MIT School of
Bioengineering Sciences
& Research
Breathe Life into Engineering Career!

MIT-ADT
UNIVERSITY
PUNE, INDIA
A Leap Towards World Class Education

Course Code: 21BBM 901

Subject :Design and Development of Medical Devices

Class – Int. M.Tech. (Sem-IX), Div. A

Unit - I
Introduction and Exploring Medical Devices in design perspectives

SEM-I

AY 2025-2026

Unit-1

Introduction and Exploring Medical Devices in design perspectives

Syllabus

Medical devices definition, design life cycle, Man-machine dialogue and Industrial design, user centered design, five elements of successful design, cognition, ergonomics, Design models Pahl, Beitz and Pugh.

Books

1. Peter Ogrodnik, “Medical Device Design Innovation from Concept to Market”, Elsevier, 2013.
2. Richard C. Fries, “Handbook of Medical Device Design”, Marcel Dekker AG, 2ndedition, 2005.
3. Kenneth R. Ong, “Medical Informatics: An Executive Primer”, 2015, 1st Edition,

Medical Device

As per WHO guideline, A medical device is any instrument, apparatus, implement, machine, appliance, implant, in vitro reagent, software, material, or other similar, intended by the manufacturer to be used, alone or in combination, for human beings for one or more of the specific medical purposes of:

- Diagnosis, prevention, monitoring, treatment, or alleviation of disease
- Diagnosis, monitoring, treatment, alleviation, or compensation for an injury
- Investigation, replacement, modification, or support of the anatomy or of a physiological process
- Supporting or sustaining life
- Disinfection of medical devices
- Providing information by means of in vitro examination of specimens derived from the human body

A medical device is any instrument or component used to treat, diagnose or prevent a disease or abnormal physical condition.

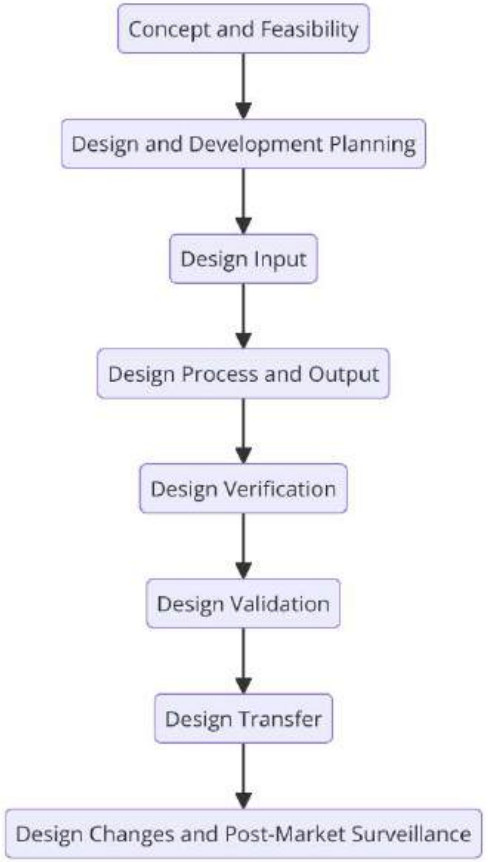
Product Life Cycle

The design life cycle of a medical device involves a series of phases that guide the development from initial concept to final product.

These phases ensure that the device is safe, effective, and compliant with regulatory standards.

The typical design life cycle includes:

1. **Concept and Feasibility**
2. **Design and Development Planning**
3. **Design Input**
4. **Design Process and Output**
5. **Design Verification**
6. **Design Validation**
7. **Design Transfer**
8. **Design Changes and Post-Market Surveillance**



1. Concept and Feasibility

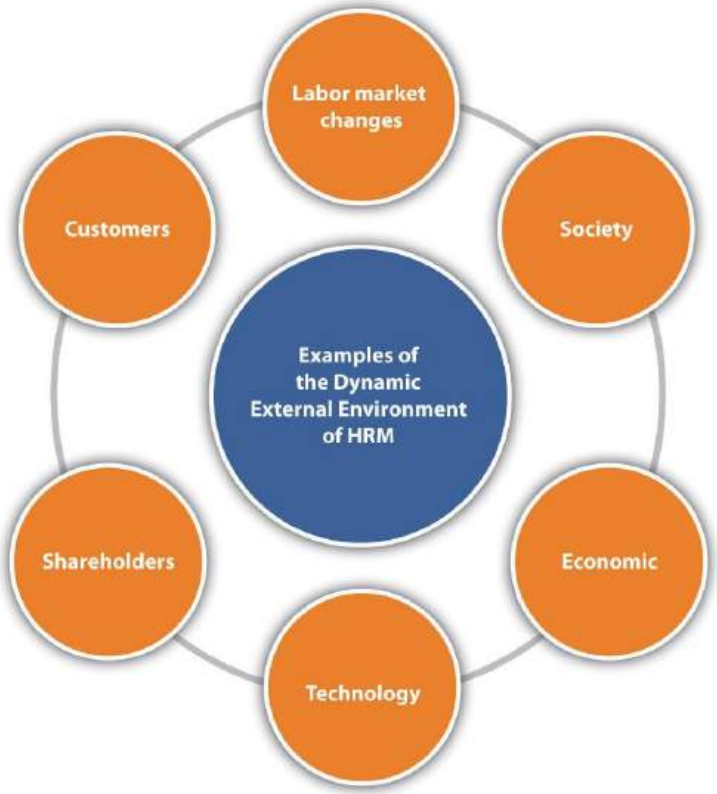
1. **Concept Generation**: Identify unmet medical needs and generate ideas for new devices or improvements to existing ones.
2. **Feasibility Study**: Conduct preliminary research to determine the technical, commercial, and regulatory feasibility of the concept. This includes evaluating potential risks, market demand, and the competitive landscape.
3. **Stakeholder Input**: Engage with key stakeholders, including healthcare professionals, patients, and regulatory bodies, to gather input and refine the concept.

Example: A feasibility study for a new type of insulin pump would involve assessing technical requirements, potential market size, competitive products, and regulatory hurdles.

