatment, Alleviation** of **disease ……**

Design Challenges-Standards & Regulation

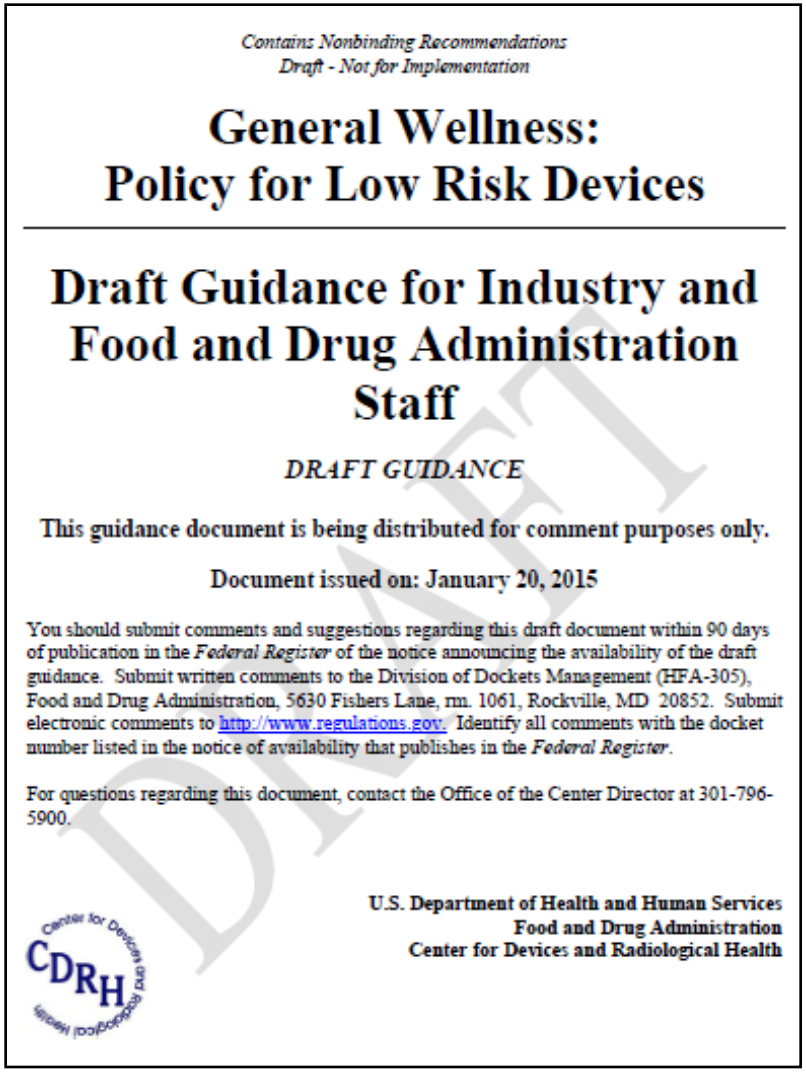
Medical Device?

WATCH

Design Challenges-Standards & Regulation

Examples of Low Risk General Wellness Products:

- …plays music to "**soothe and relax**"…and to "**manage stress**"
- …monitors and records **daily energy** expenditure…
- …monitors and records **food consumption**…
- …monitor the **pulse rate** during exercise and hiking……
- …**exfoliate** the face, hands and feet to make the skin smoother and softer



Contains Nonbinding Recommendations
Draft - Not for Implementation

General Wellness: Policy for Low Risk Devices

Draft Guidance for Industry and Food and Drug Administration Staff

DRAFT GUIDANCE

This guidance document is being distributed for comment purposes only.

