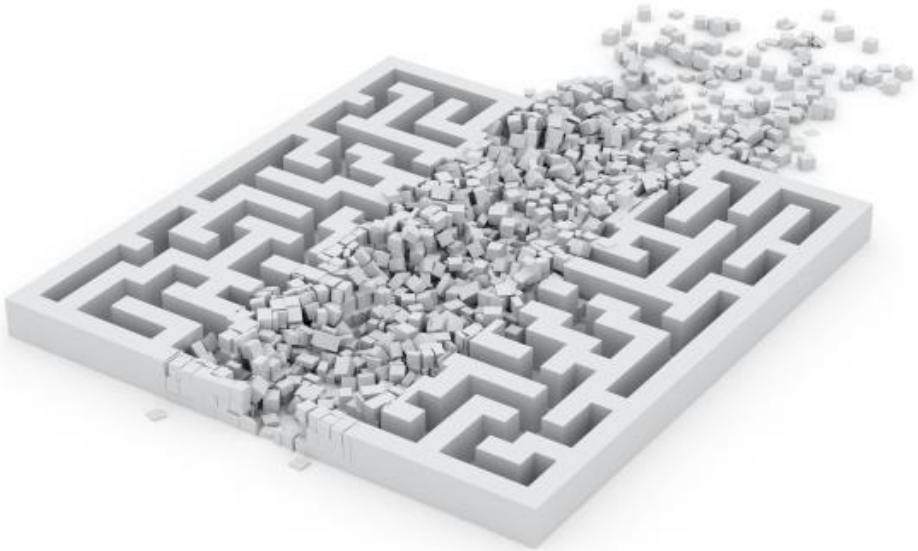
Commercialization 101

A Primer for Medical Imaging Innovators

March 26, 2015



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Today's Presenter:

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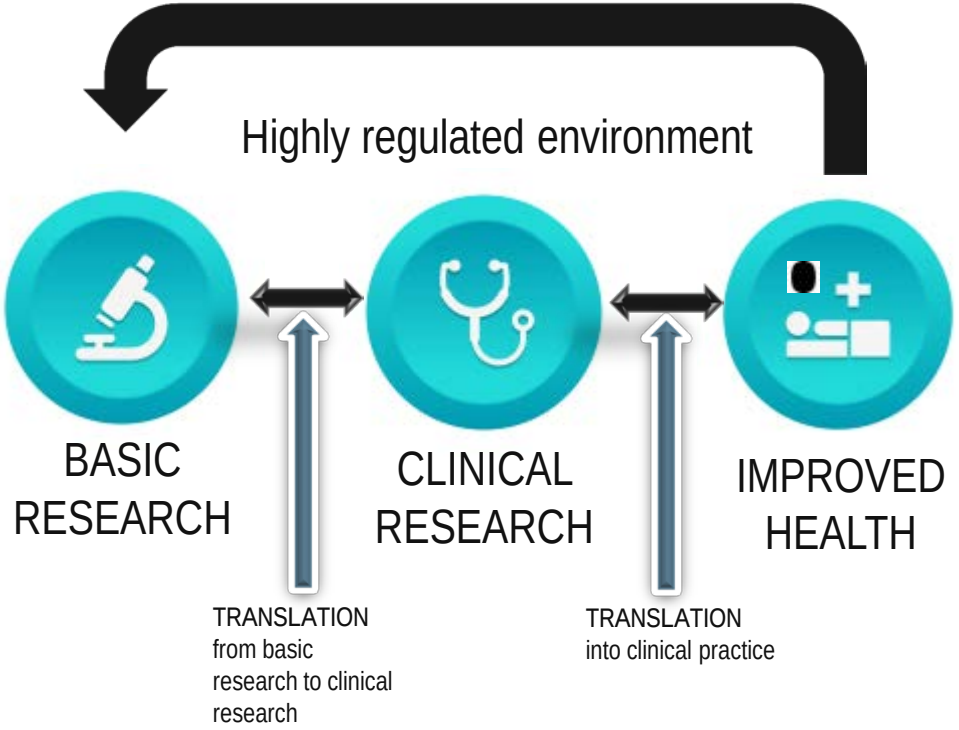
From Bench to Bedside