2. Design and Development Planning

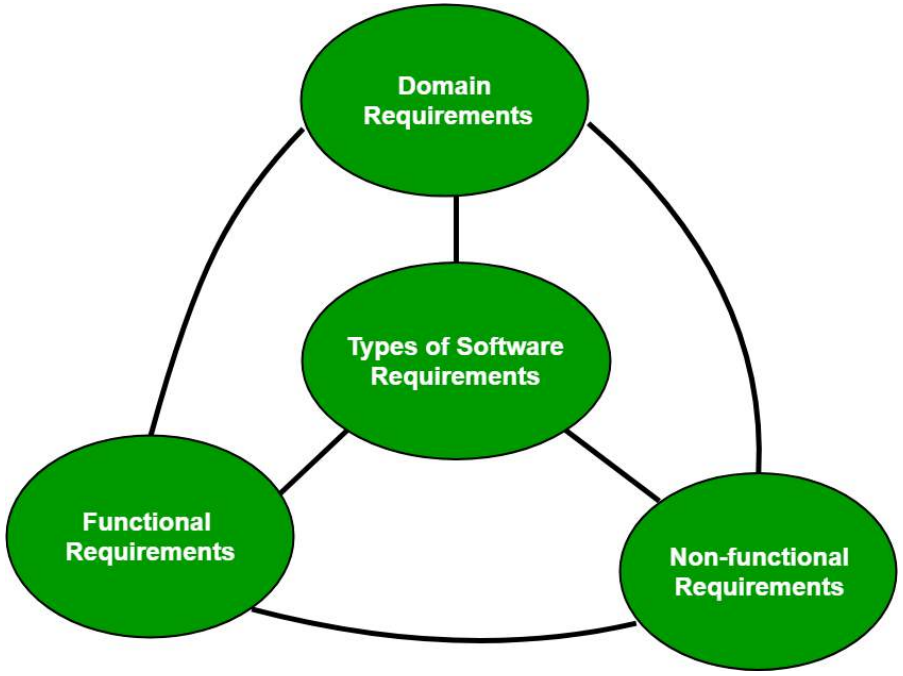
1. **Project Plan**: Develop a detailed project plan outlining the scope, timeline, resources, and key milestones for the design and development process.
2. **Regulatory Strategy**: Define the regulatory pathway and requirements for the device, including the classification, necessary approvals, and compliance standards.

Example: The project plan for an implantable cardiac device would include a timeline for design phases, prototype development, testing, and regulatory submissions.



3. Design Input

- **Requirements Specification**: Document detailed design inputs, including functional, performance, safety, and regulatory requirements.
- These inputs should be based on user needs, clinical data, and risk management.
- **User Needs**: Clearly define the needs and expectations of end-users, such as ease of use, accuracy, durability, and compatibility with other devices.



Example: For a wearable ECG monitor, design inputs would specify requirements for data accuracy, battery life, comfort, and user interface design.

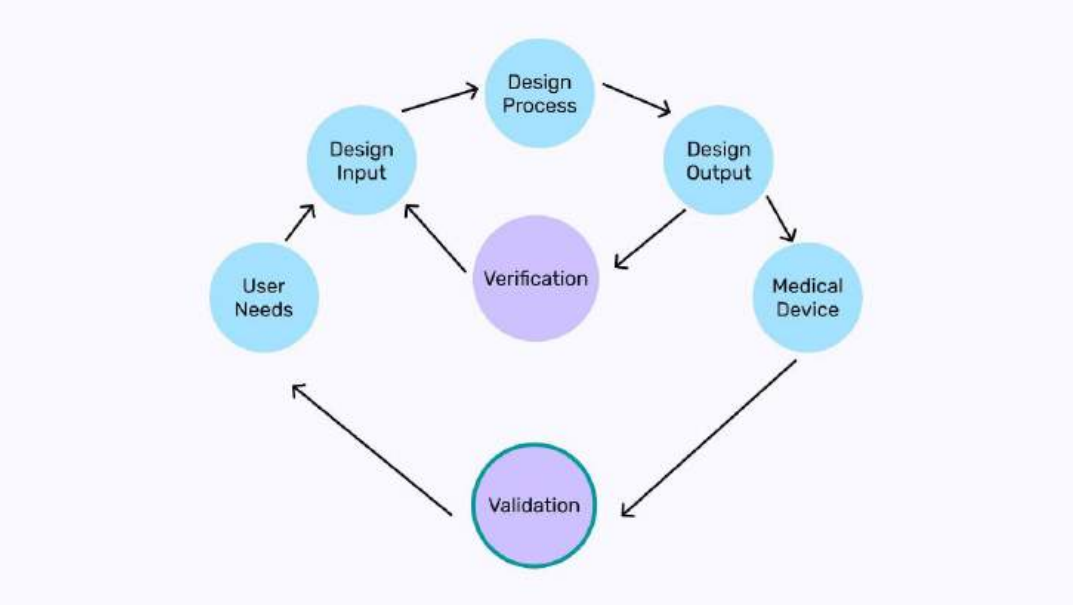
4. Design Process and Output

- **Conceptual Design**: Develop initial design concepts and select the most promising options for further development.
- **Detailed Design**: Create detailed design specifications, including drawings, schematics, software algorithms, and material specifications.
- **Prototyping**: Build and test prototypes to refine the design and identify potential issues.

Example: The detailed design phase for a surgical robot would include mechanical design, control system development, and software programming.

5. Design Verification

- **Testing**: Conduct tests to verify that the design outputs meet the design inputs and requirements. This includes bench testing, simulations, and inspections.
- **Documentation**: Maintain comprehensive documentation of verification activities and results to demonstrate compliance with regulatory standards.

