Design and Development for medical devices

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Usability Engineering EE-600

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Human Factors Guest Speaker

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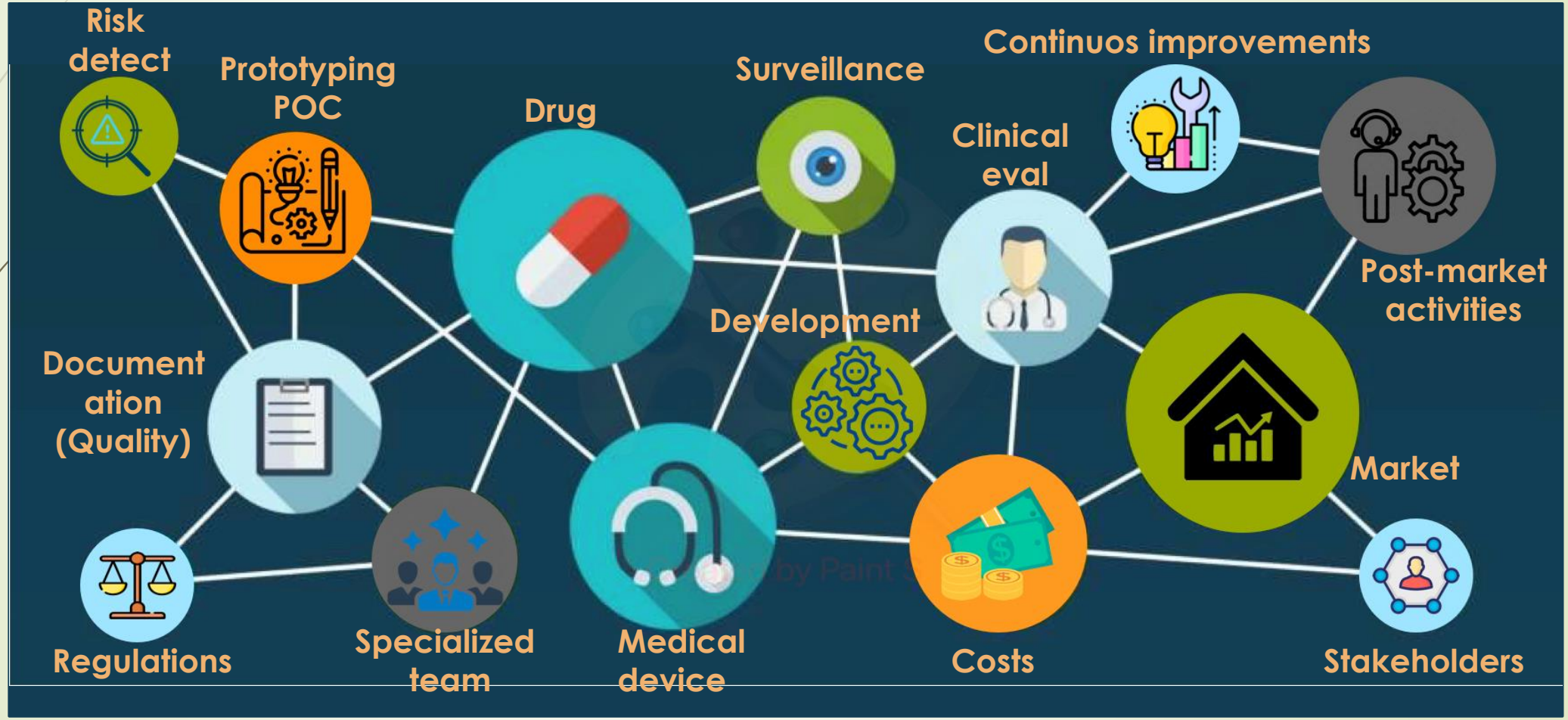
Agenda

- Theory about Medical Devices development
  - Product lifecycle
  - Human Factors activities within product lifecycle
- Theory about usability data gathering techniques
- Q&A question for project kickoff

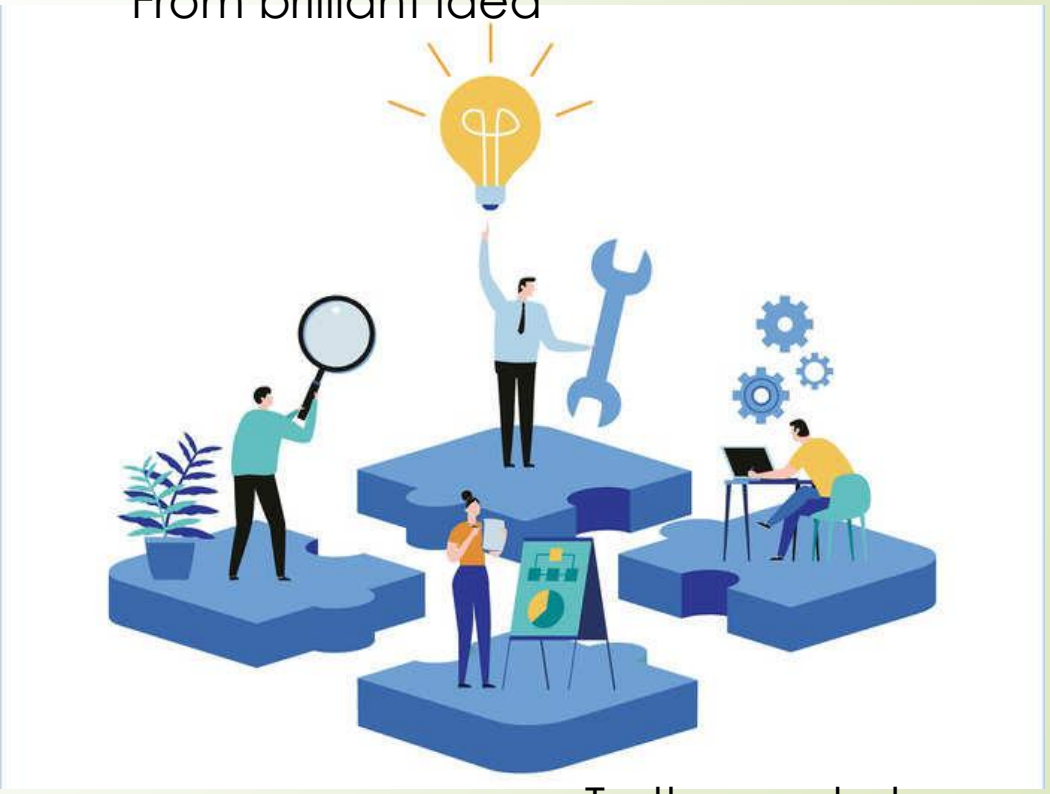
Medical device development as complex business



From idea to market

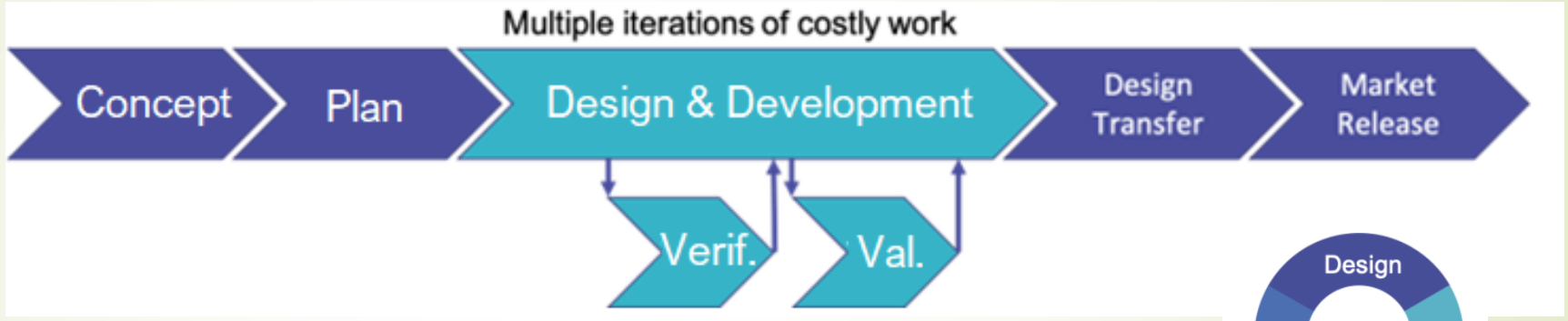
- The medical device development process requires specific stages to be followed to ensure the final product is **effective** & **safe for use.**
- It takes a significant amount of effort to deliver the right healthcare product that meets customer demands.
  - Strong scope definition from end user's need,
  - Collaborative efforts across the teams,
  - Adherence to product specification and requirements,
  - Identification and implementation of risk mitigations,
  - Ensure product quality.

