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A REVIEW OF DESIGN FOR X METHODS FOR MEDICAL DEVICES: THE INTRODUCTION OF A DESIGN FOR FDA APPROACH

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Outline

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- FDA
  - Literature about the FDA
  - Overview of the FDA regulations
- DfX for Medical Devices
  - DfX
  - Relevant DfX methods
  - DfFDA
- Conclusions and Future Work

Objective

- Identify relevant Design for X (DfX) concepts for medical device development.
- Introduce the Design for FDA (DfFDA) concept to increase awareness about regulatory compliance and to complete the DfX framework for medical devices.
- DfFDA is proposed as a method to be used in parallel with other DfX methods when applicable. The DfX methods identified include:
  - Design for Validation (DfV)
  - Design for Reliability (DfR)
  - Design for Quality (DfQ)
  - Design for Manufacturing (DfM)
  - Design for Assembly (DfA)
  - Design for Usability (DfU)

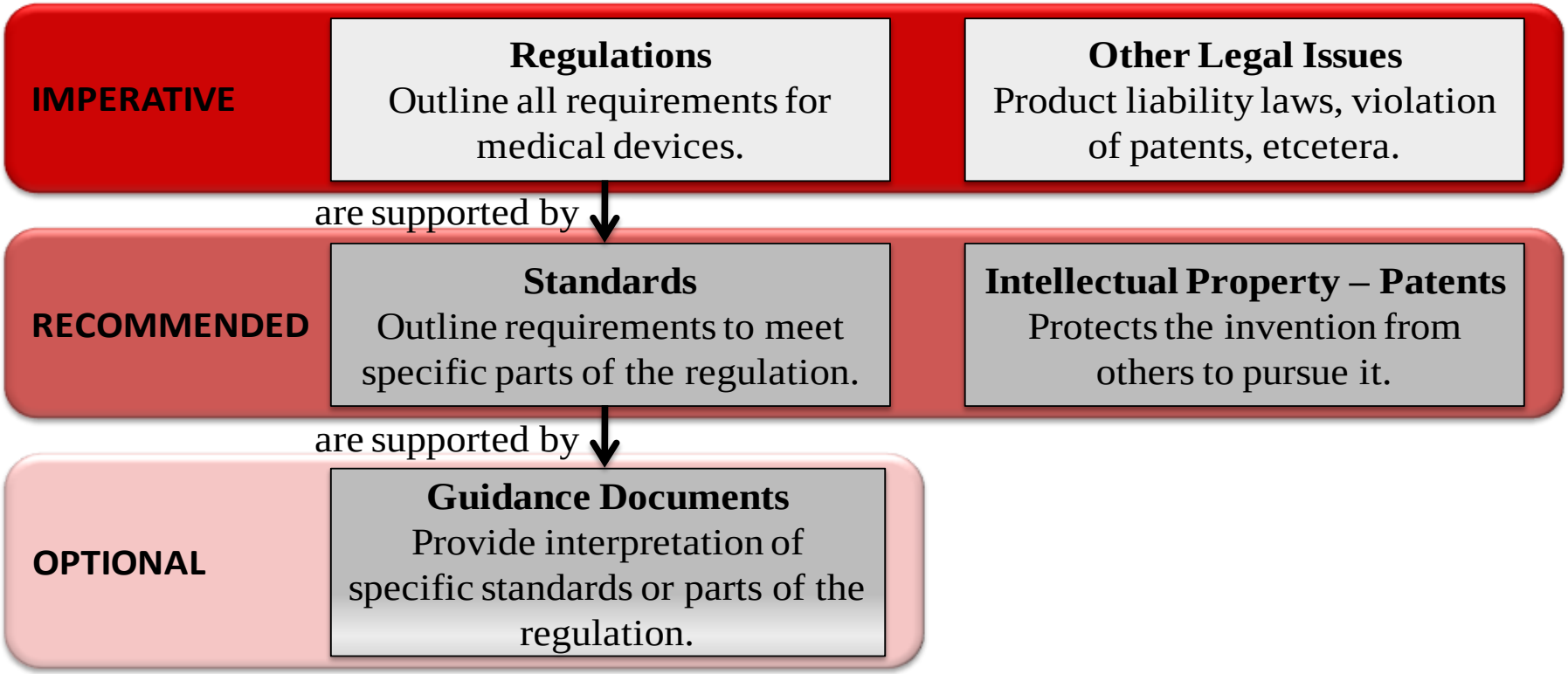
Motivations

Motivations

- AdvaMed (2003)'s survey reported the FDA as 1st factor:
  - affecting companies' ability to develop new medical technology
  - influencing companies' product development priorities
- FDA regulation components are considered at every stage of the development process (Pietzsch et al., 2009).
- The FDA is an inhibitor factor for discovery, while NIH promotes it(Foote, 1996).
- The FDA regulation impacts all the stakeholders of medical device development due to their absolute power over the specification of requirements for medical devices.
- Studies addressing the FDA regulations show the importance of FDA and need for DfFDA. Current DfX methods are not sufficient.

Motivations

- Development environment:



Adapted from Alexander and Clarkson (2000)

Literature about FDA

- FDA regulations are reviewed to inform specific stakeholders in the context of specific components of the regulation or particular applications.
  - Publications focus on physician, manufacturers , engineers and designers.
  - Saviola (2005) looked at the FDA's role in clinical studies with human subjects for retinal visual prosthetic devices.
  - Ciarkowski (2000) described the FDA regulations for medical devices with an automatic control system.
- Relevant topics include: legal/ethical issues, risk management, manufacturing safer products, reducing liability costs, market surveillance, and improvement of the regulations.
- Contemporary issues include: combination products and harmonization of the regulations.

Overview of the FDA Regulations

- Device classifications
  - Panel review
  - Product code
  - Risk-based classifications
- Pathways for approval
  - Exemptions
  - Premarket Notification (510(k))
  - Premarket Approval (PMA)
  - Humanitarian Device Exemption
- QS regulation
- Post-market requirements

FDA's role in the regulation of medical devices consists of the **risk assessment of the tradeoffs** between assuring:

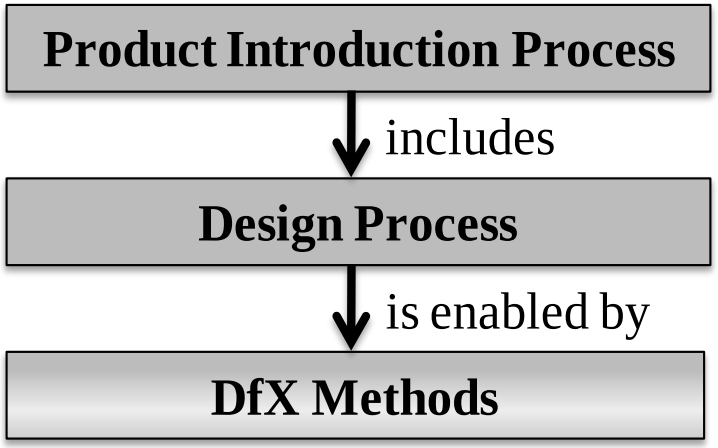
(1) complete safety and effectiveness

(2) rushing a product into the market

FDA CDRH Center for Devices and Radiological Health

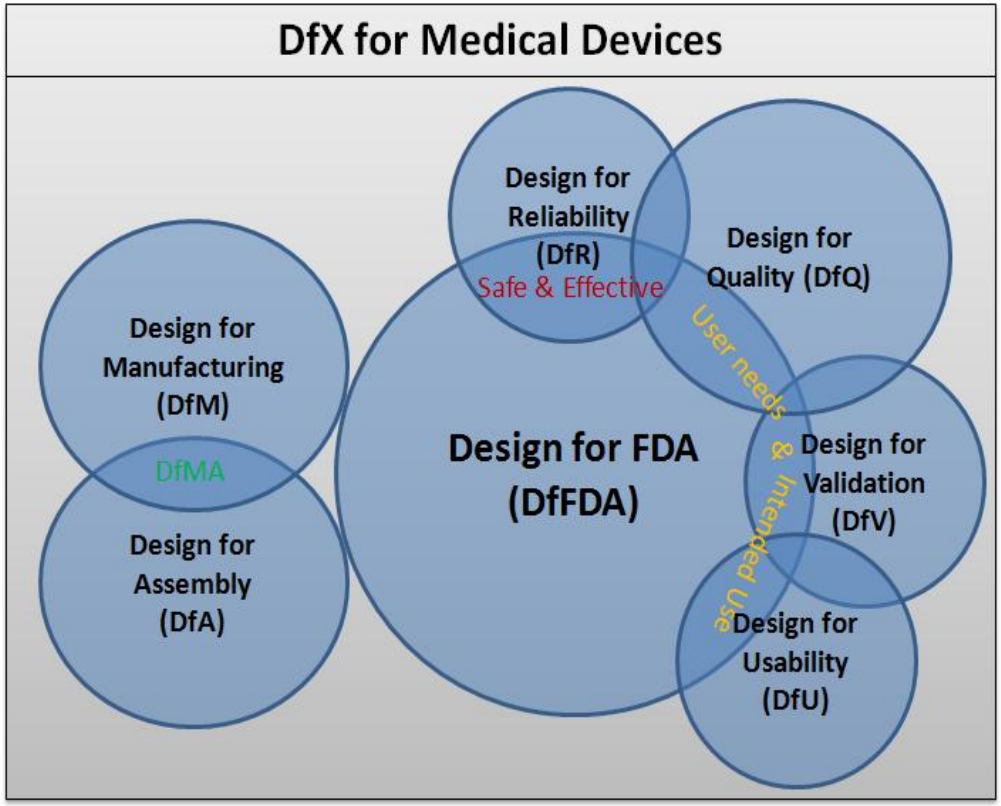
DfX

- The application of DfX methods has been identified by Alexander and Clarkson (2000) as a good design practice for medical device development.