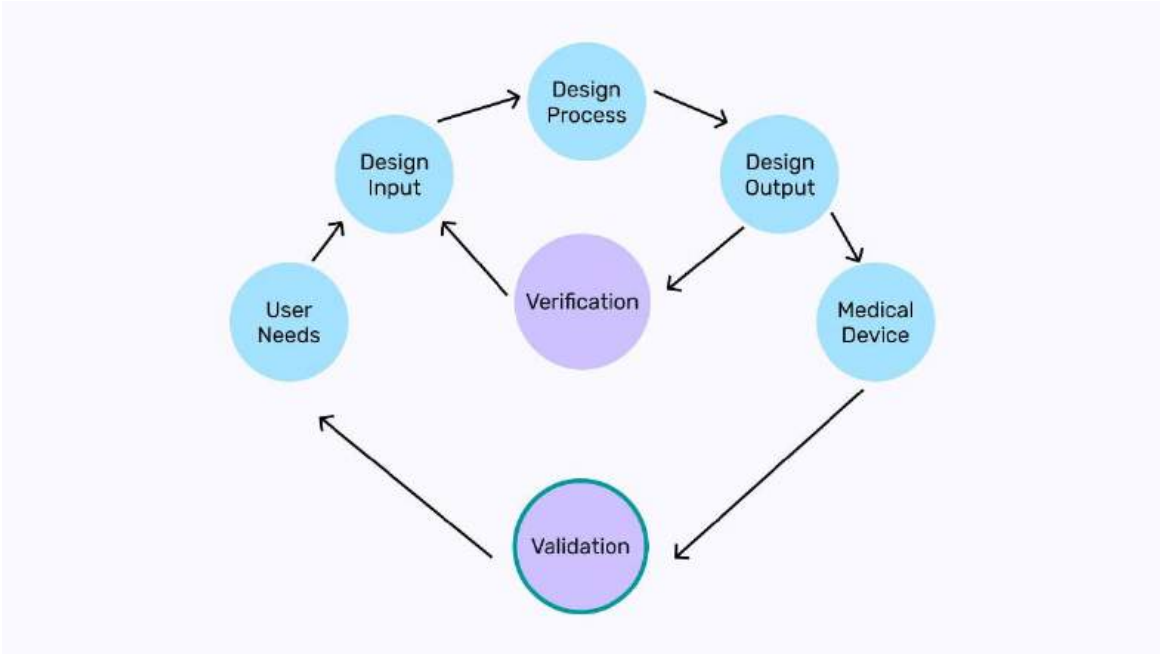


Example: Verification testing for an infusion pump would include checking flow rates, alarm functions, and user interface operations against the design specifications.

6. Design Validation

- **Clinical Evaluation**: Perform clinical trials or studies to validate that the device meets user needs and performs as intended in real-world conditions.
- **Usability Testing**: Evaluate the device's usability with actual users to ensure it is easy and safe to use.

Example: Validation for a new diagnostic imaging device would involve clinical trials in a hospital setting to confirm diagnostic accuracy and usability.



7. Design Transfer

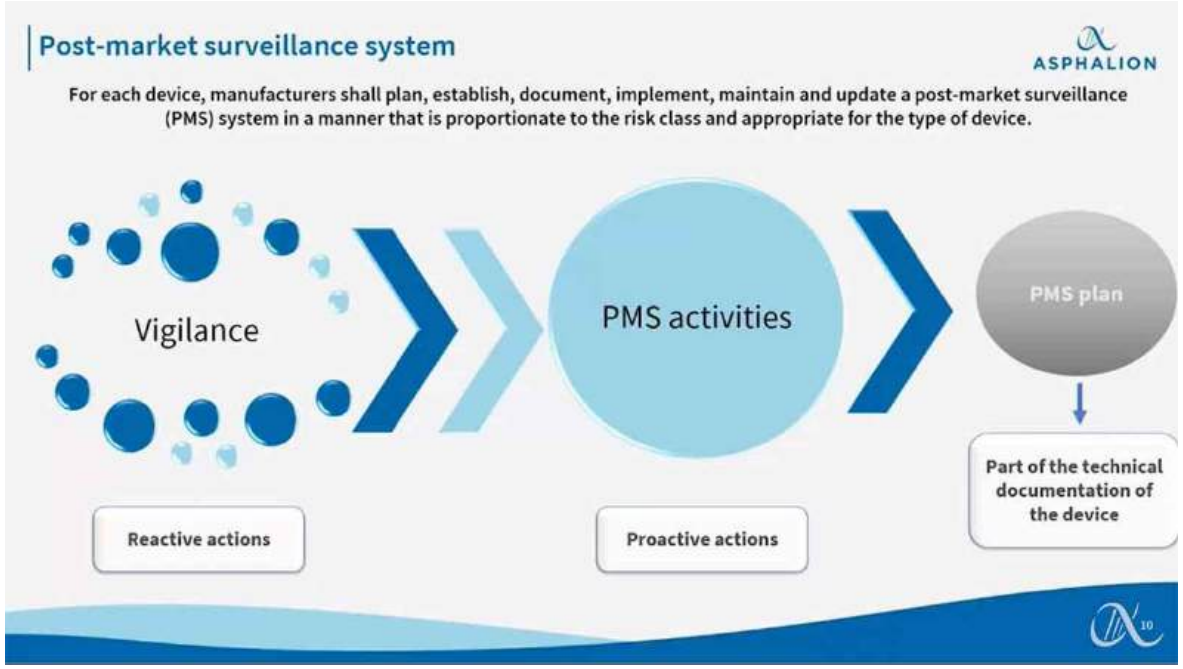
- **Manufacturing Transfer**: Transfer the design to manufacturing, ensuring that production processes can consistently produce devices that meet design specifications.
- **Quality Assurance**: Implement quality control measures and establish standard operating procedures (SOPs) for production.

Example: Design transfer for an orthopedic implant would involve setting up manufacturing processes, quality control tests, and supplier qualification.