From brilliant idea



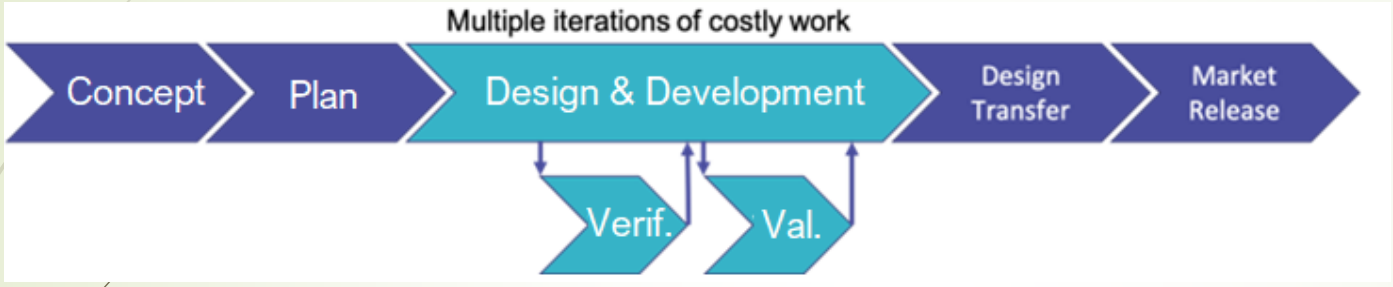
To the market

Product lifecycle

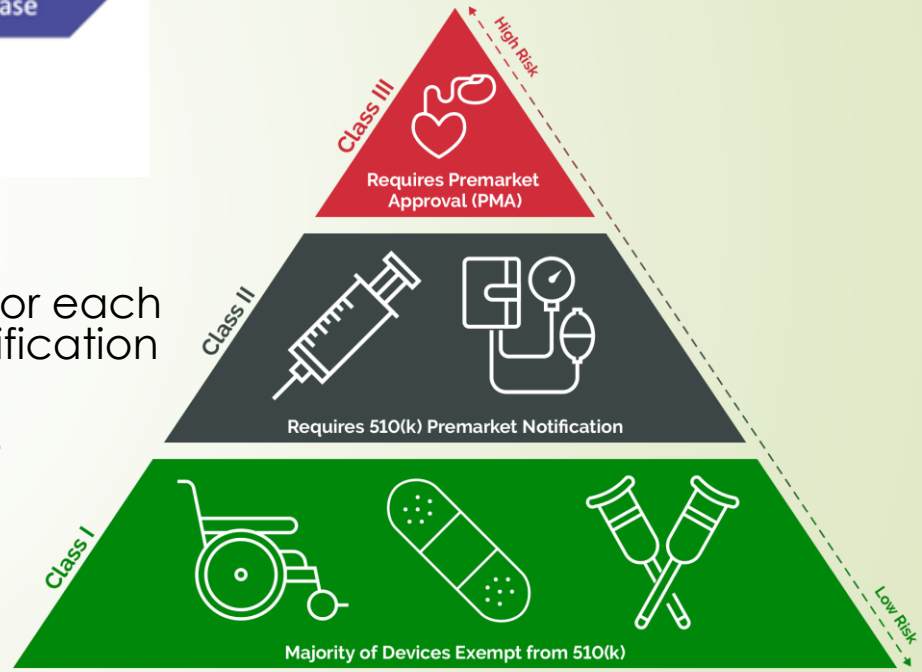


- Medical device development lifecycle follows well established steps that define a process from **conceptualization** to final **introduction into the market.** (Quality management system: 21 CFR 820 for US and ISO13485 for EU)

What to consider if the product is a Medical Device?

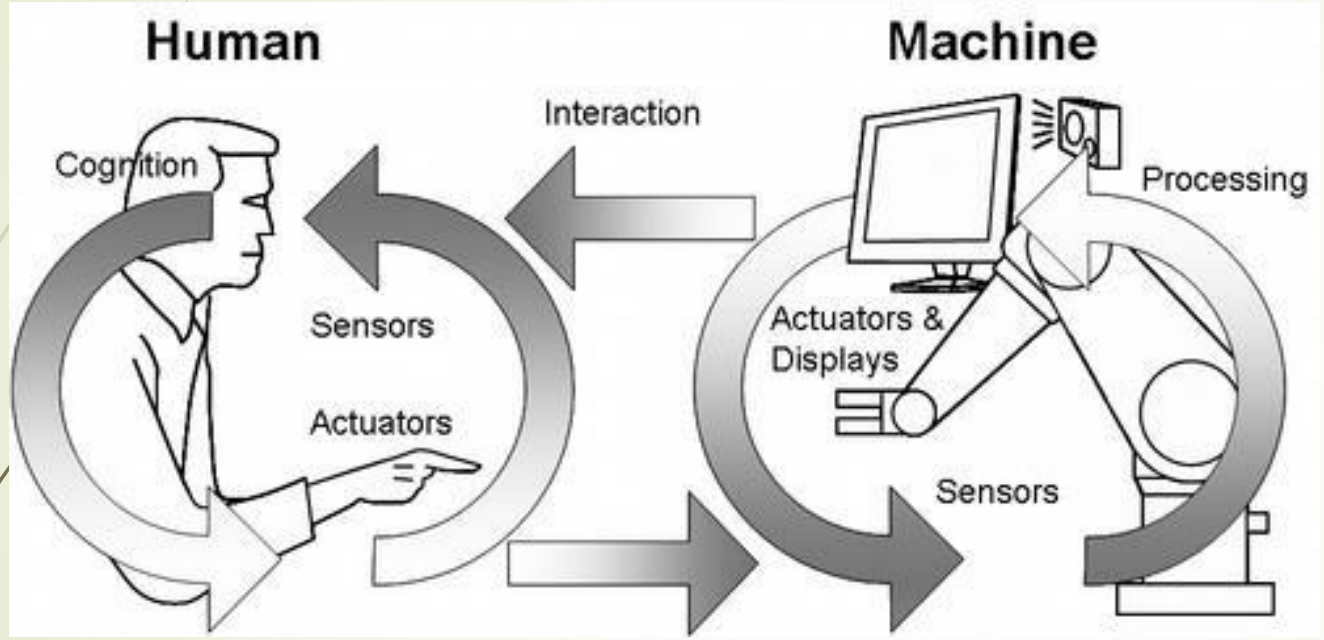


- Medical device products are regulated on a risk-based classification system → Different activities are requested for each of the product lifecycle phases depending on the classification of the device
- The higher the risk of the medical device, the higher the medical device classification → with a higher classification more stringent data requirements are requested to demonstrate the device's safety, effectiveness and performance.
- Regulatory strategy requirements based on the classification of the device.



Example of safety classification according to FDA (US)

Human Machine Interaction



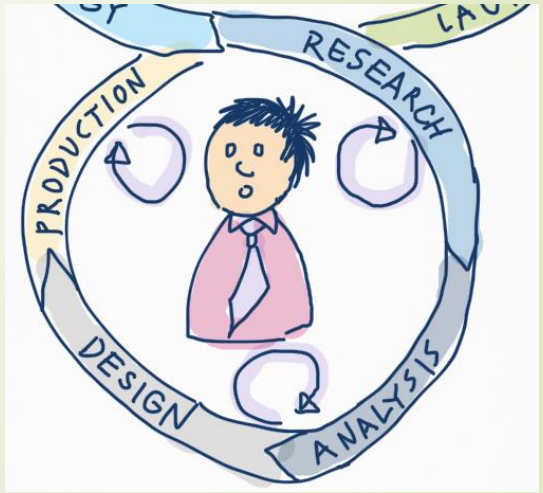
- While developing a product, it is crucial to consider that it will be used by USERS

Therefore, not only technologies and engineering solutions are important for realizing a succesfull device, **but also** the Human interaction aspects

Human-centred design

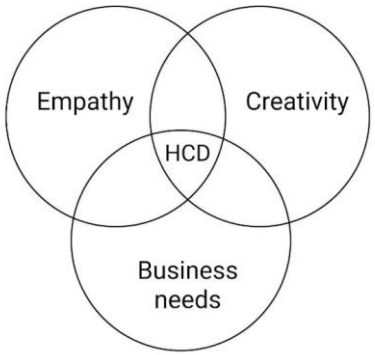
- An approach to design aiming to realize the device more usable. It focuses on the use of the entirety of the system and it applies human factors, ergonomics and usability knowledge and methods to develop it.
- 5 principles (ISO9241)
  - Design is based on understanding of users, goals, tasks, resources and environment
  - Users are involved through the entire design lifecycle
  - Design is driven and refined by usability evaluation
  - Process is iterative (continue until user needs are met)
  - Design addresses the whole user experience

    (End user, their environment, technology interaction, etc.)