  - Recommended with a concurrent engineering approach.
- Chiu and Okudan (2011) defined the DfX methods in three ranges of perception: product s, system and eco-system scope.
  - For medical devices development the product scope is considered.



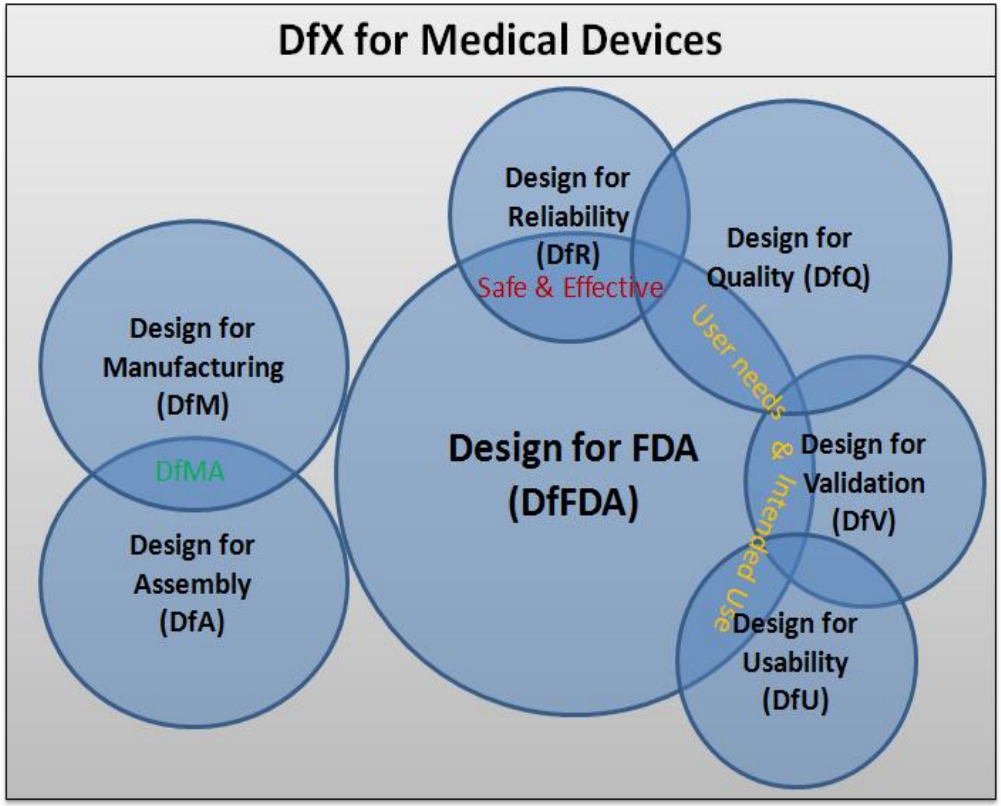
Modified from Alexander and Clarkson (2000)