8. Design Changes and Post-Market Surveillance

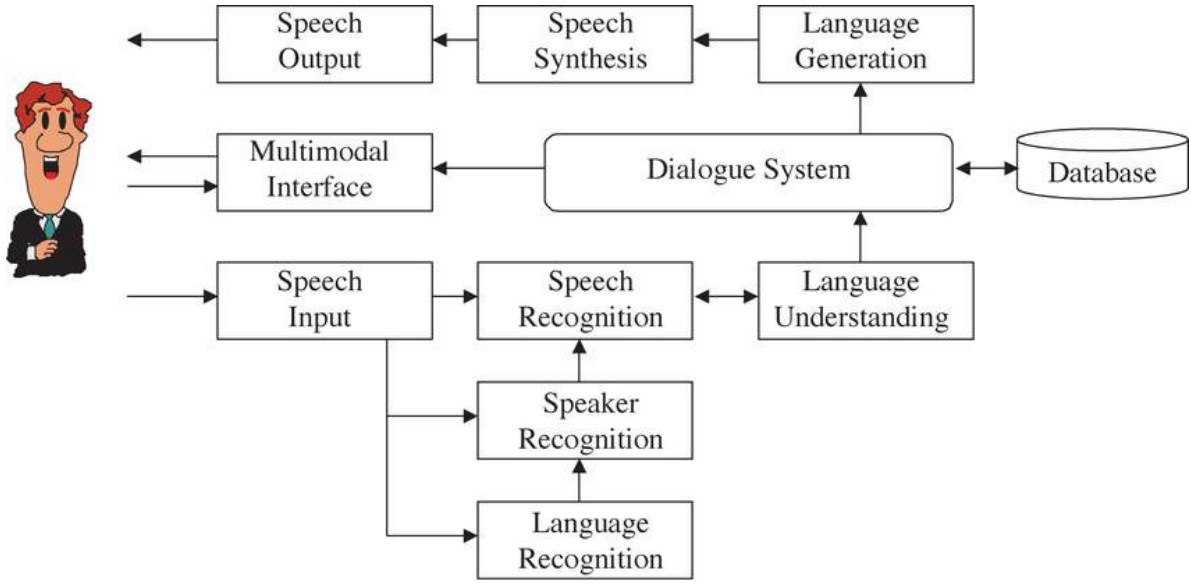
- **Design Changes**: Implement and document any necessary design changes based on feedback from manufacturing, regulatory updates, or post-market surveillance.
- **Post-Market Surveillance**: Monitor the device's performance in the market, gather user feedback, and track any adverse events to identify areas for improvement.

Example: Post-market surveillance for a home dialysis machine might involve collecting user feedback on device reliability and ease of use, leading to iterative design improvements.



Man-Machine Dialogue

- Man-Machine Dialogue (also known as Human-Machine Interaction or Human-Computer Interaction) refers to the communication and interaction between a human user and a machine, system, or computer.
- This interaction can occur through various interfaces and devices, including screens, keyboards, voice commands, and more.
- The goal is to design interfaces that are intuitive, efficient, and effective, enabling users to interact with machines in a natural and seamless manner.

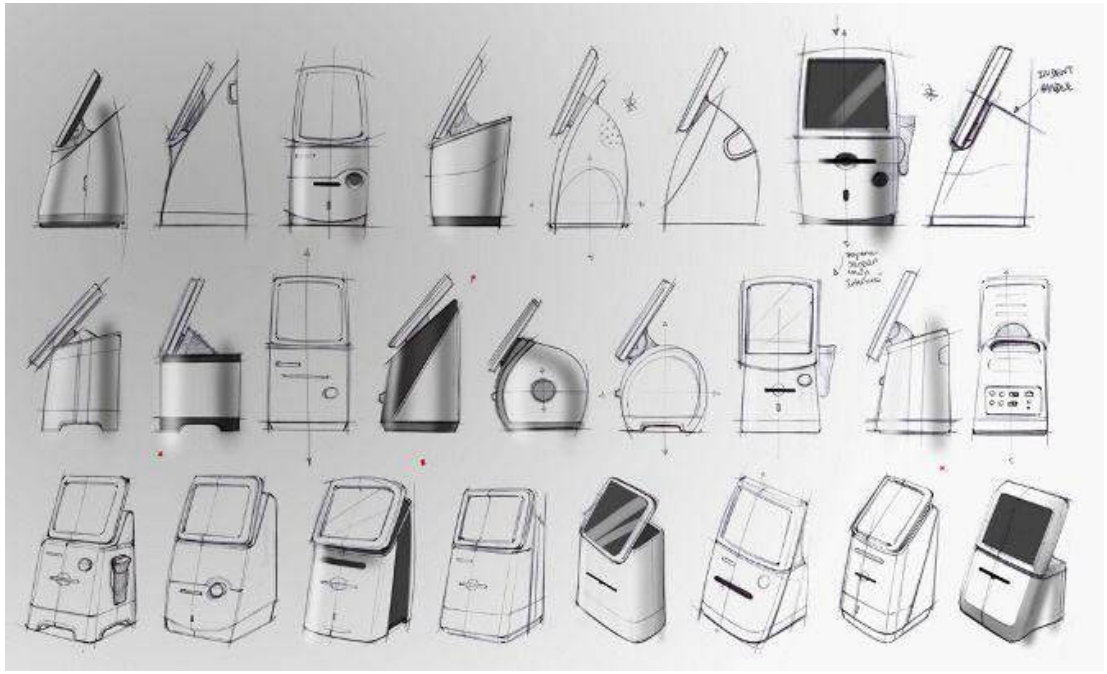


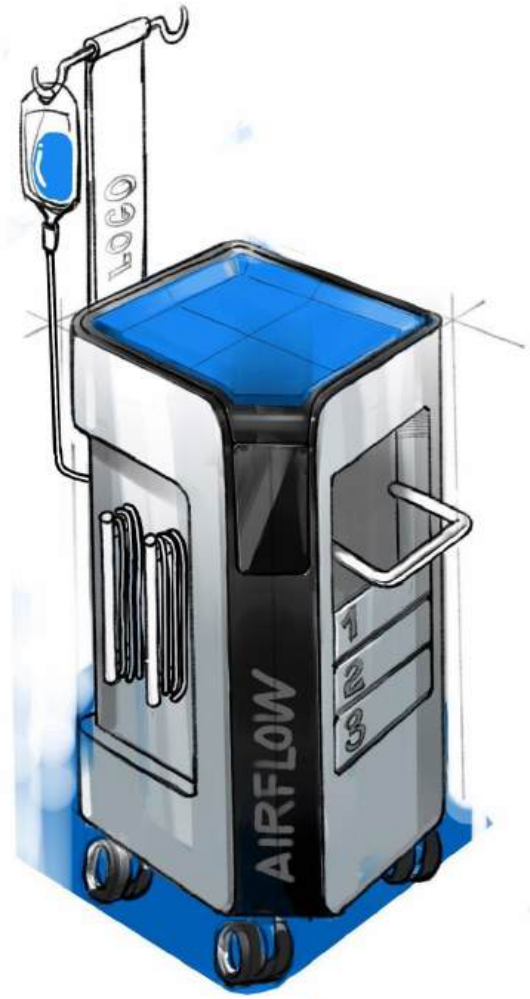
Key Aspects of Man-Machine Dialogue:

1. User Interface (UI) Design
   - Visual Design
   - Interaction Design,
   - Consistency
2. Natural Language Processing (NLP):
   - Voice Recognition
   - Chatbots
   - Multilingual Support
3. Feedback Mechanisms:
   - Immediate Feedback,
   - Error Messages
   - Progress Indicators
4. Usability and Accessibility
   - Ease of Use
   - Accessibility
   - User Testing

Industrial Design

- Industrial design focuses on the aesthetic and functional aspects of physical products, ensuring that they are both visually appealing and user-friendly.
- It encompasses the creation and development of concepts and specifications that optimize the function, value, and appearance of products for both the user and manufacturer.