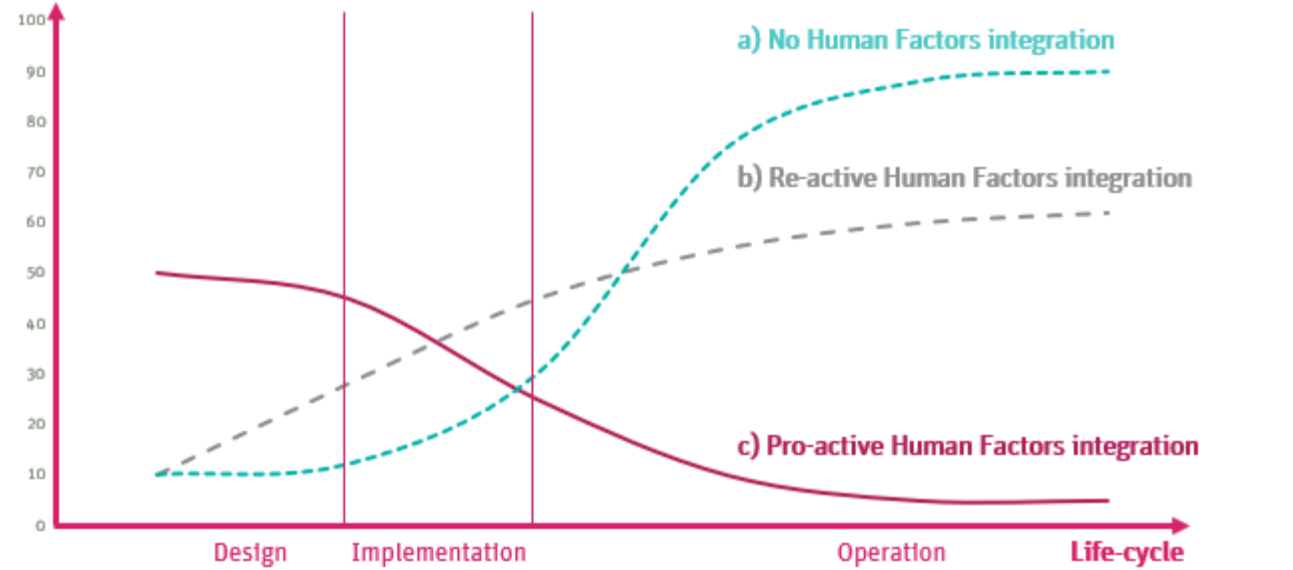


Relationship between Human Factors Principles and Human-Centered Design

- Human-Centered Design considers how humans will interact with the device in its intended use and intended environment.
- Human Factors takes all parts of the "system" into consideration. Human mental and physical limitations, human capabilities, human actions, environment, technology, etc.
- The study and applications of Human Factors should be utilized to create a Human-Centered Design. The combination of the two concepts will help to create an inclusive, safe, and successful product.



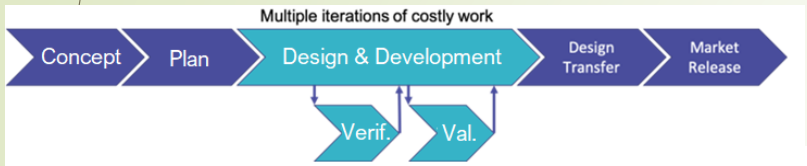
Cost advantages of integrating Human Factors since start of project

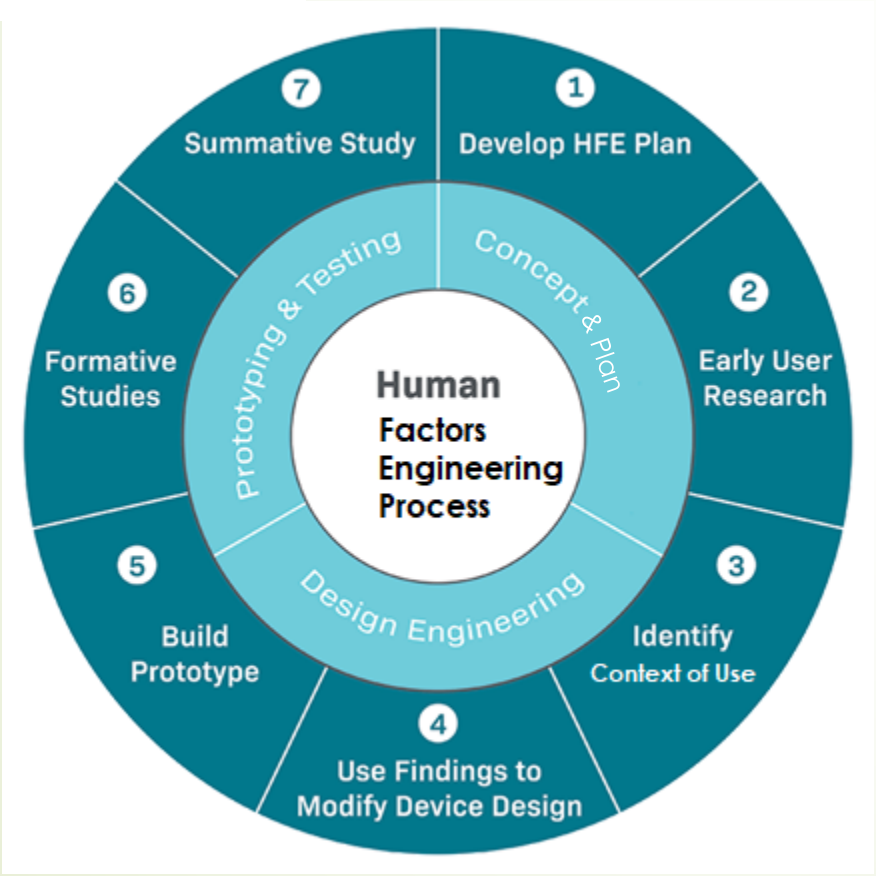


Cost of Detecting and Resolving Human Performance Issues (Source: Eurocontrol)

@Think

Human Factors Engineering Process

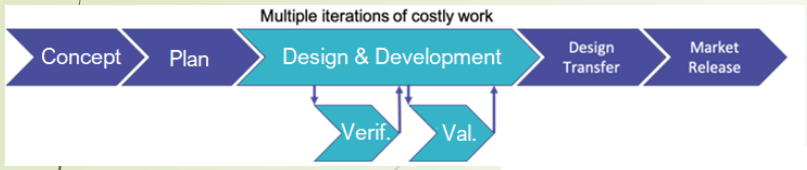


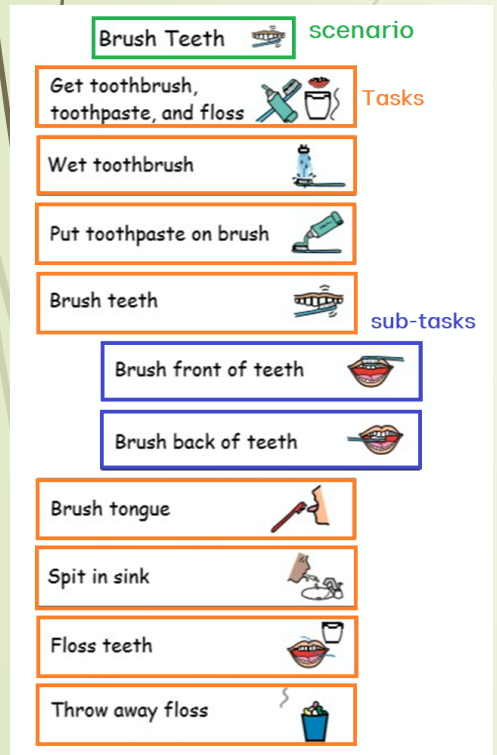


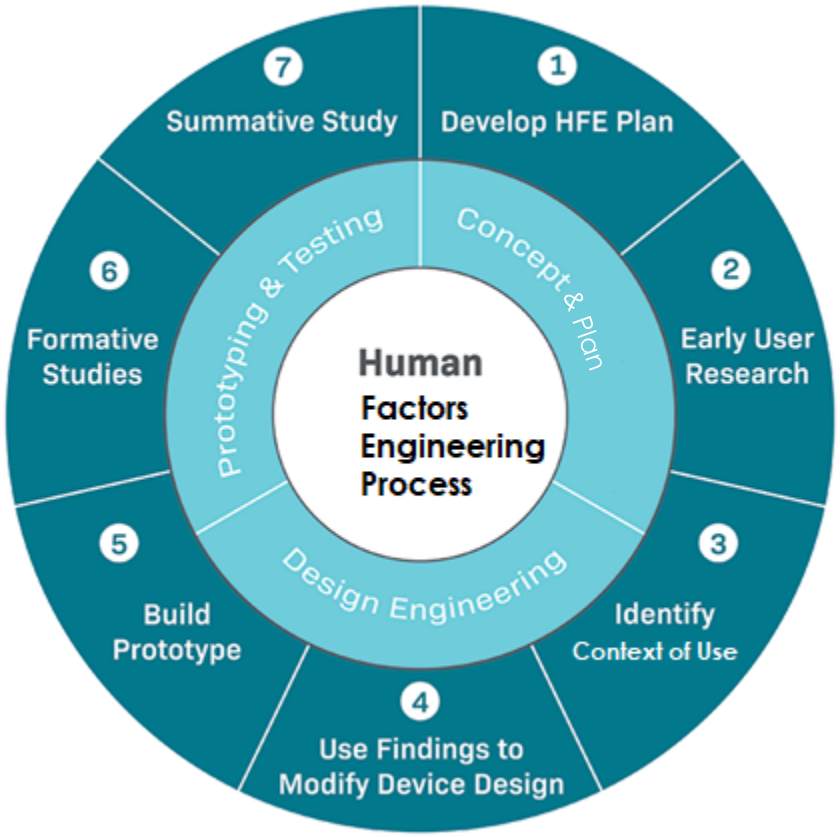
1) Planify how to design and demonstrate your device is safe and effective in use.
Can be updated while project advances.