- Go-to-market strategy
- Understand the pitfalls
- Minimize risk

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Product Concept

- User requirements
- Market and product requirements
- Functional specifications
- Proof-of-concept
- Identify critical risks prior to building prototype

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The Business Plan

- Key opportunity
- Monetization strategy
- Funding requirements
- Development costs vs. Return on Investments
- Markets/marketing
- Market size and opportunity
- Risks
- Partnerships
- Clinical/Regulatory
- Intellectual property
- Quality management systems

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Monetization Strategy

Establish partnerships

Spin-off creation

Merger/acquisition

Licensing

Funding Strategy

- Public funds
  - Federal grants
  - Provincial grants
  - Awards

- Private funds
  - Venture capital
  - Angel investors
  - Friends
  - Family
  - Bank loans

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for Seeking Funding

- Real problem and clear solution
- Superior clinical results at lower costs
- Ability to pass through the Value Analysis Committee
- Large, addressable market
- Reimbursement
- Attractive business model
- Quality management team
- Realistic financial forecasts

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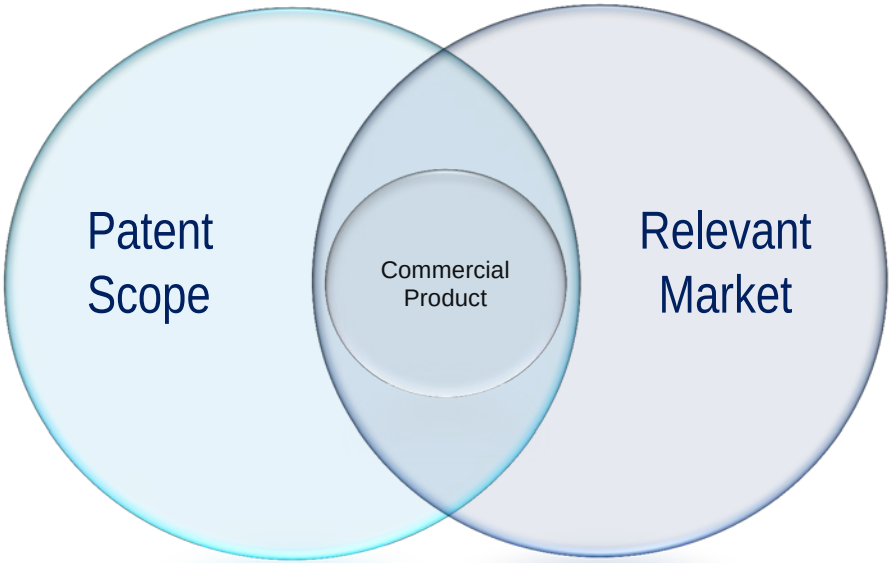
Source: Rik Vandevenne, Director of Capital Funds, River Cities Captial Funds, SEMDA January 2014 Newsletter

IP Protection

- Consider all methods for protecting and exploiting assets
- Secure intellectual property rights early in device ideation and development
- Competitive advantage
- Do not take the “do-it-yourself” approach
- Conduct patentability assessment
- Determine your freedom to operate
- Make sure you own your IP outright



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Customer/Market Research

- New opportunity evaluation
- Unique selling proposition/product positioning
- Target market
- Market size/growth potential
- Needs of payers and users
- Competitive intelligence
- Pricing research
- Human factors considerations
- Identify product characteristics to address market needs/ Product refinement

Regulatory Strategy

- Classification of device dictates route, cost, time-to-market
- Global access considerations
- Reimbursement plan
- Meet with FDA early
- Align regulatory activities with business objectives and strategy for that product
- Starts with the collaboration of a cross functional team to identify important questions about the product