Relevant DfX Methods



- DfM – should be addressed early in the development process in parallel with the device concept and prototype development
- DfA - part of the concept generation process to minimize the number of parts and assembly operations, and to have an ease to assemble geometry
- DfR - plays an important role in life-supporting/life-sustaining devices, whose failure represents a life-threatening situation to the users
- DfV – assuring satisfaction of user needs and conformity with the intended use

Relevant DfX Methods

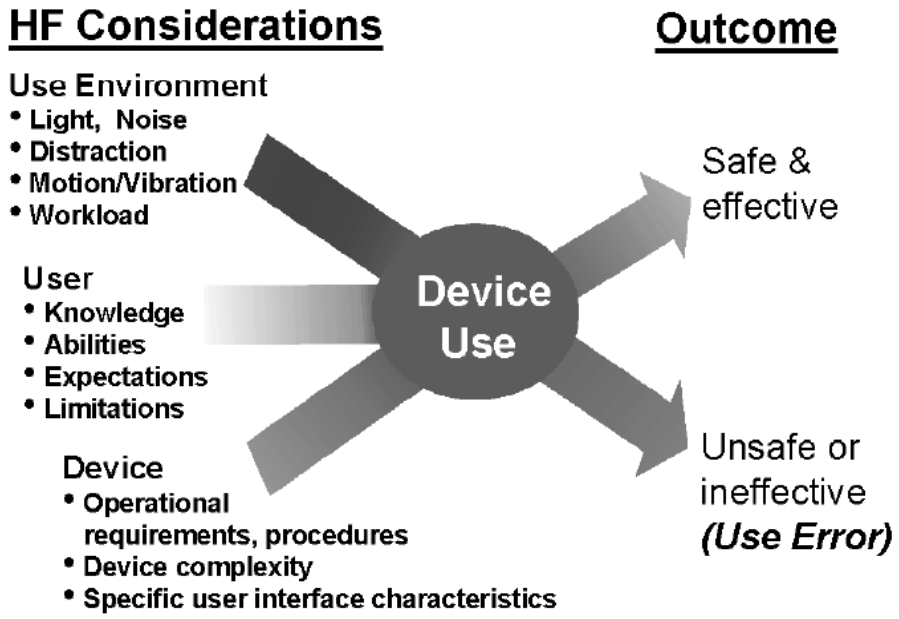


- DfQ - meeting customer requirements, having enough robustness to minimize the effect of changes in the product's manufacturing or environment, and being able to continuously improve the product's reliability, performance and technology.
- DfU - making medical devices easier to use, assuring the fulfillment of user needs and the correctness of the intended use.
- DfFDA - none of the existing DfX methods focuses specifically on the regulations. The regulations are the major differentiation factor between regulated and non-regulated products.

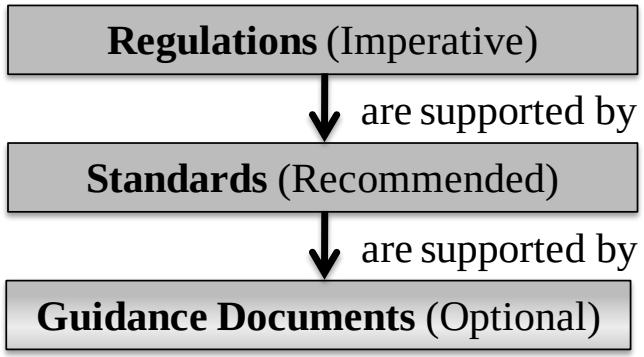
DfX for Medical Devices

DfFDA

- Considering FDA early and throughout the development process.
- Communication to close the gap between FDA and the industry.
- Incorporate human factors considerations for verification and validation.
- Considering standards and guidance documents.
- Exploiting FDA resources and being attentive to changes.