2) Conduct early research to understand the actual conditions a given product is or will be used in a normal day/routine (e.g., who will be using, in which environment, for which scope)

Human Factors Engineering Process







1) Planify how to design and demonstrate your device is safe and effective.
Can be updated while project advances.

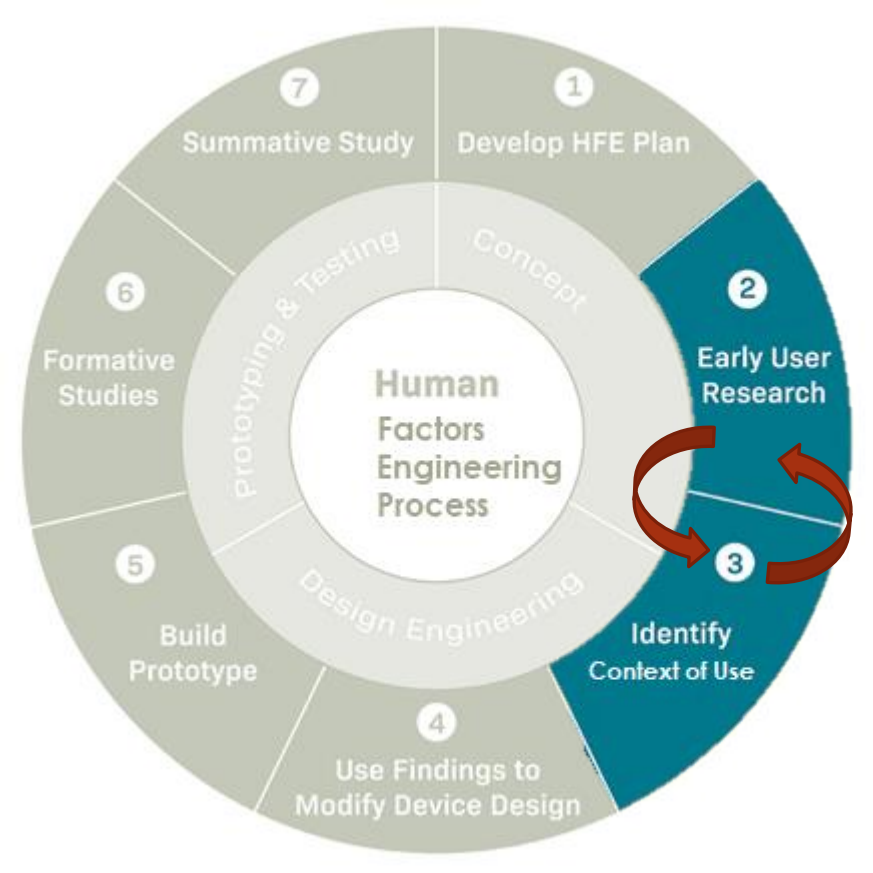
2) Conduct early research to understand the **actual conditions** a given product is or will be used **in a normal day/routine** (e.g., who will be using, in which environment, for which scope)

3) <u>What is the *«Context of use»*?</u>

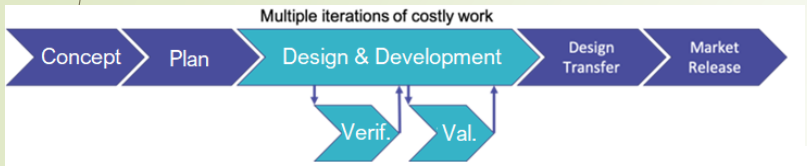
- Intended Users
- Intended Use
- Intended Use Environment
- Task Analysis - Identifies all the interactions a user has with the medical device. These are observable interactions

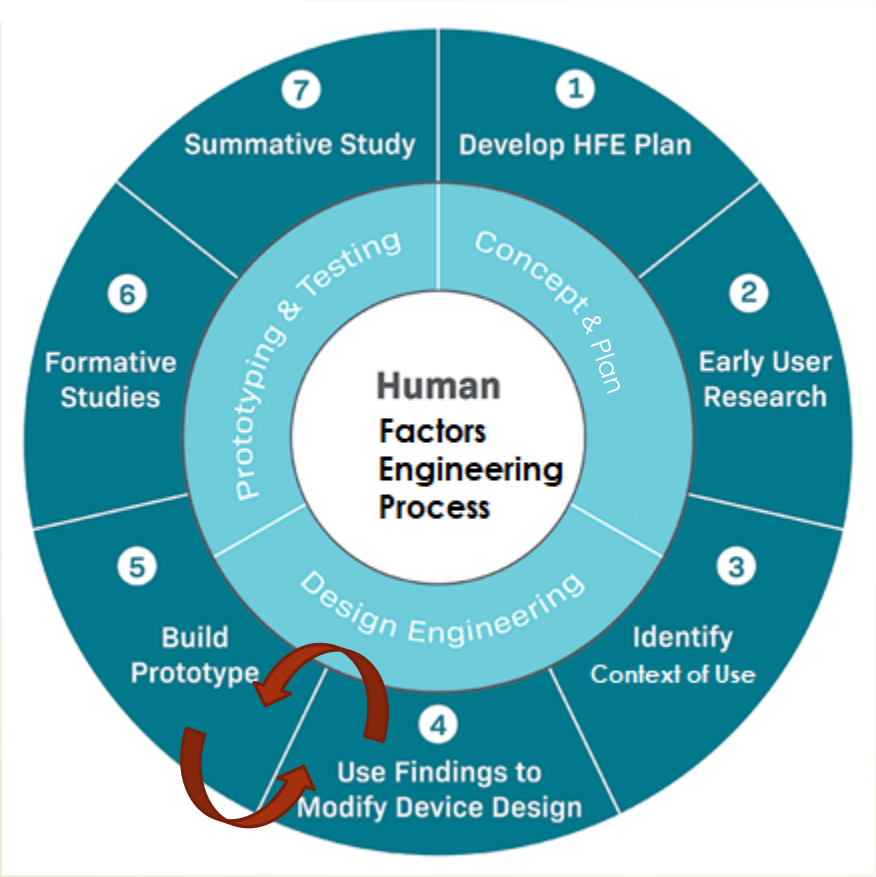
HF activities during Early User Research

- Research Methodology:
  - Qualitative Data
- How to Collect?
  - Contextual Inquiry
  - Interviews
  - Surveys
  - Structured Focus Groups
- How to Interpret?
  - Analyze commonalities in the data to determine user needs, context of use, user groups



Human Factors Engineering Process





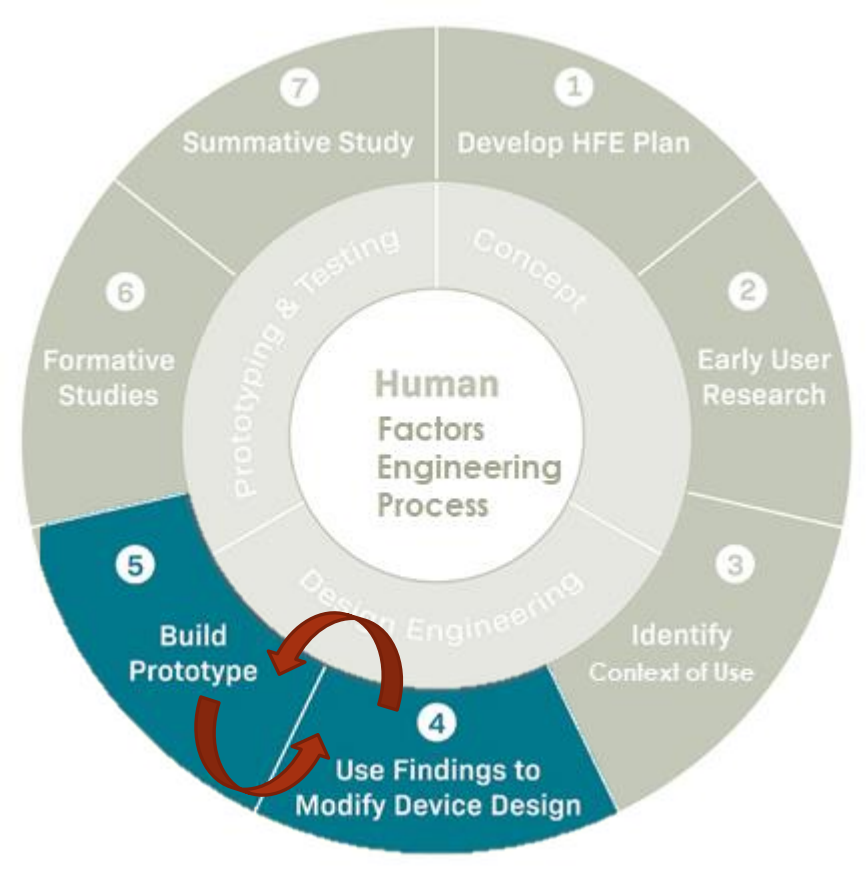
4&5) Based on the identifed Context of use and User Needs, prototypes of the product are defined.