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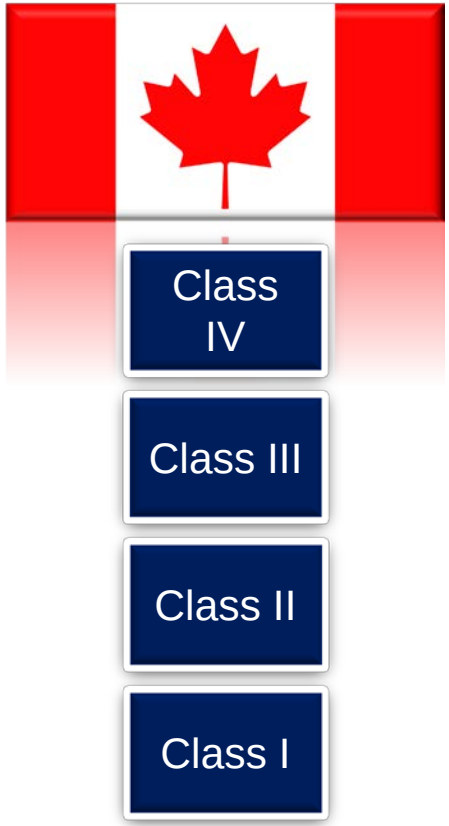
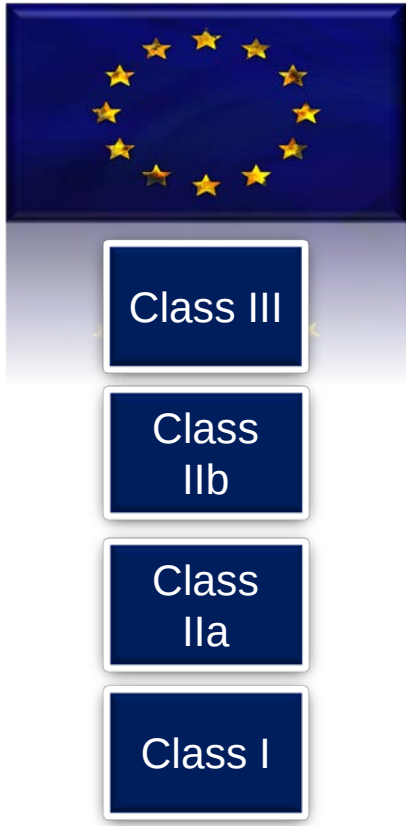
Medical Device Classification





Intended Use/Indication for Use

"Intended use" means the general purpose of a device, or what the device does, and encompasses the indications for use

"Indications for use" describes the disease or condition the device will diagnose, treat, prevent, cure, or mitigate, including a description of the patient population for which the device is intended.

Source: The 510(k) Program: Evaluating Substantial Equivalence in Premarket Notifications [510(k)] Guidance for Industry and Food and Drug Administration Staff

Medical Device License and Registration

Device Class	Risk	Examples	Licence Requirements
Class I	Lowest	Surgical instruments, laboratory culture media	A device licence is not required, but the establishment where it is made and/or distributed must be licensed
Class II	Low	Contact lenses, pregnancy test kits, endoscopes, ultrasound scanners	Manufacturers require a Health Canada licence before importing, selling or advertising Class II, Class III, and Class IV devices. Must meet safety and effectiveness requirements of MDR. Annual licence renewals are required.
Class III	Moderate	Orthopedic implants, glucose are required monitors, dental implants, hemodialysis machines	
Class IV	High	Cardiac pacemakers, angiography catheters, cranial shunts	

Routes to Market in United States

510(k) Submissions	PMA Submissions
Primarily for Class II devices	Primarily for Class III devices
A Class I or II pre-amendment or legally marketed device (predicate) exists	A Class I or II pre-amendment or legally marketed device (predicate) does <u>not</u> exist
Third party review option is available for devices not requiring clinical data	Device is life supporting and/or has potential risk to patient
Documented proof of Substantial Equivalence to a predicate is required in terms of intended use, technological characteristics, and performance testing, as needed	Documented safety and effectiveness data for the device is required