Document issued on: January 20, 2015

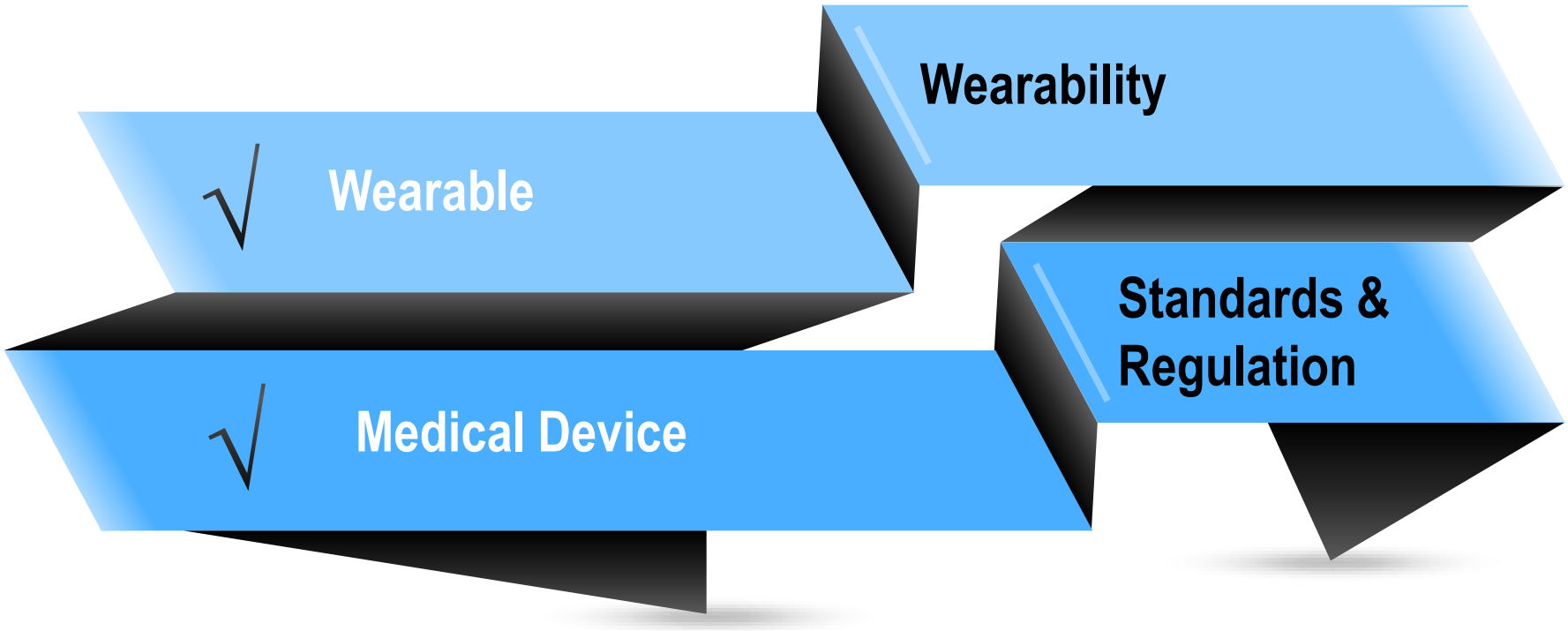
You should submit comments and suggestions regarding this draft document within 90 days of publication in the *Federal Register* of the notice announcing the availability of the draft guidance. Submit written comments to the Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Submit electronic comments to http://www.regulations.gov. Identify all comments with the docket number listed in the notice of availability that publishes in the *Federal Register*.

For questions regarding this document, contact the Office of the Center Director at 301-796-5900.

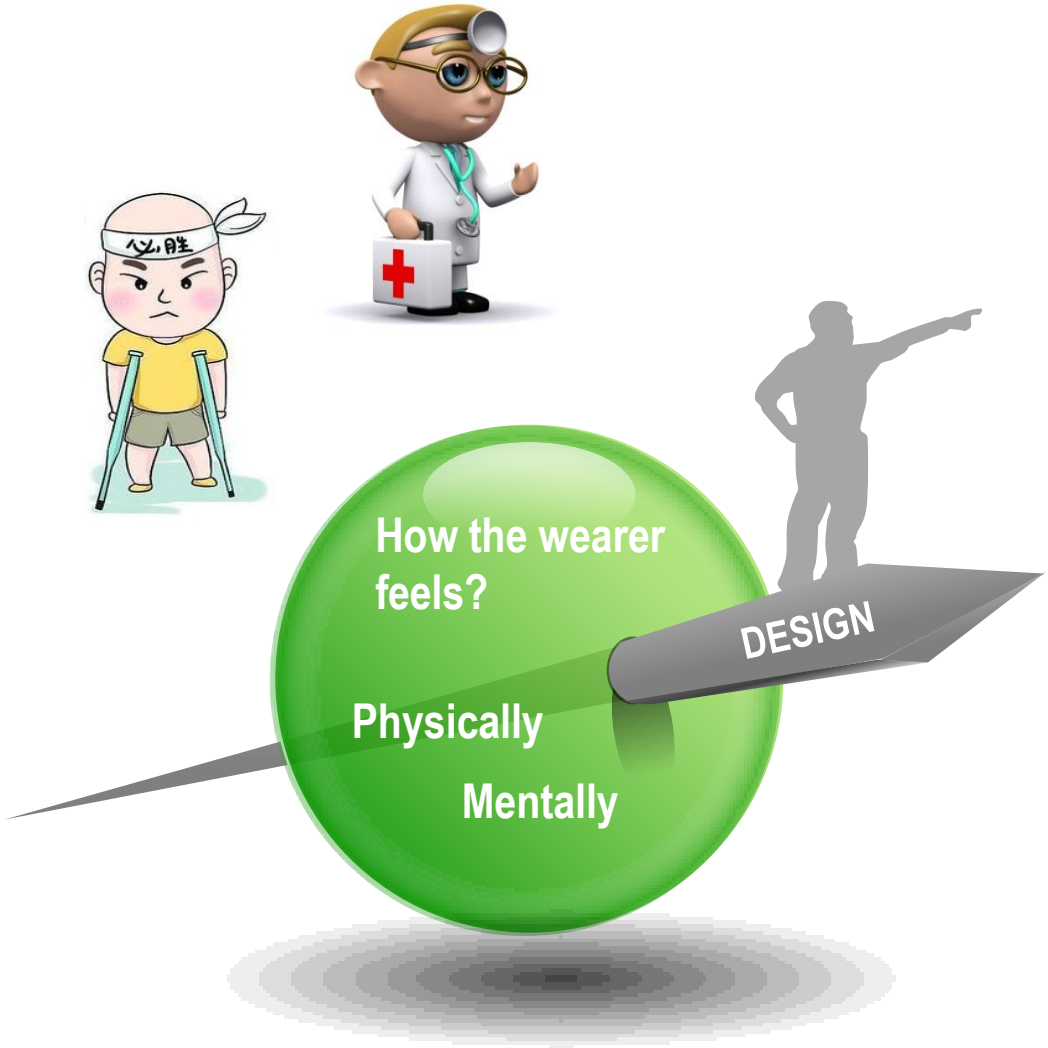
U.S. Department of Health and Human Services
Food and Drug Administration
Center for Devices and Radiological Health