Key Aspects of Industrial Design:

1. **Form and Aesthetics**
2. **Functionality**
3. **Ergonomics**
4. **Materials and Manufacturing**
5. **Sustainability**

1. Form and Aesthetics

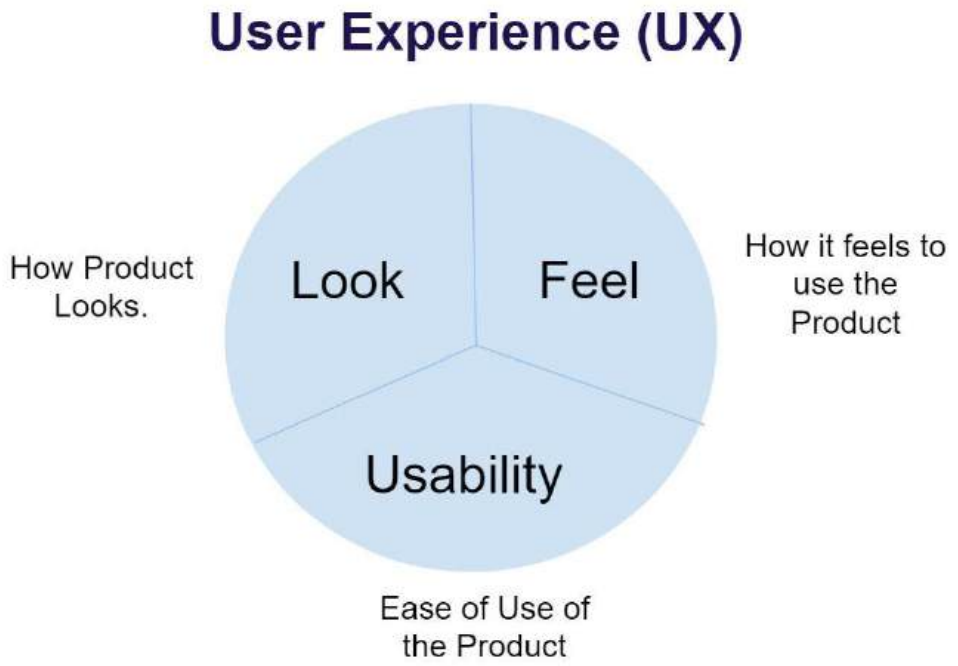
- **Visual Appeal**: Design products that are visually appealing and align with brand identity. This includes considerations of shape, color, texture, and overall styling.
- **Branding**: Ensure that the design reflects the brand's values and image, creating a recognizable and cohesive product line.

Example: Apple's design philosophy emphasizes sleek, minimalist aesthetics that align with its brand identity, making its products instantly recognizable.

2. Functionality

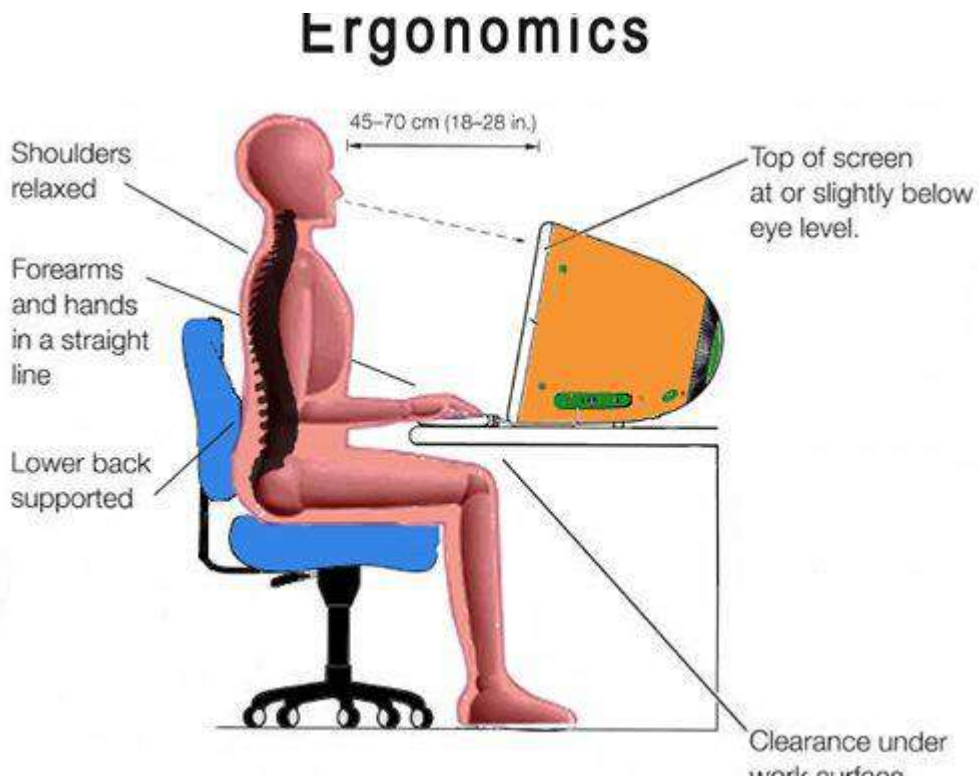
- **Usability**: Ensure that the product performs its intended functions effectively and is easy to use. This involves understanding user needs and incorporating features that meet those needs.
- **Performance**: Design products that perform reliably and efficiently under various conditions.