→ Early iterations assessing the prototypes with users helps in providing use related input since early phases of the design development process

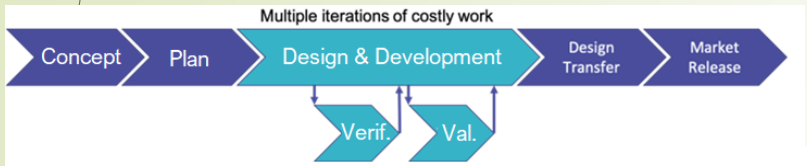
→ Use Related Risk Analysis activity starts and evolves iteratively by integrating use-related observations

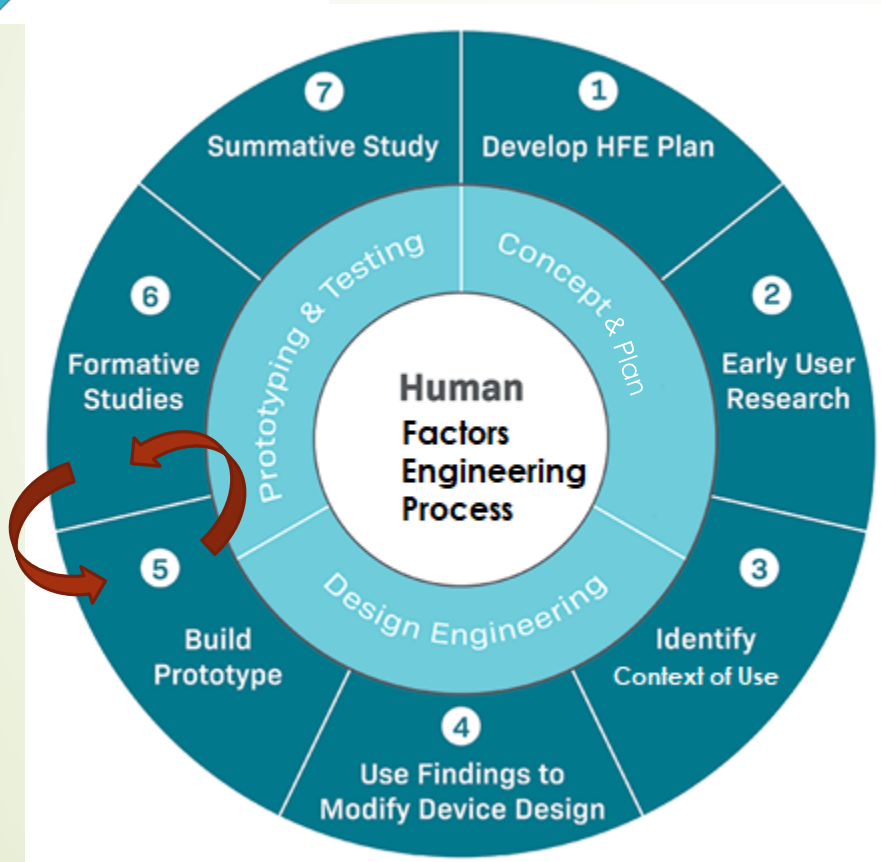
HF Activities during Design Input Planning and Modification

- Research Methodology:
  - Qualitative
- How to Collect?
  - User Feedback
  - Structured Focus Groups
  - Review of Previous Research
- How to Interpret?
  - Map system requirements to Human Factors guidelines.
  - Example: HE75:2009 labeling, button design, limit workload, natural or conventional mappings, etc.



Human Factors Engineering Process

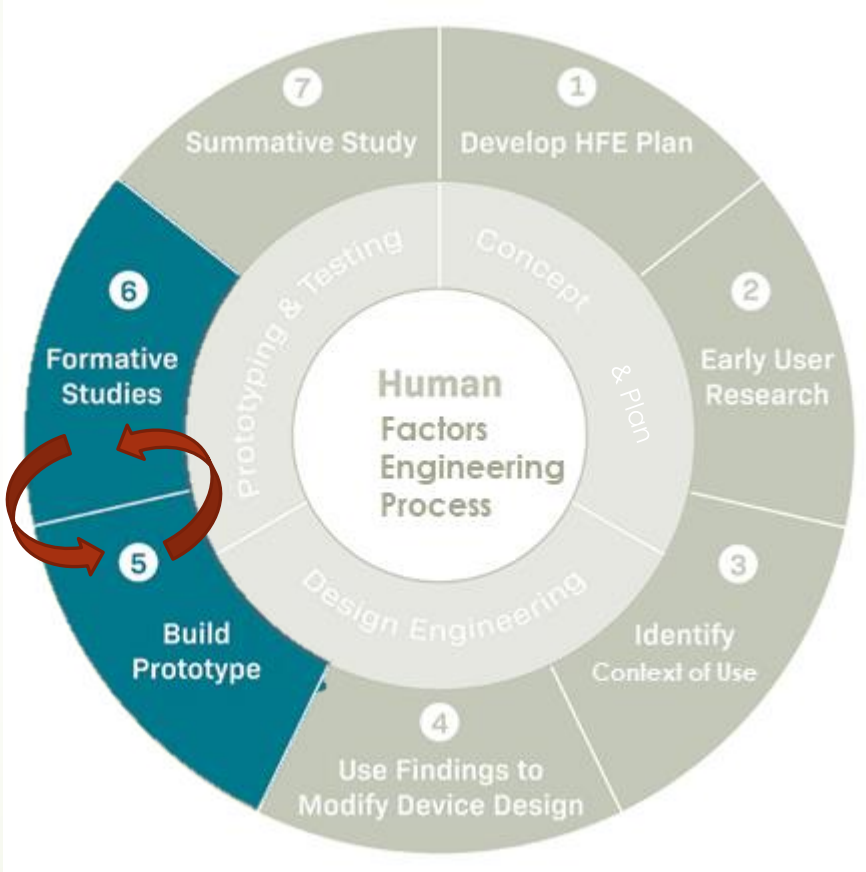




5&6) When device prototype achieve a certain level of maturity (e.g. The different subparts are ready to be integrated at system level). It is possible to perform more structured formative studies at system level.

HF Formative Activities during Prototype Testing

- Research Methodology:
  - Quantitative Data with Limited Participants
- How to Collect?
  - Formative Evaluations.
    - Examples: Ergonomic review, iterative design inputs, review of HF regulations.
- How to Interpret?
  - The design and labeling guidelines provided in HE75:2009 will provide research driven specifications.
  - Non-Parametric test because n is too small.



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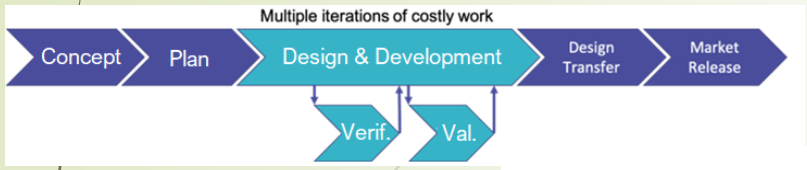
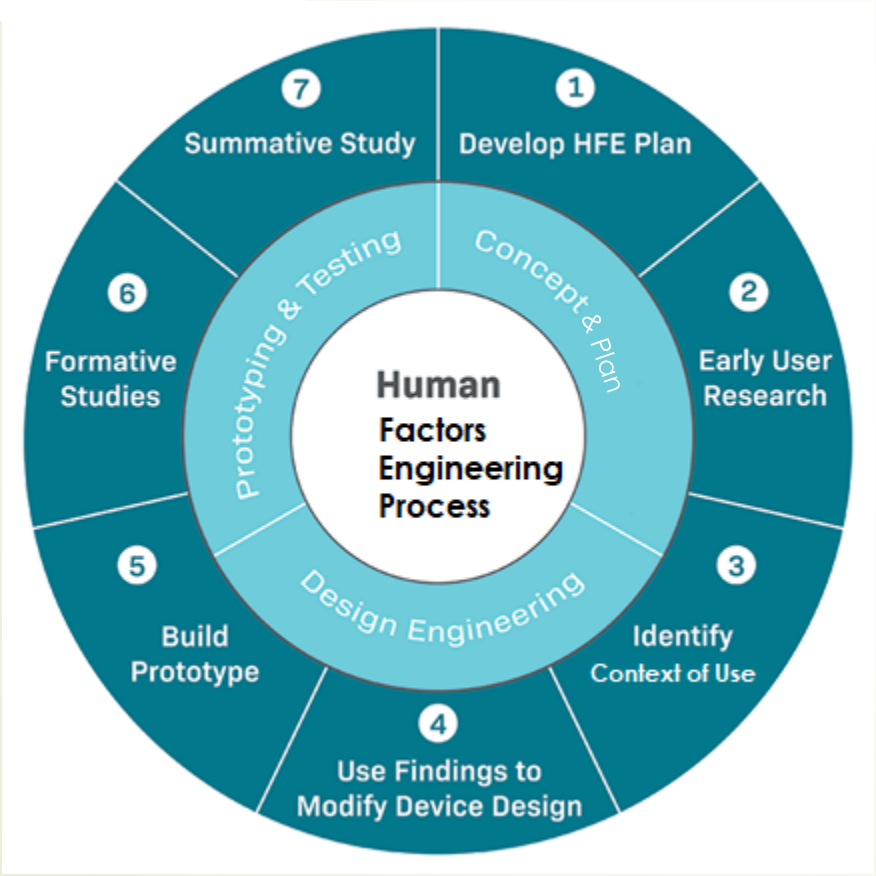