DRAFT

Design Challenges of Wearable Medical Device

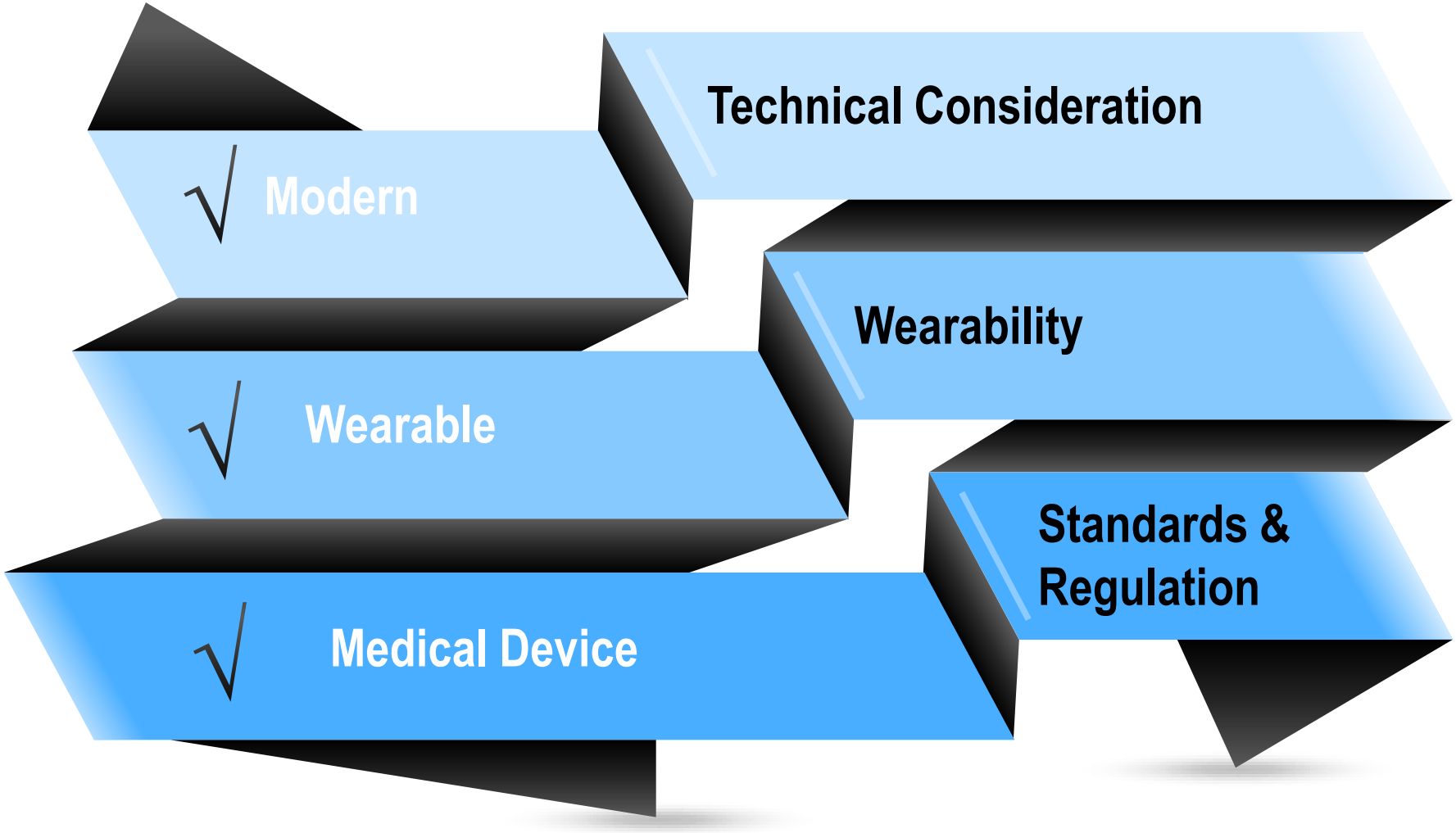


Design Challenges-Wearability

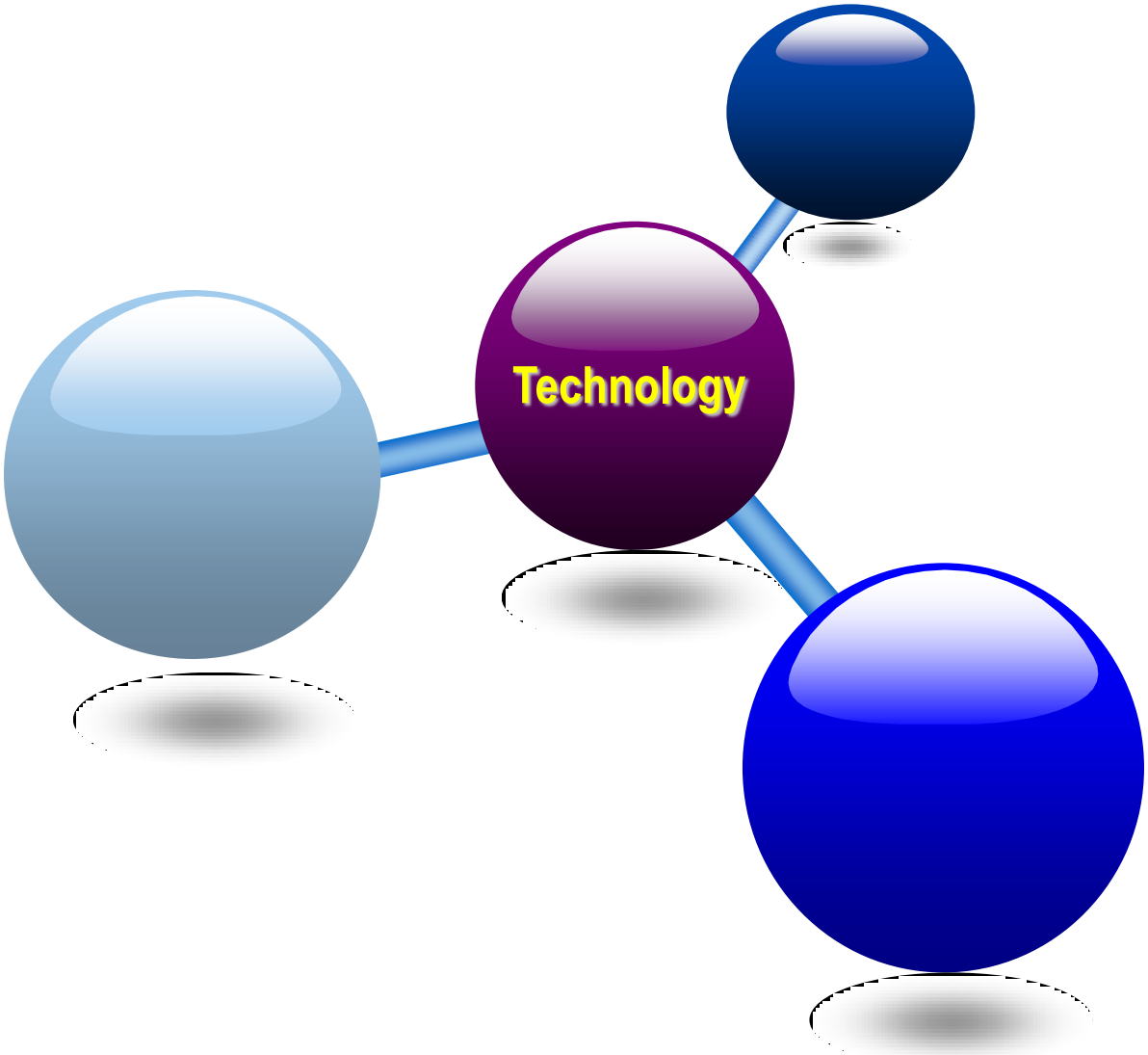


- Placement
- Sizing
- Weight
- Attachment
- Containment
- Human Movement
- Sensory Interaction
- Thermal Aspects
- Long-term Effects
- Aesthetics