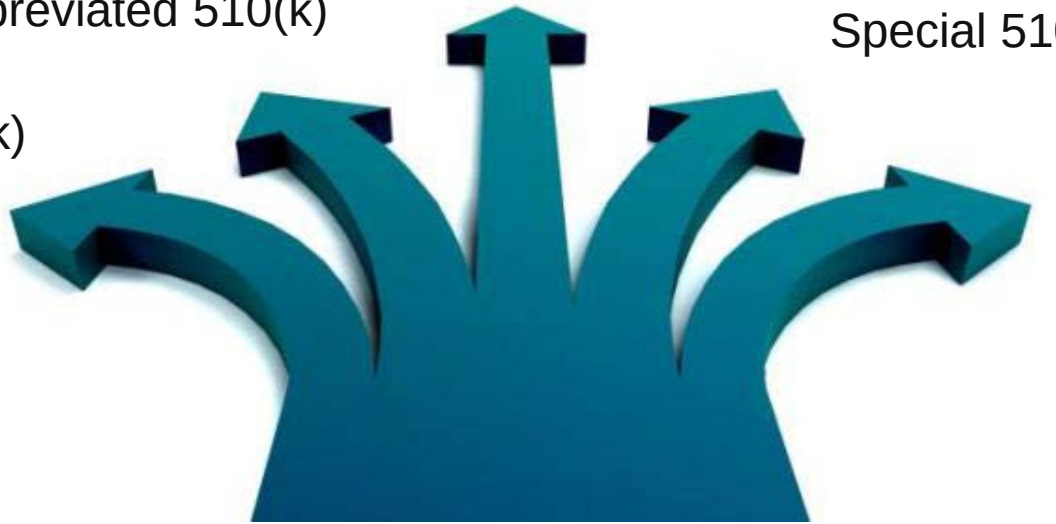
The 510(k) Paradigm

Abbreviated 510(k)

Special 510(k)

Traditional 510(k)

De novo 510(k)



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Conformity Assessment Routes

- Conformity Assessment Routes Six conformity assessment routes to acquiring the CE marking are identified in Annexes II, III, IV, V, VI, and VII of the MDD.
- Conformity assessment routes are determined by the class of the product
- Annex II – Full Quality Assurance System, III – Type Examination, IV – Product Verification, V – Production Quality Assurance, VI – Product Quality Assurance

Quality System Requirements in Canada

ISO 13485

- Quality system certificate issued by the Canadian Medical Devices Conformity Assessment System (CMDCAS)
- The Medical Devices Regulations require Class II, III, and IV medical devices to be manufactured (Class II) or designed and manufactured (Class III & IV) under CAN/CSA ISO 13485:2003
- There are no regulatory quality system requirements for Class I medical devices

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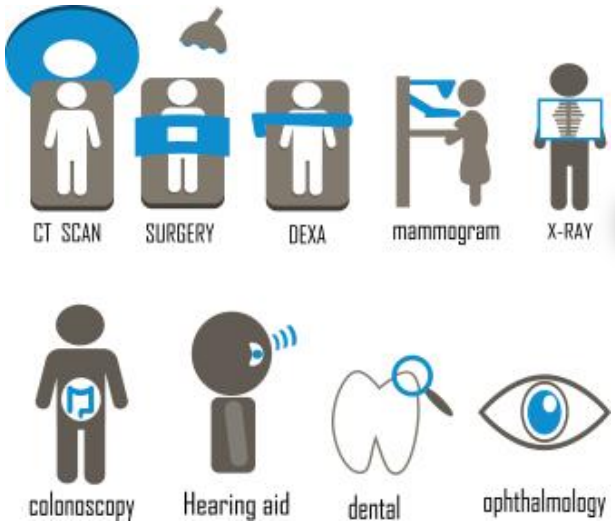
Basis of QMS Model

Customer/ market requirements



Customer satisfaction

PRODUCT REALIZATION

Quality Management System

Good Manufacturing Practice (GMP)/ Quality System Regulations

- Defined in 21 CFR 820: production and testing practices to help ensure safe and quality products
- Required for “finished” medical devices intended for commercial distribution in the United States

Covers the following:

- Quality management and organization
- Device design
- Buildings
- Equipment
- Purchase and handling of components
- Production and processing control
- Packaging and labelling control
- Device evaluation
- Distribution/Installation
- Complaint handling
- Servicing
- Records

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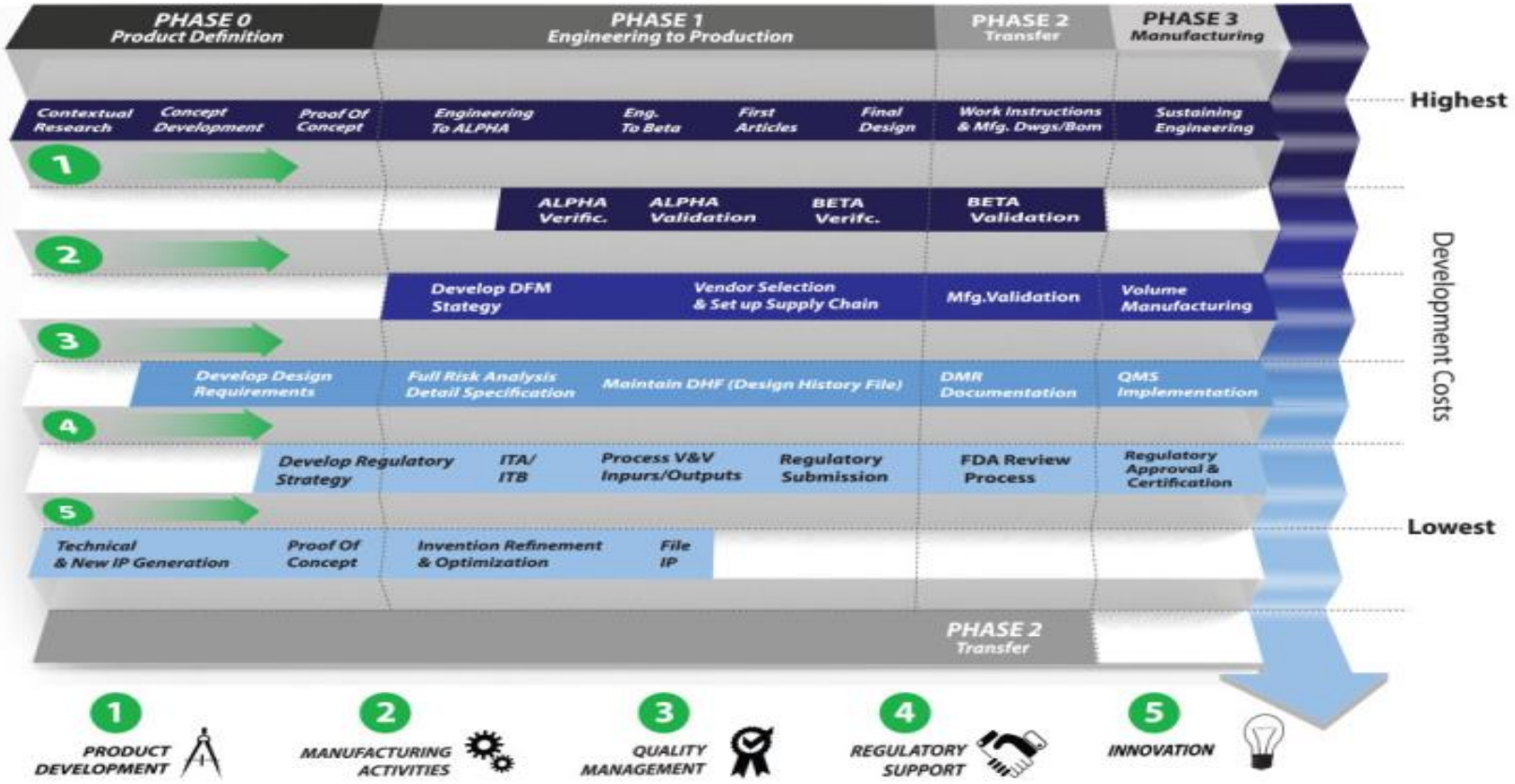
Quality System Overview for Europe

- EN (European National) ISO 13485 is a regional standard harmonized with the European Union Medical Device Directive,
- Notified Body assesses compliance with EN ISO 13485 via audits of a manufacturer's facilities and practices.