From FDA (2000)



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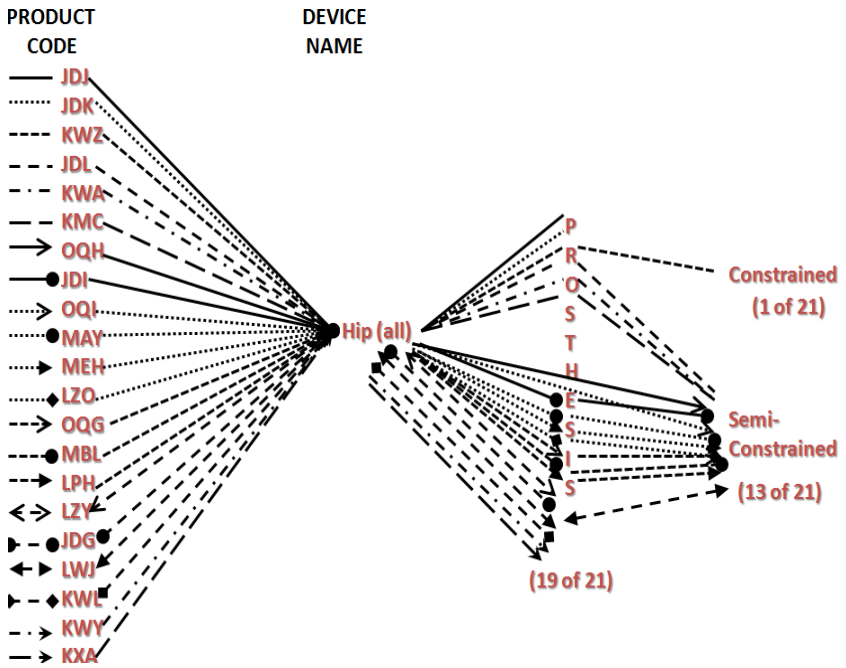
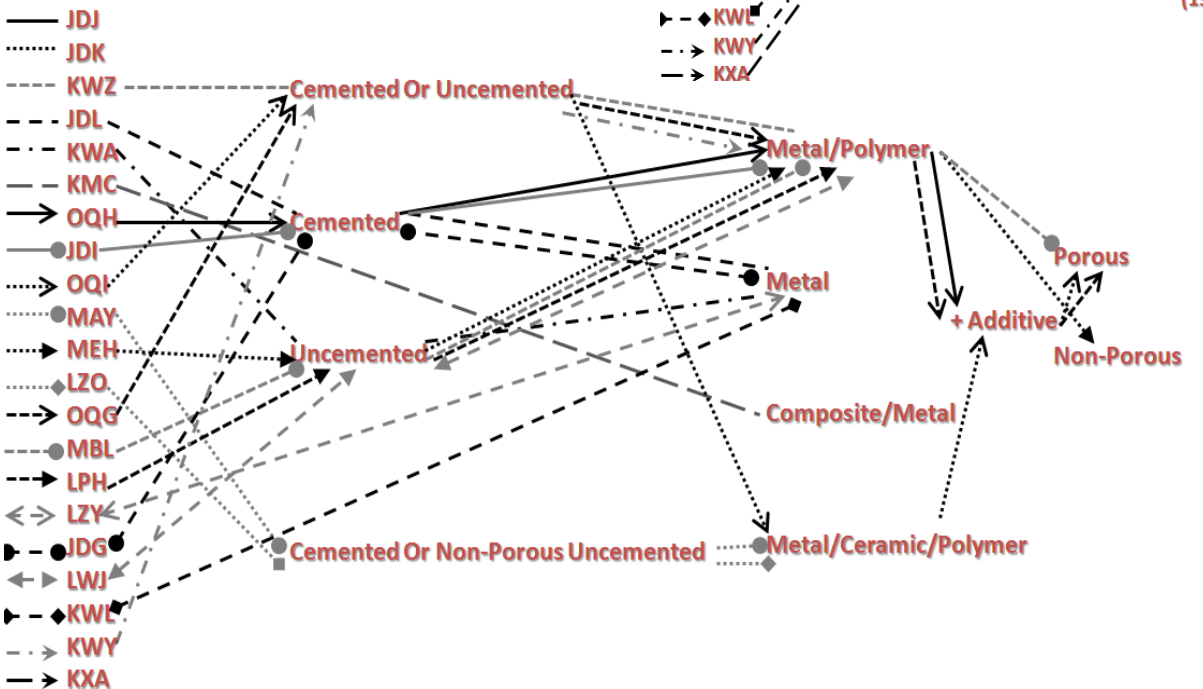
DfX for Medical Devices