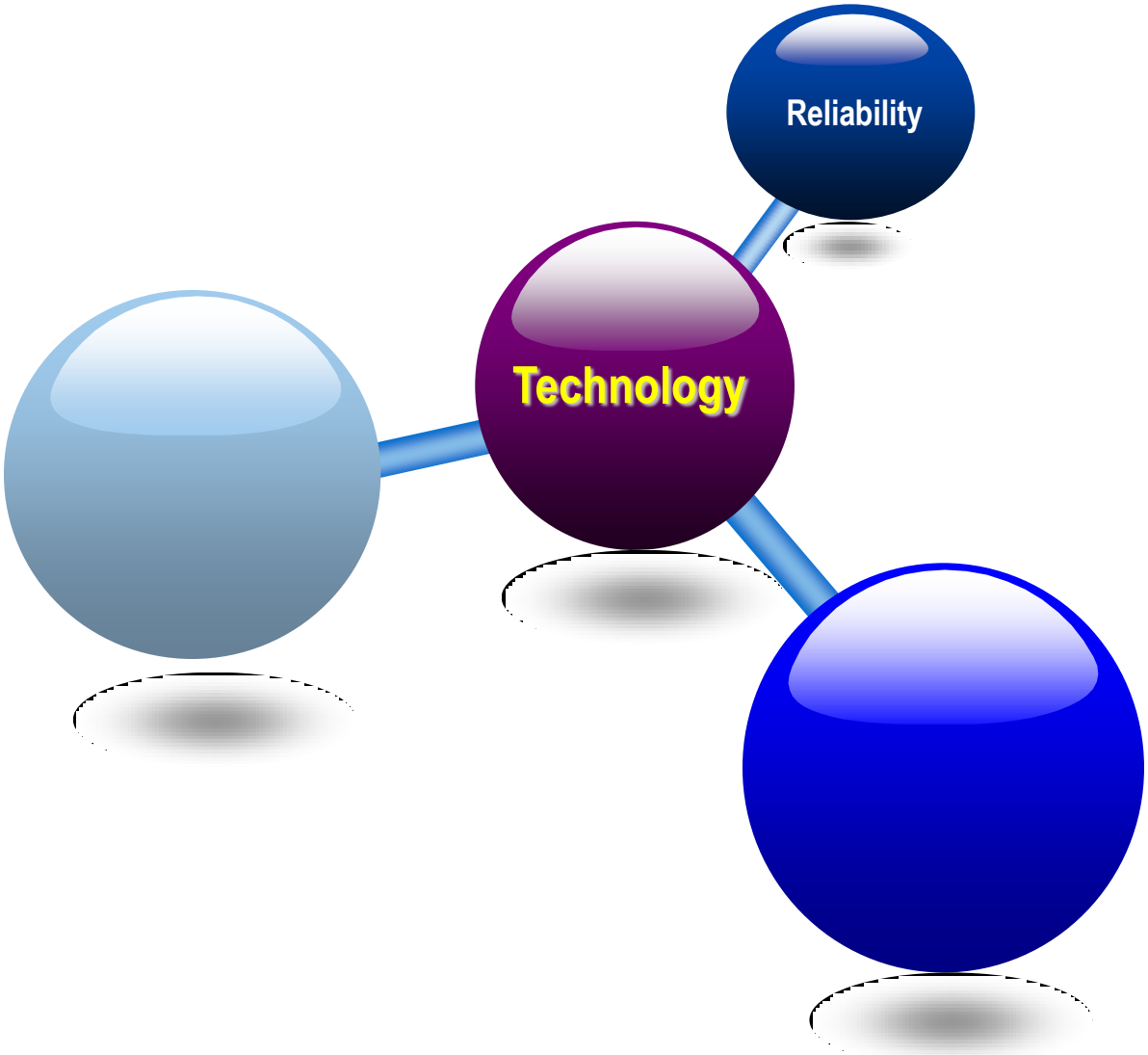
Design Challenges of Wearable Medical Device



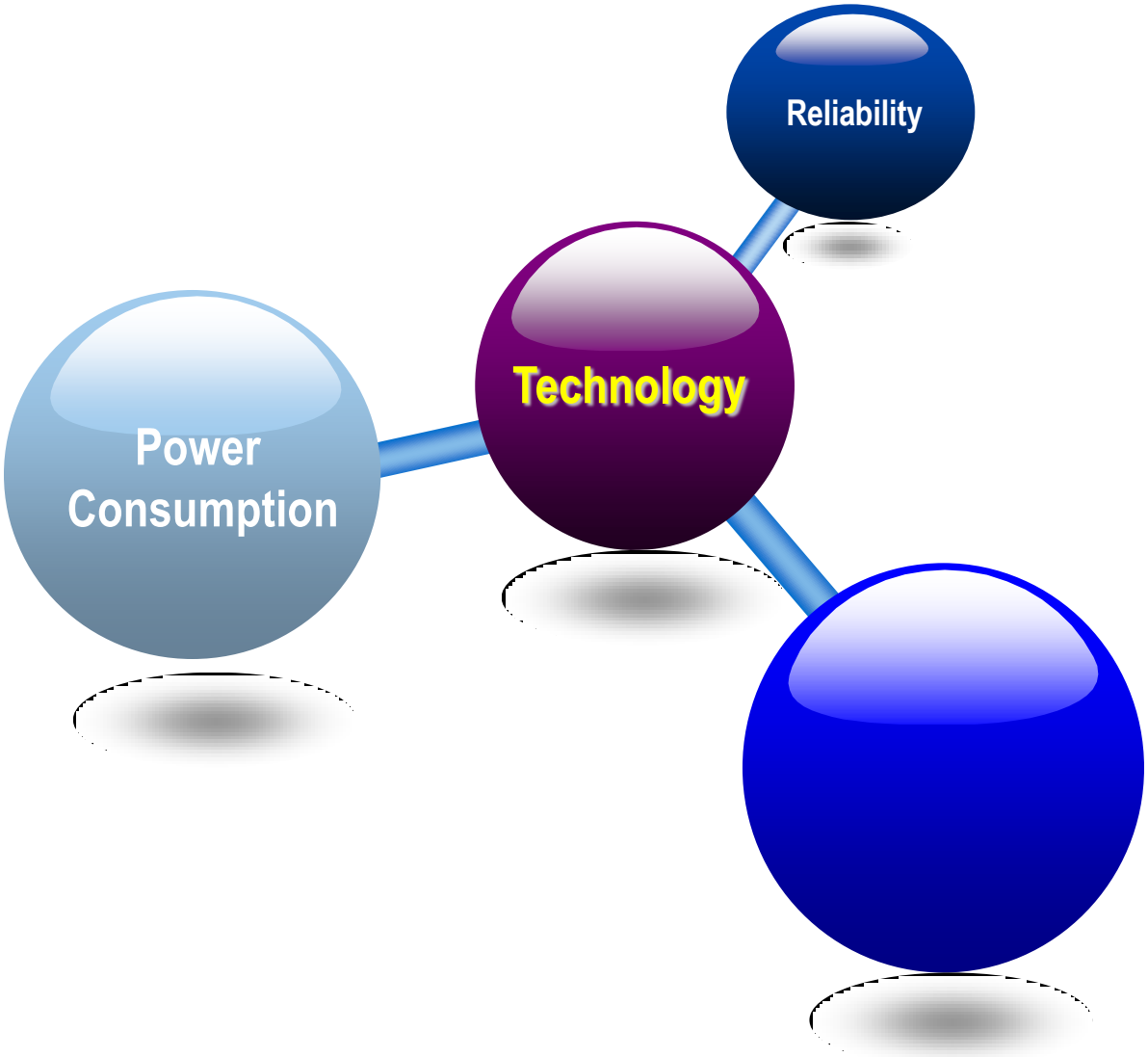
Design Challenges-Technical Consideration