Example: A high-performance bicycle designed with lightweight materials and ergonomic features to enhance speed and comfort for the rider.



3. Ergonomics

- **User Comfort**: Design products that are comfortable to use and reduce physical strain. This includes considering the shape, size, and weight of the product.
- **Intuitive Use**: Ensure that the product's controls and interfaces are easy to understand and operate.

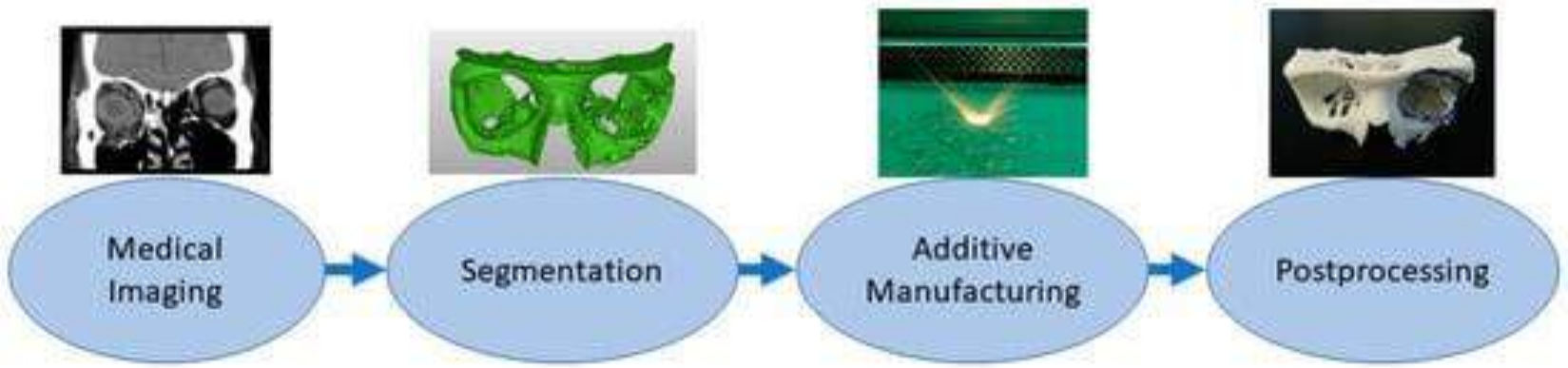


Example: An ergonomic office chair designed to support the user's posture and reduce the risk of back pain during long periods of sitting

4. Materials and Manufacturing

- **Material Selection**: Choose appropriate materials that balance durability, cost, and aesthetics. Consider the environmental impact of material choices.
- **Manufacturing Processes**: Design products that can be efficiently manufactured using available technologies. This includes considering assembly processes, tolerances, and quality control.

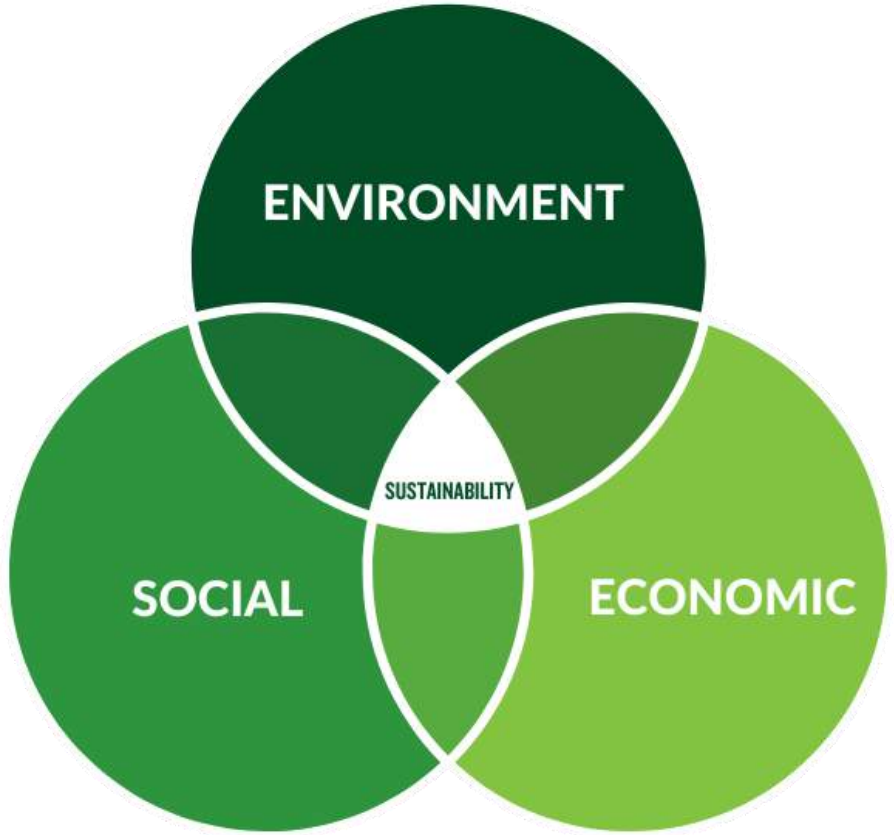
Example: A durable water bottle made from BPA-free, recyclable plastic, designed for easy assembly and mass production.