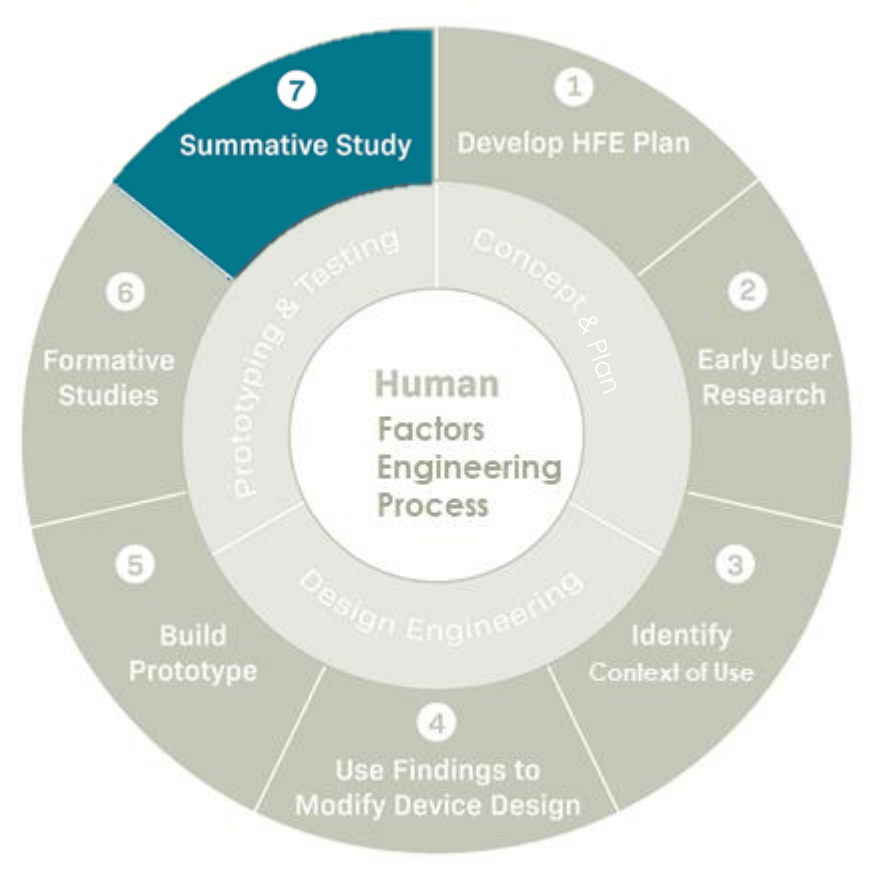
7) When finally the product is finalized:

- production equivalent HW
- fully-verified SW/FW

the Human Factor validation step is achieved with Summative study

HF Summative Activities during Design Validation

- Research Methodology:
  - Qualitative Data
- How to Collect?
  - Summative Testing – Participant observations in a simulated environment.
- How to Interpret?
  - Evaluate use errors, close calls, and operational difficulties to determine root causes. Analysis of the root causes will help determine risk mitigation procedures.

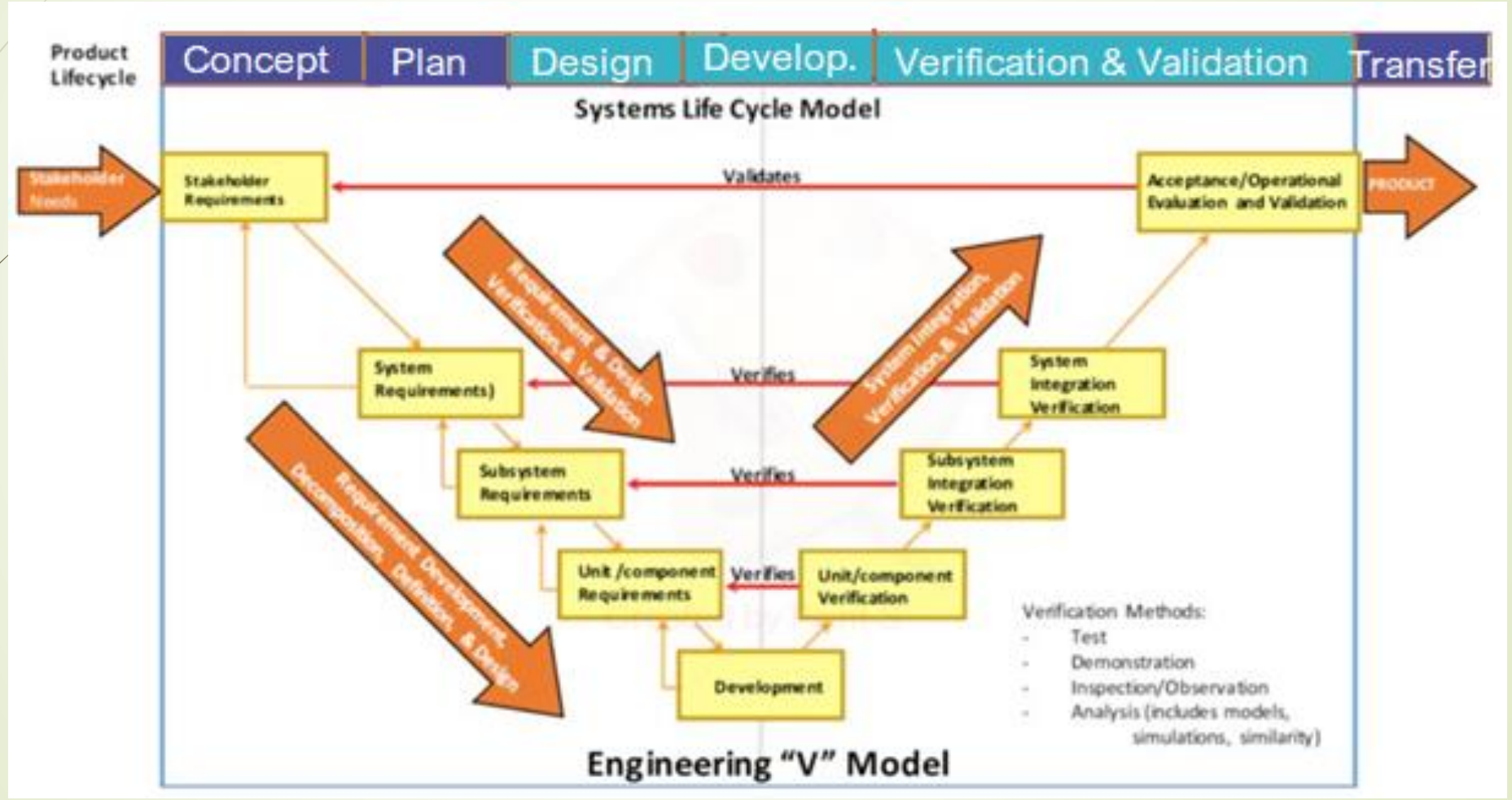


But your work is not finished yet....

Post-Market Surveillance and Vigilance

- Post-market surveillance plan (Reactive)
  - Manufacturer's must implement and maintain a surveillance system that tracks data on the quality, performance, and safety of the device.
- Post-market vigilance plan (Proactive)
  - Observations
  - Participant Interviews

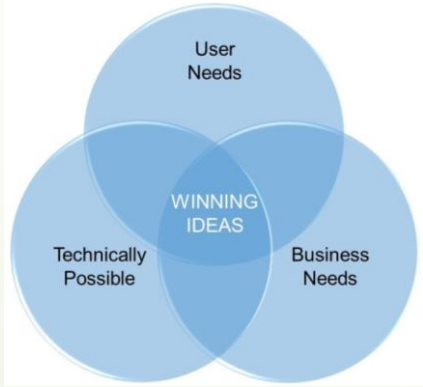
Applied Example: HF Engineering File for medical devices