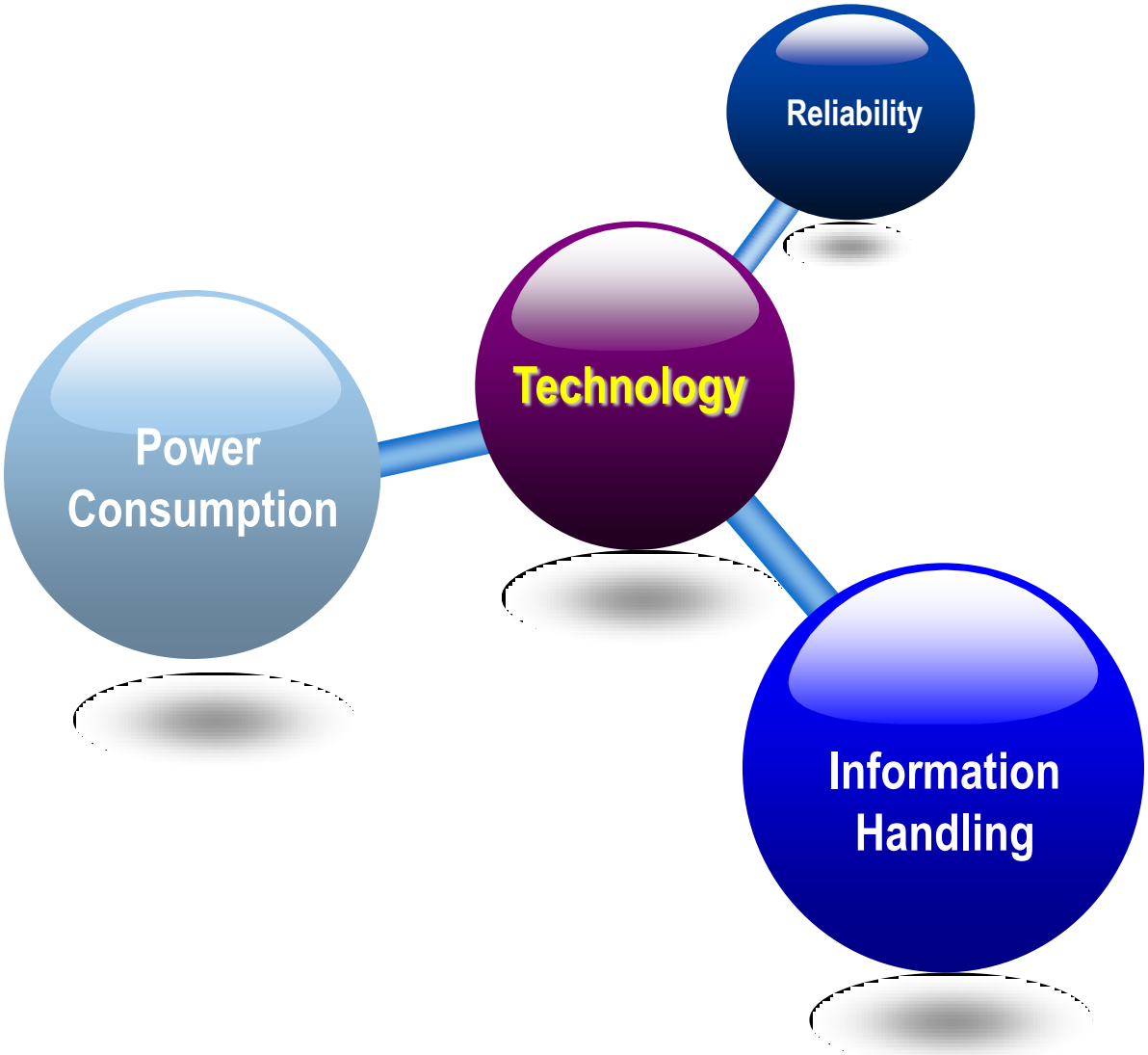
Design Challenges-Technical Consideration