5. Sustainability

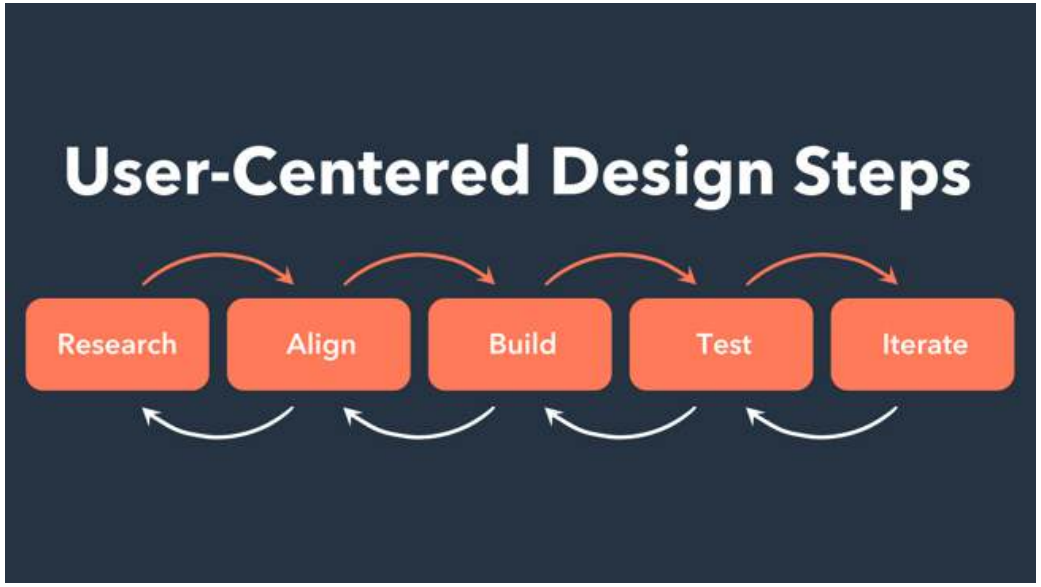
- **Eco-Friendly Design**: Incorporate sustainable practices in the design process, such as using recyclable materials, reducing waste, and minimizing energy consumption.
- **Lifecycle Considerations**: Design products with their entire lifecycle in mind, from production and use to disposal and recycling.

Example: A solar-powered lamp designed to provide sustainable lighting in off-grid areas, made from recyclable materials and designed for easy disassembly and recycling at the end of its life.



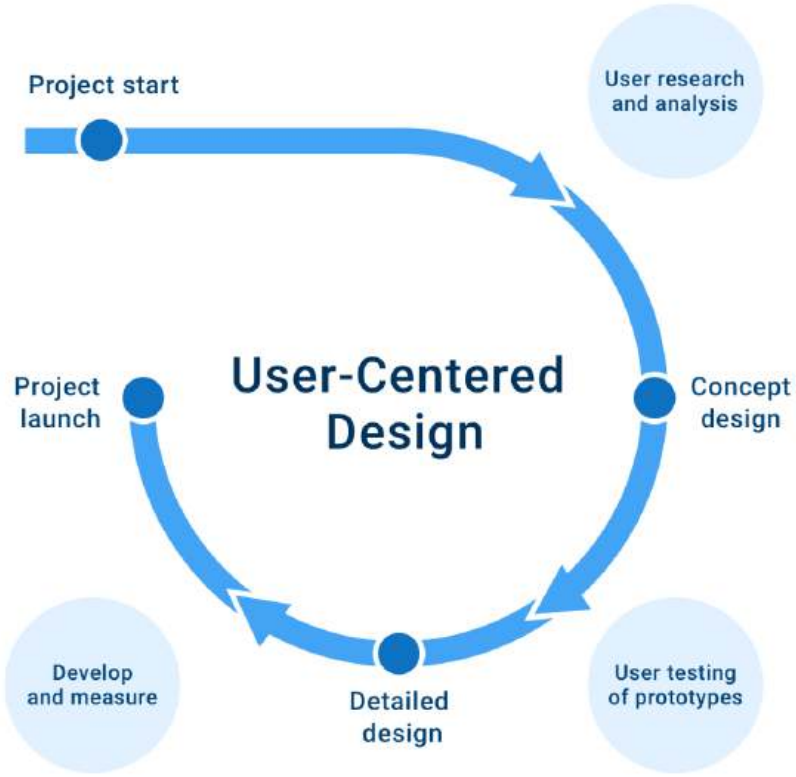
User-Centered Design (UCD

- User-Centered Design (UCD) is an iterative design process that focuses on the needs, preferences, and limitations of the end users at every stage of the design process.
- The goal is to create products that are highly usable and provide a positive user experience by involving users throughout the development process.



Key Principles of User-Centered Design:

1. **Early Focus on Users and Tasks**
   - User Research
   - Task Analysis
2. **Empirical Measurement**
   - Usability Testing
   - Metrics
   - Feedback
3. **Iterative Design**
   - Prototyping
   - User Testing
   - Refinement
4. **Integrated Design**
   - Collaborative Approach
   - Holistic View