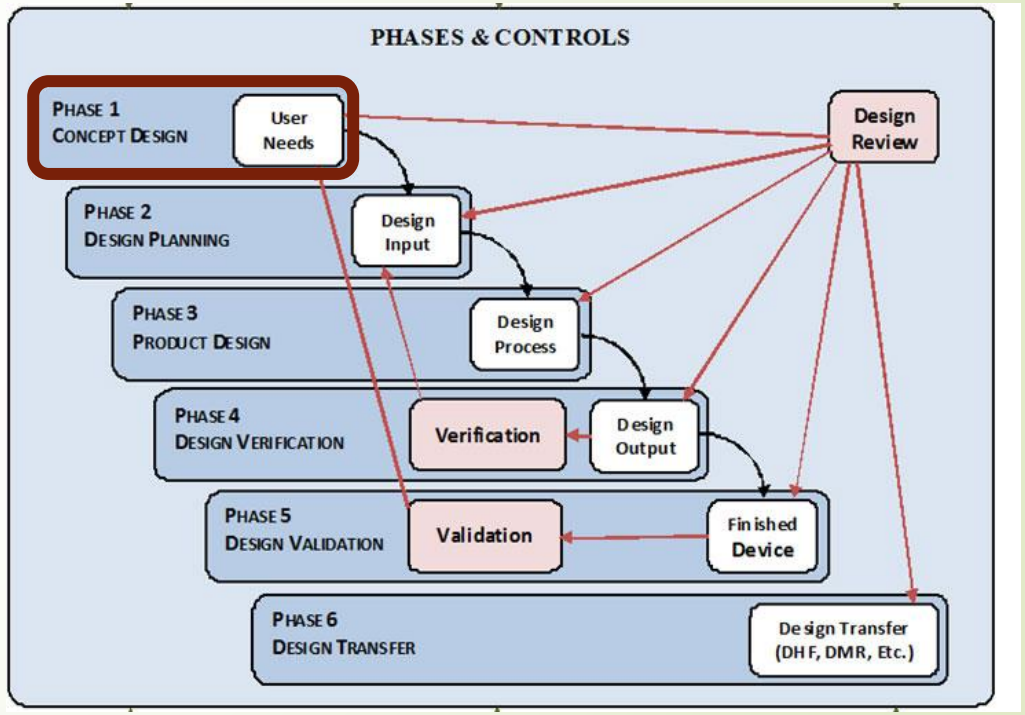


Design Controls: Concept Design

- Identification of «context of use»
- Feasibility and proof of concept analysis
- Initial assessments & planning activities
- Initial risk assessment

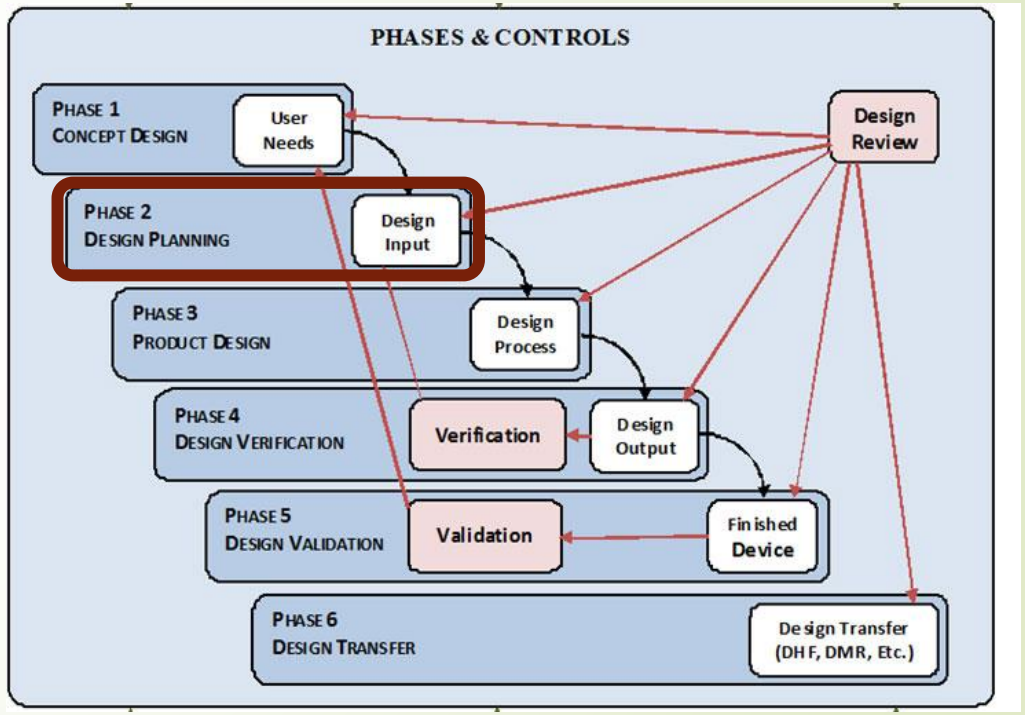
- Output of this phase are:
  - **User needs**
  - **Use specifications (context of use)**
  - Regulatory classification





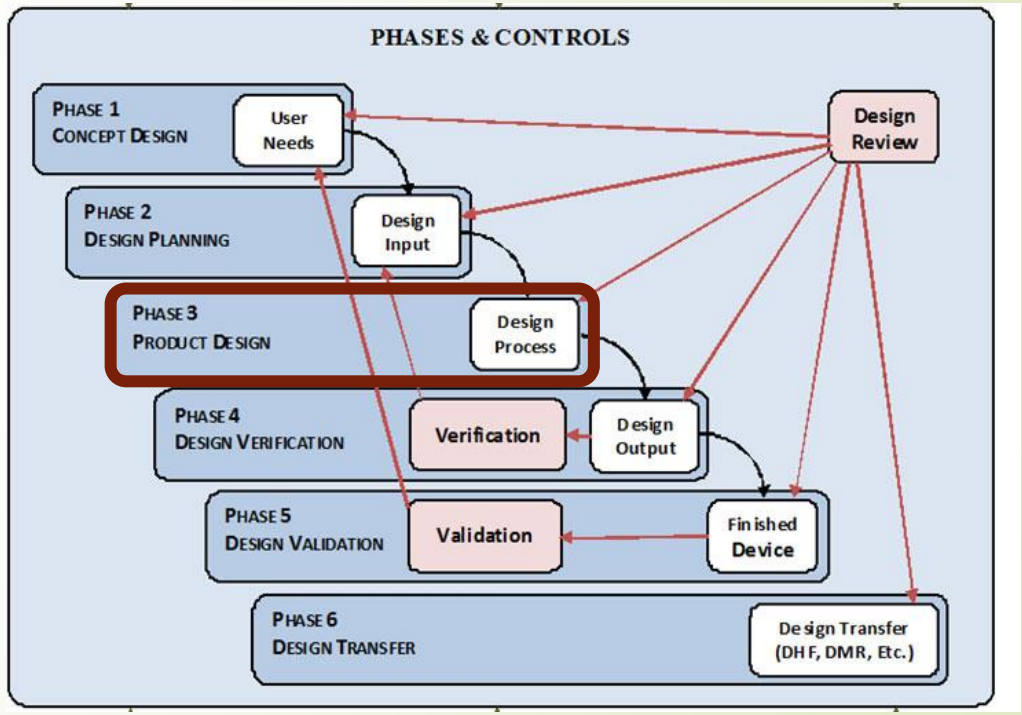
Design Controls: Design Input

- Translation of marketing product requirements (user needs) into fully detailed system requirements (design input)
- Output of this phase are:
  - Project Plan
  - System Requirements
  - High level Traceability: ensuring system req. are appropriate and address intended use of device and user needs
  - Initiation of Risk Analysis **(including URRA)**
  - Regulatory strategy
  - **Human Factors strategy/plan**
  - **Task Analysis**



Design Controls: Design Output

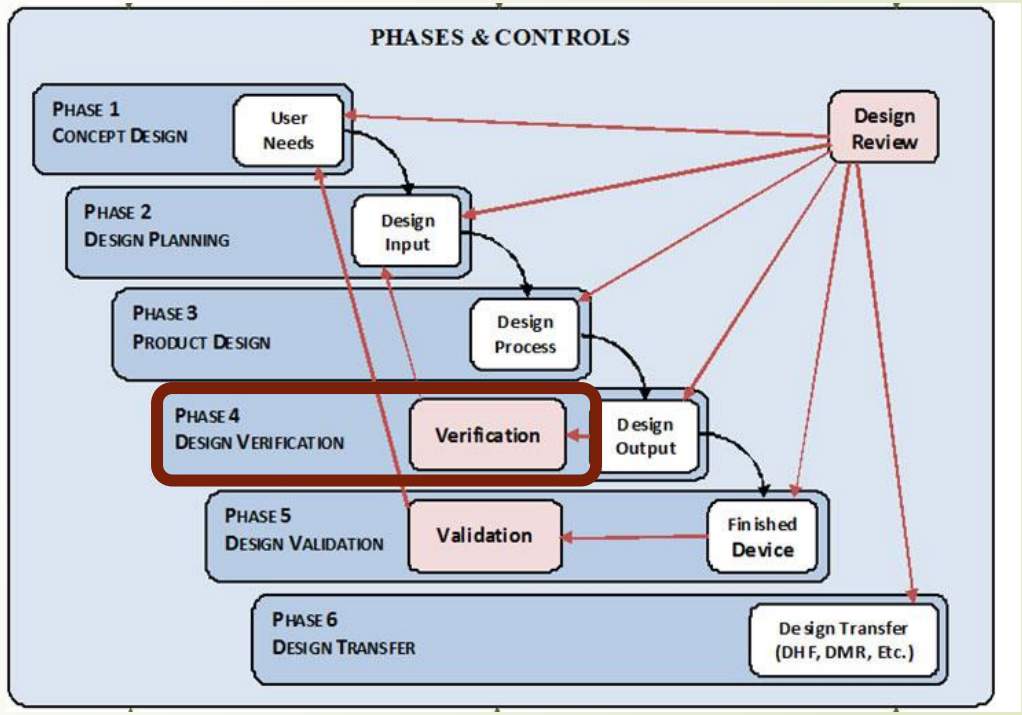
- Translation of the system requirements (design input) into specifications (design output) while developing the system solution
- Output of this phase are:
  - System Specifications – **User Interface-Interaction Specifications**
  - Develop verification tools
  - Device development