DfFDA

- Paying specific attention to product code classifications.
  - Product code descriptors for hip devices





DfX for Medical Devices

DfFDA

- Obtaining feedback from experts and paying attention to the **historical reference** of the device.

Qualitative Variables	Quantitative Variables
Year of Decision	FDA Historical Reference per Product Code
Decision	FDA Historical Reference of Other Hip Devices
Submission	Company Historical Reference
Type	Number of Recognized Consensus Standards
Applicant	Number of Recognized ISO standards
Review Advisory Committee	Number of Recognized ASTM standards
Risk Classification	Number of descriptors
Regulation No.	Number of materials
Constrained/Semi-constrained	Number of components-materials
Cemented/Uncemented	Historical Reference for Constrained/Semi-constrained
Material	Historical Reference for Cemented/Uncemented ID
Porous/Non-porous	Historical Reference for Material
Other Descriptors	Historical Reference for Other Descriptors ID

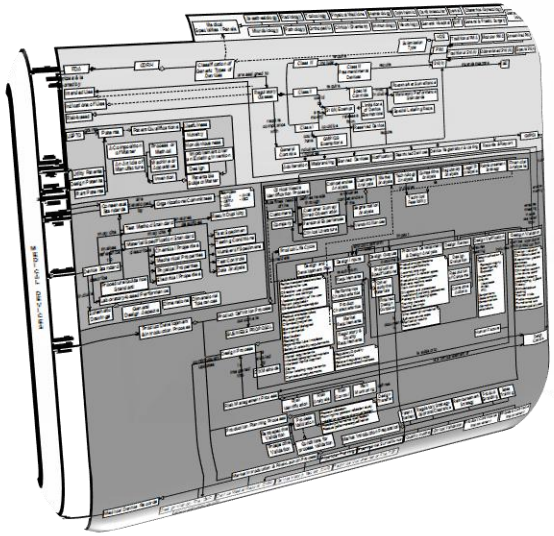
Source	DF	Type III SS	Mean Square	F Value	Pr > F
Type	3	47.71176103	15.90392034	159.03	<.0001
RegNoID	9	8.12638381	0.90293153	9.03	<.0001
OtherDesc	8	8.30910707	1.03863838	10.39	<.0001
DecisionYR	1	15.10840750	15.10840750	151.07	<.0001
Companyhr	1	1.18406573	1.18406573	11.84	0.0006
hrConstrained	1	12.37575740	12.37575740	123.75	<.0001
ReviewAdComm	7	1.77772457	0.25396065	2.54	0.0133
hrCemented	1	1.03741275	1.03741275	10.37	0.0013
hrMaterials*Decision	6	2.30289847	0.38381641	3.84	0.0008
hrConstra*hrOtherDes	1	0.85721891	0.85721891	8.57	0.0035
hrCemente*hrOtherDes	1	1.33604466	1.33604466	13.36	0.0003
hrMateria*hrOtherDes	1	0.58883795	0.58883795	5.89	0.0153
hrCemente*FDAhrProdC	1	1.54830062	1.54830062	15.48	<.0001
hrMateria*FDAhrProdC	1	1.04927784	1.04927784	10.49	0.0012