Design Challenges-Technical Consideration



Design Challenges-Technical Consideration

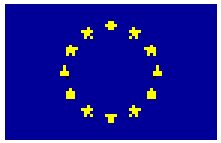


01 Development of Wearable Medical Device

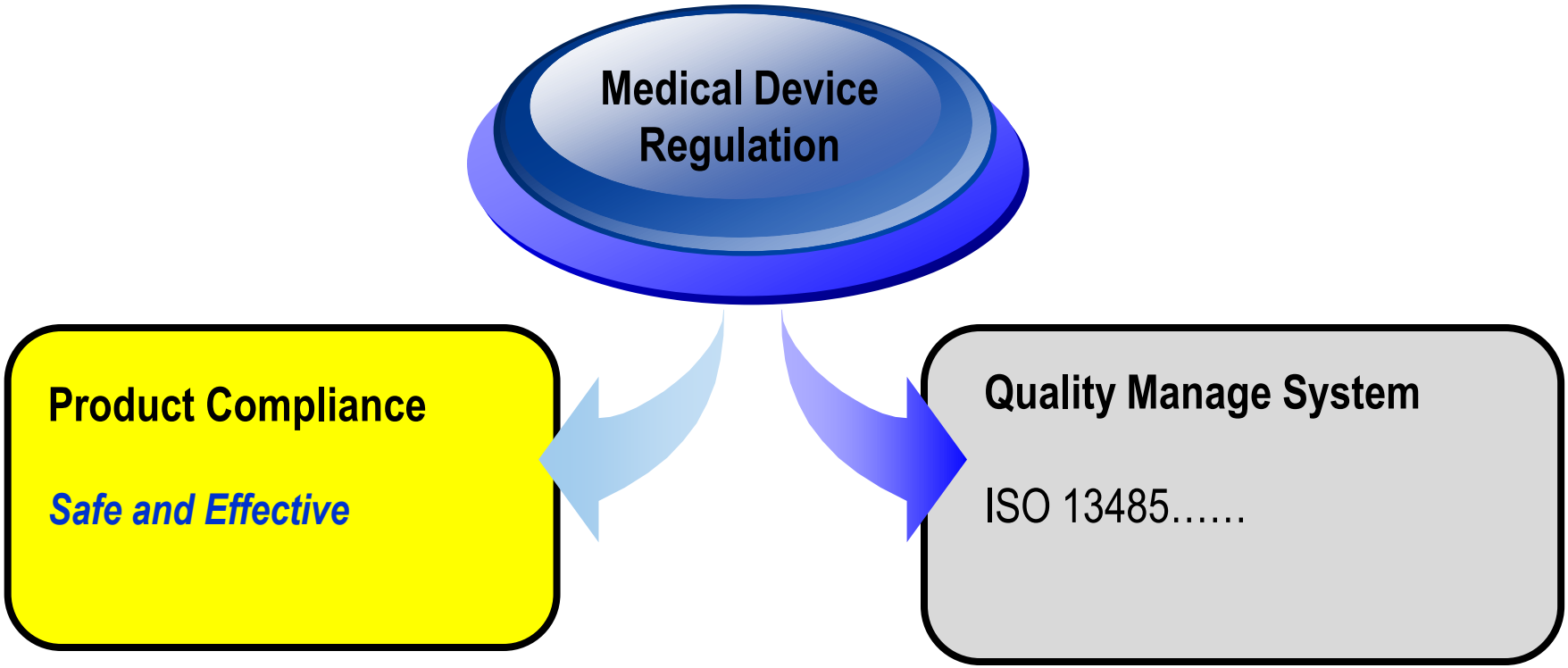
02 Design Challenges of Wearable Medical Device