Product Development Overview

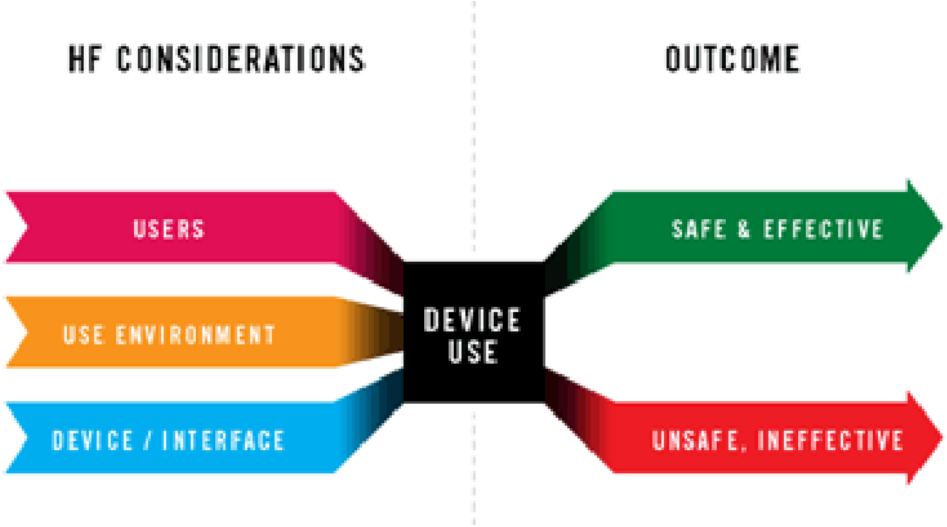


http://www.devicelab.com/services/overview/

Human Factors/Usability Engineering

Device Users

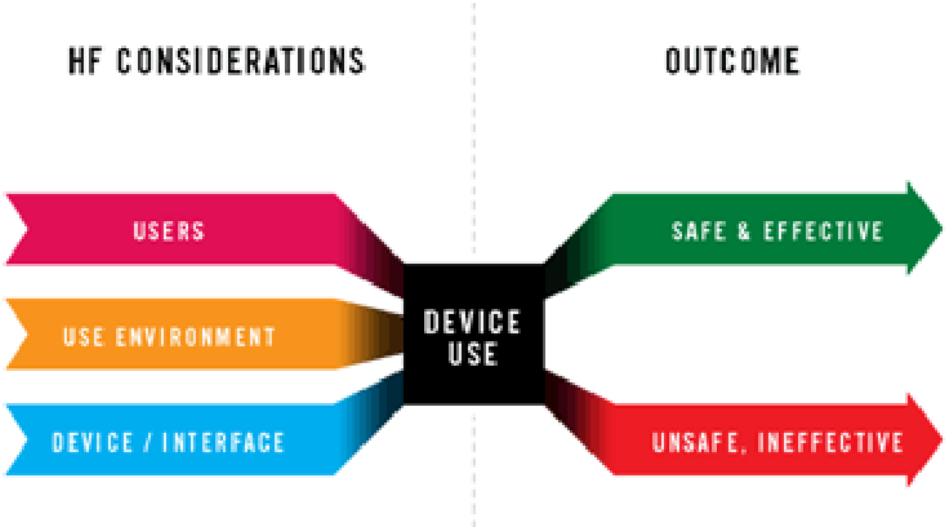
- Identification of the end-users of the device
- The level of training users will have/receive
- User characteristics that could impact the safe and effective use of the device
- Ways in which users might use the device that could cause harm



Source: FDA Draft Guidance Applying Human Factors and Usability Engineering to Optimize Medical Device Design