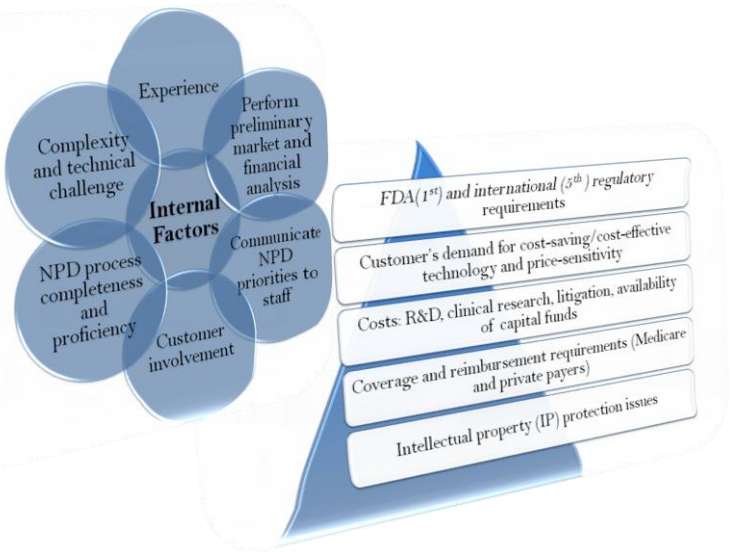
Conclusions and Future Work

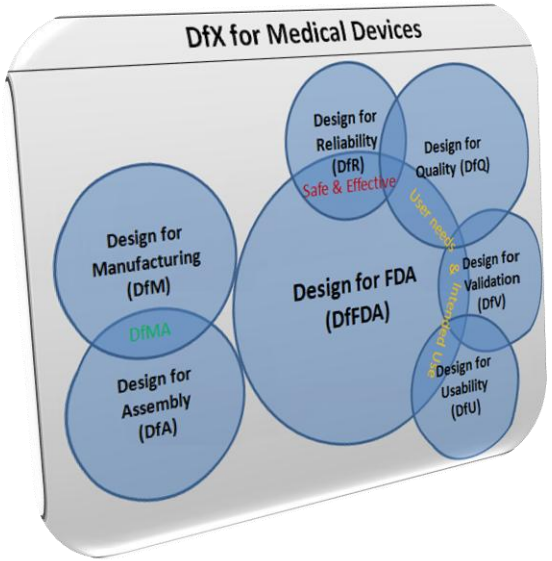
- This paper advances the existing literature addressing the FDA regulations and DfX by providing a detailed overview of the regulations and proposing a new DfX concept – DfFDA.
- DfX methods applicable to medical devices and FDA are identified and DfFDA guidelines are developed with a basis on the structure of the regulations, critical factors identified for development and contemporary issues as the challenges with innovation.
- DfFDA is developed to increase awareness about regulatory compliance and promote designers to consider the regulations throughout the development process of medical devices.

Conclusions and Future Work

- Future work relates to the integration of current research efforts that include:
  - Conceptual model of the medical device development process
  - Identification of critical factors
  - DfX for medical devices







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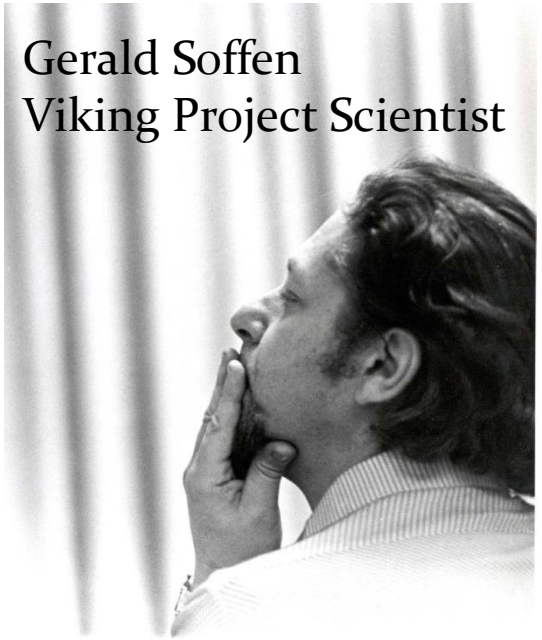

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