03 **Design Requirements Based on Regulations**

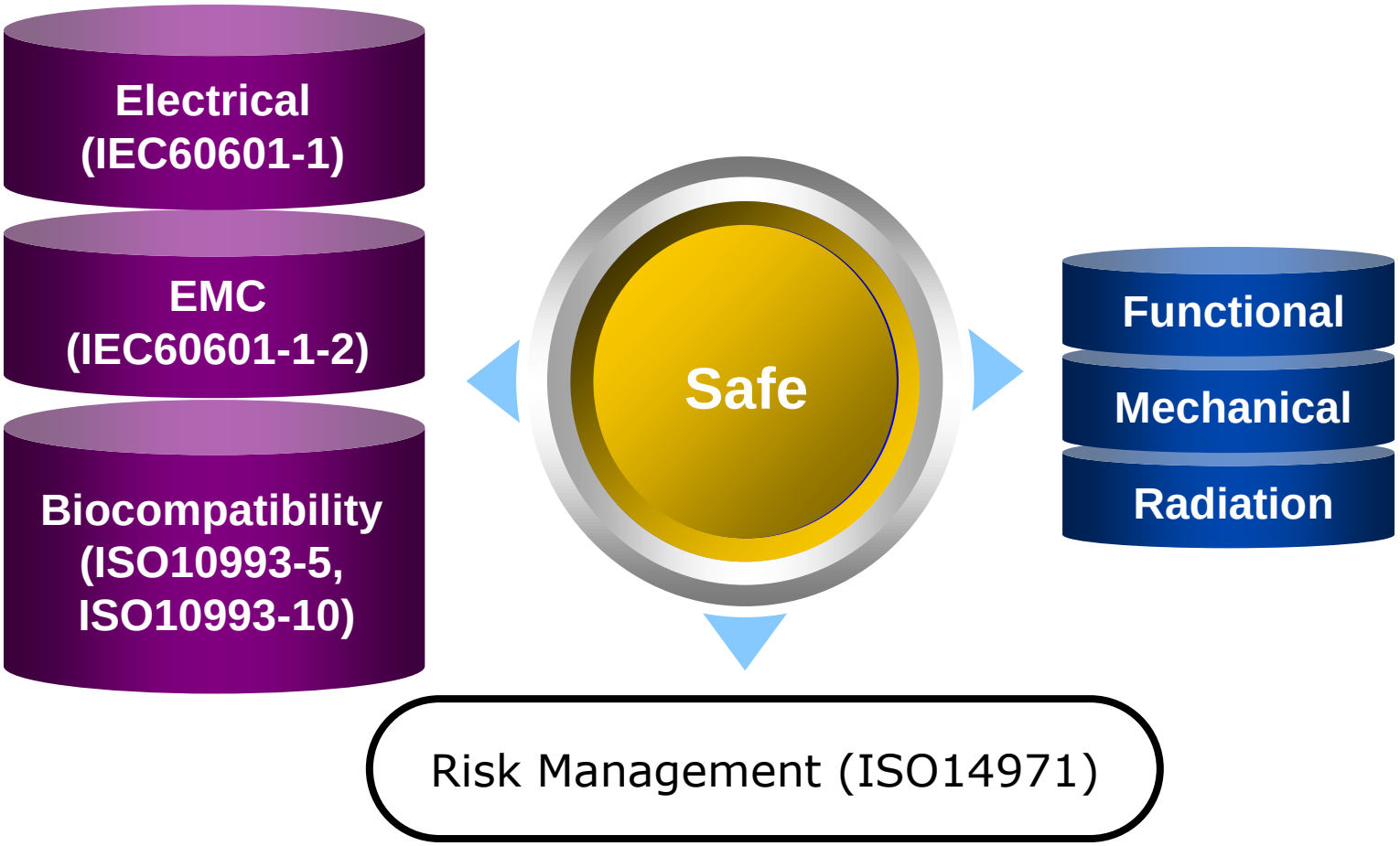
Regulations for Medical Devices

Country/Region 国家/地区	EU欧盟 	U.S美国 	Canada加拿大 	Japan日本 	Brazil巴西 	China中国 
Regulation 医疗器械上市监管法规	医疗器械三大指令 **MDD 93/42/EEC** IVDD 98/79/EC AIMD 90/385/EEC	Federal Food Drug and Cosmetic Act 《联邦食品、药品和化妆品法》 21 CFR 联邦法律第21条	CMDR	PMD Act (Since 2014.11.25) 医药医疗器械法案	**RDC No.185** of 22, Oct., 2001	Regulations for the Supervision & Administration of Medical Devices 医疗器械监督管理条例
Certification body 上市批准机构	Notified Bodies 第三方公告机构 (TÜV SÜD)	**FDA** 部分产品文件可由3rd party reviewer制定的第三方评审机构评审	**Health Canada** 加拿大卫生部	**PMDA** RCB(TÜV SÜD)	**ANVISA**	**SFDA**
QS requirements 体系要求	EN ISO 13485:2012 /AC:2012	Quality System Regulation 21 CFR Part 820	CMDCAS ISO 13485	JGMP	BGMP	GMP
Standard 标准	EN	UL AAMI ANSI	CSA	JIS	ABNT NBR	GB, YY

Regulations for Medical Devices



Design requirements based on regulations



Design requirements based on regulations

Choose certainty.
Add value.

Thank You!

www.tuv-sud.com
info@tuv-sud.com