Human Factors/Usability Engineering

Environment



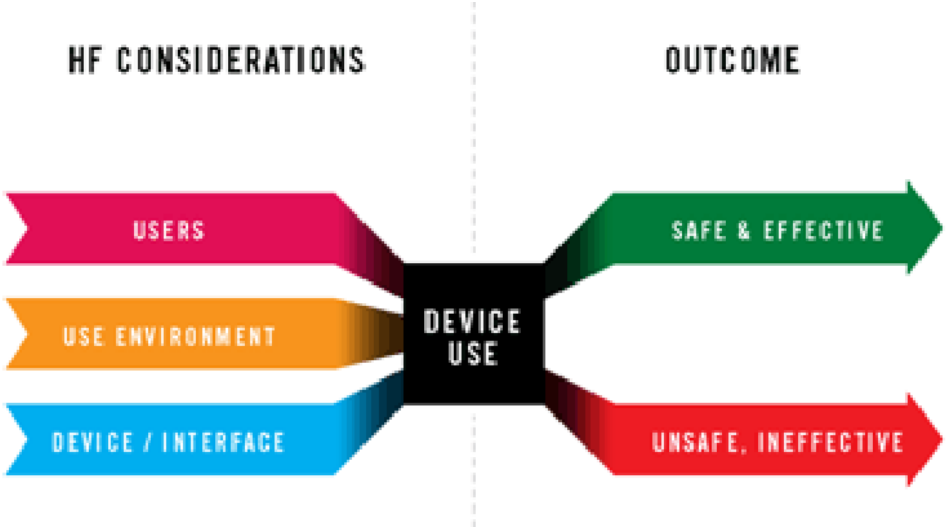
- Hospital, surgical suite, home, emergency use, public use, etc.
- Special environments
- Interoperability with other devices
- Manoeuverability, lighting, noise, crowding

Source: FDA Draft Guidance Applying Human Factors and Usability Engineering to Optimize Medical Device Design

Human Factors/Usability Engineering

Interface

- Functions, capabilities, features, maintenance requirements
- Indicated uses



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Source: FDA Draft Guidance Applying Human Factors and Usability Engineering to Optimize Medical Device Design

Clinical Testing

Feasibility/Pilot Study

- Conducted early
- Evaluate the device design product
- Establish performance characteristics
- Establish preliminary safety and effectiveness
- Explore eligibility criteria
- Aid in the design of the pivotal clinical study

Pivotal Study

- Determine safety and effectiveness of a device for a defined intended use, in a certain patient population and in a statistically justified number of subjects
- Involves one or more studies
- Final product configuration

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Clinical Testing

Address the following characteristics/features:

1. How and why the device works, i.e., the scientific principles underlying the device function and mechanism of action.
2. Required level of skill and training for user.
3. Expected learning curve for the user.
4. Consideration of human factors, including the user interface, the user's expectations of the device and the user's abilities and training.

Regulatory Clearance/Approval

- Choose the correct predicate device
- Describe the device and intended use correctly
- Understand the regulations and guidance documents
- Ensure you have obtained all required clinical and performance testing data

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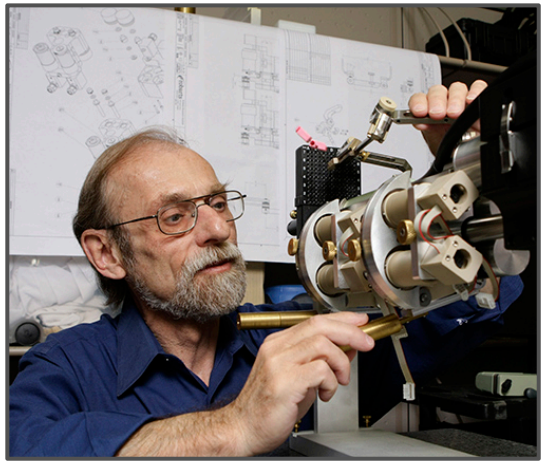
www.cimtecimaging.com



Technology Development

Business Development

Clinical Testing

Thank You!

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Centre for Imaging Technology Commercialization