Design Controls: Verification

- Completion of the design verification, regulatory submission and prepare for clinical trials & process validation

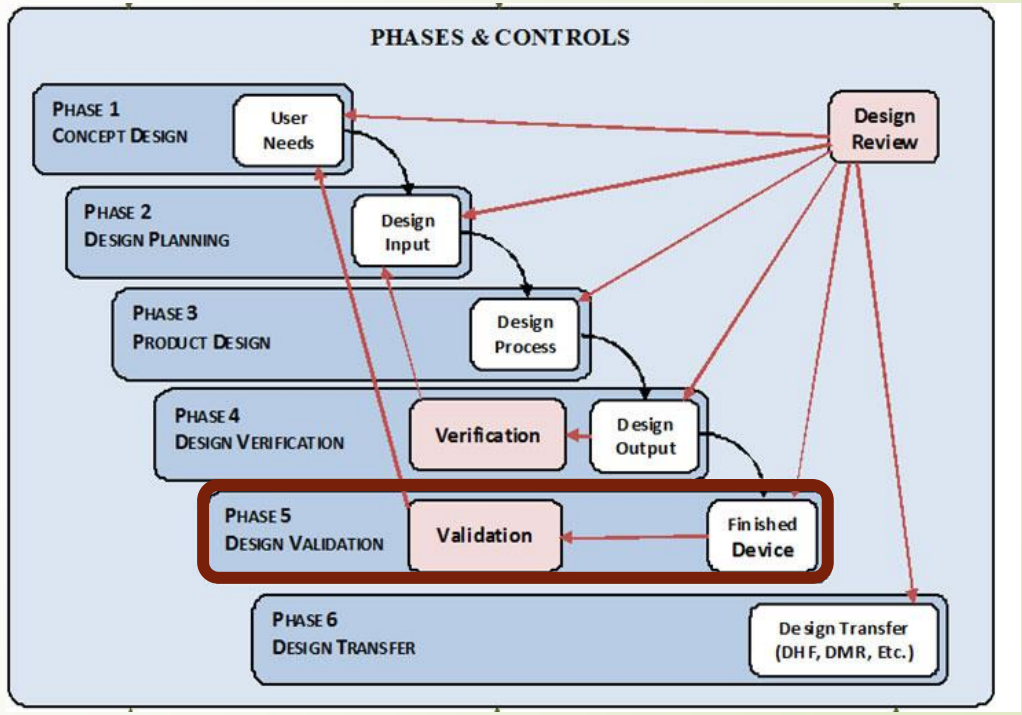
- Output of this phase are
  - Verification report (OQ, PQ)
  - Low-level Traceability: ensuringdevice specifications (design output) address high-level system requirements (design input)
  - Risk Management analysis (FMEAs/**URRA**)--> **identification of Critical Tasks**
  - **Formative evaluations (plan/report)**



Design Controls: Validation

- Test of the full system, including connections, interfaces, sub-systems as required for the intended use. It has to demonstrate the device meets the intended use and user needs & that the design control measures are effective.

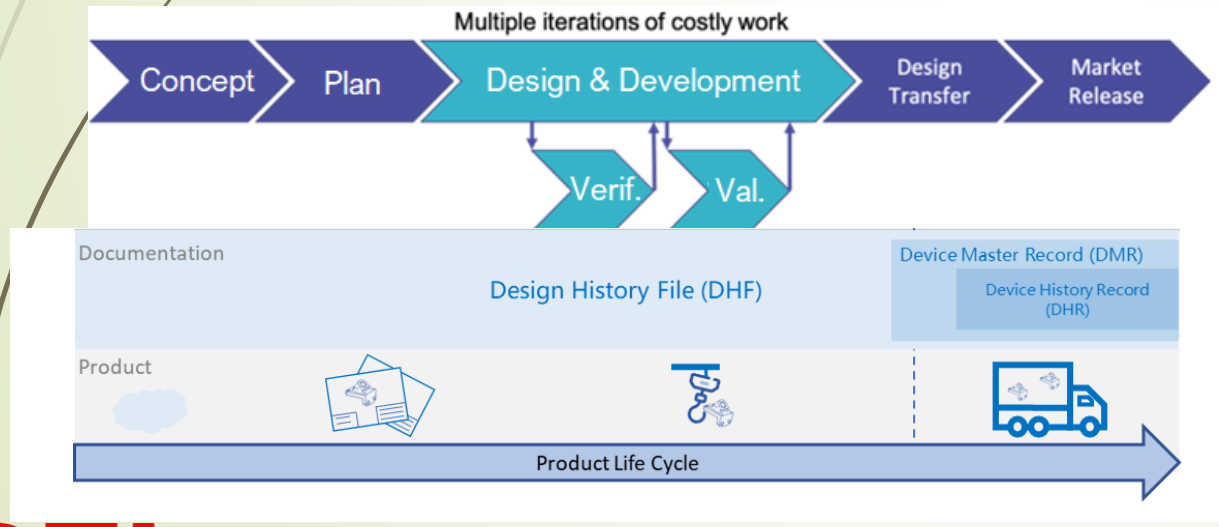
- Output of this phase are
  - Validation report
  - Full Traceability: demonstrate 100% coverage of requirements
  - **Summative evaluation (plan/report)**
  - **Summary report**
  - Risk Management Report

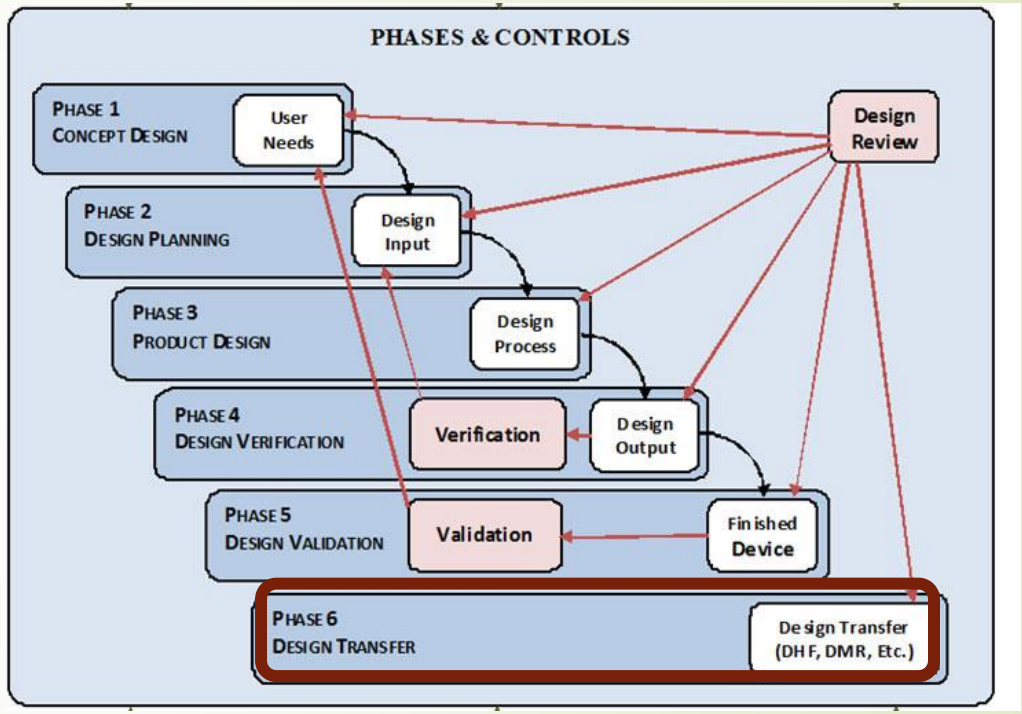


Design Controls: Transfer

- Culminate the medical device design team's effort: the product and process designs ar etransferred to production

- Output of this phase are
  - Design History File (DHF)
  - Device Master Record (DMR)





Extra Slides

Q&A session

- When you performed your first project is there any parallel to how you completed the project and this lifecycle model?

- How does the flow of this model help you in the project you proposed yesterday?

Q&A session

- How would you collect your data to appropriately determine user needs for the project you proposed yesterday?
- How would you analyze the data?
- How are you going to apply the data?

Q&A session

- What method of data collection would you use to determine if the system requirements fulfill the user requirements?
- How would you analyze the data?
- How are you going to apply the data?

Q&A session

- How would you collect HF input to further develop your project you proposed yesterday?
- How would you analyze the data?
- How are you going to use the data?

Q&A session

- How would you collect your data to ensure that the device/product is used as intended and does not lead to unforeseen use errors?
- How would you analyze the data?
- How are you going to apply the data?

Q&A session

- How would you collect your data to ensure safe and effective use of the final device/product?
- How would you analyze the data?
- How are you going to apply the data?

Group Activity Report

- Each group to present the answers of the Q&A sessions for their project