UCD Process Steps

1. Understand the Context of Use

- User Analysis
- Contextual Inquiry

2. Specify User Requirements

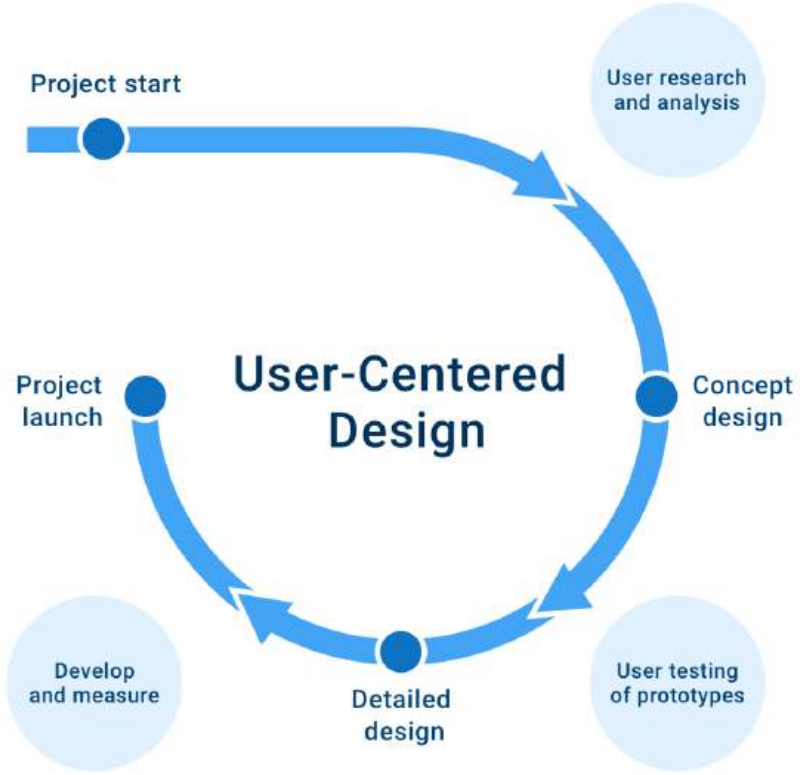
- User Stories and Scenarios
- Personas

3. Design Solutions

- Ideation and Sketching
- Prototyping

4. Evaluate Designs

- Usability Testing
- Iterative Feedback



Benefits of User-Centered Design

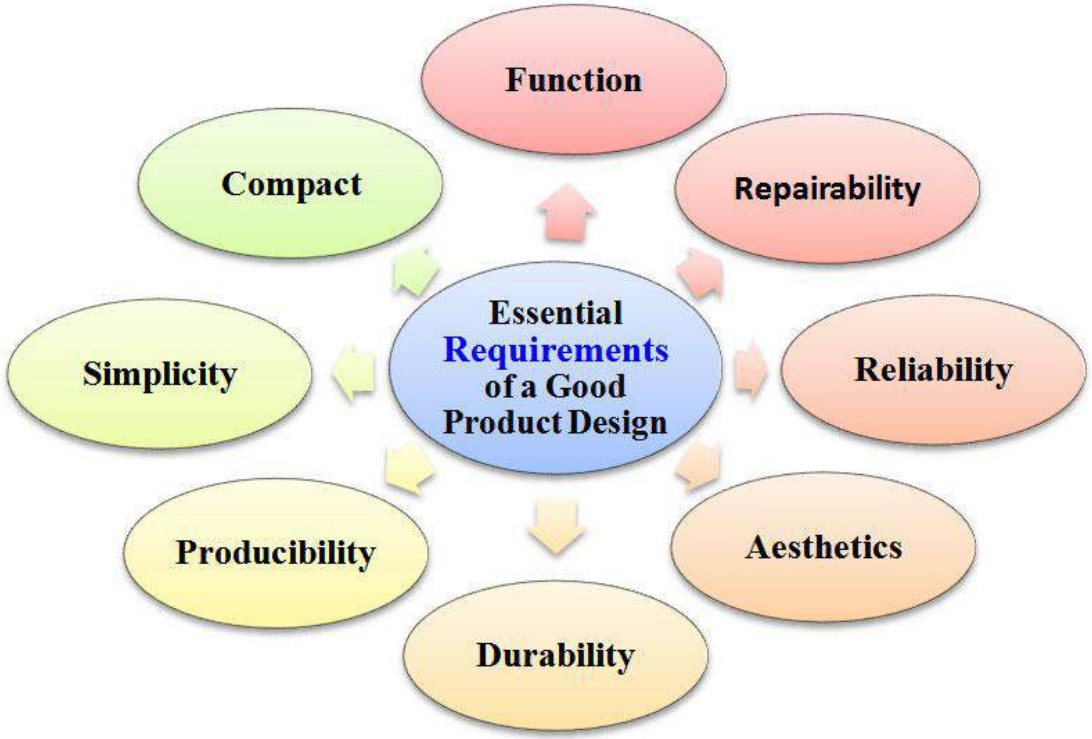
- **Improved Usability**: Products are easier to use and more effective in meeting user needs.
- **Increased Satisfaction**: Users are more satisfied with products that are tailored to their preferences and requirements.
- **Reduced Development Costs**: Identifying and fixing usability issues early in the design process is cheaper than making changes after launch.
- **Competitive Advantage**: Products with better usability and user experience stand out in the market.

Challenges of User-Centered Design

- **Resource Intensive**: Requires time and resources for user research, testing, and iterative development.
- **Complexity**: Managing user feedback and integrating it into the design can be complex.
- **Balancing Needs**: Balancing the needs of different user groups and stakeholders can be challenging.

Five Element of Successful Design

- The five elements of successful design are fundamental principles that ensure a product not only meets its intended purpose but also provides a positive experience for its users.
- These elements are crucial for creating designs that are functional, safe, user-friendly, ergonomic, and aesthetically pleasing.



1. Functionality

Functionality refers to the ability of a product to perform its intended tasks effectively and reliably.

This element ensures that the design meets all the technical and operational requirements.

- **Requirements Gathering**: Clearly define what the product needs to do. This involves understanding user needs, regulatory requirements, and technical specifications.
- **Performance**: The product must perform consistently under expected conditions and usage scenarios.
- **Reliability**: It should work without failure over its intended lifespan. This includes robustness to withstand environmental and operational stresses.

Example: A medical device like a blood glucose monitor must accurately measure blood sugar levels under various conditions, ensuring reliable and consistent performance.

2. Safety

Safety is paramount, especially in medical and consumer products, to prevent harm to users and others.

- **Risk Management**: Identify potential hazards and implement measures to mitigate them. This involves conducting risk assessments and implementing fail-safes.
- **Compliance**: Ensure the product meets all relevant safety standards and regulations. This can involve testing for electrical safety, biocompatibility, and other specific safety criteria.
- **User Safety**: Design features that protect the user, such as ergonomic shapes to prevent strain, clear warnings, and intuitive operation to prevent misuse.

Example: An insulin pump must have safeguards against over-delivery of insulin, alerts for low battery, and compliance with medical safety standards to ensure it is safe for patients to use.

3. Usability

Usability focuses on how easily users can interact with the product. A product with good usability is intuitive, easy to learn, and efficient to use.

- **User-Centered Design**: Involve users in the design process to ensure their needs and preferences are met.
- **Ease of Use**: Ensure that the product is straightforward to operate. This can include clear instructions, intuitive interfaces, and straightforward controls.
- **Feedback and Response**: Provide users with immediate and clear feedback on their actions. For example, visual and auditory signals can confirm successful operations or alert users to errors.

Example: A user-friendly smartphone interface allows users to quickly navigate apps and settings without extensive training or a manual.

4. Ergonomics

Ergonomics involves designing products that fit well with the physical and cognitive abilities of users, enhancing comfort, efficiency, and safety.

- **Physical Ergonomics**: Considerations include the size, shape, and weight of the product, ensuring it is comfortable and easy to handle.
- **Cognitive Ergonomics**: Design interfaces and controls that align with how users process information and make decisions.
- **Environmental Ergonomics**: Take into account the contexts in which the product will be used, such as lighting, noise levels, and other environmental factors.

Example: An ergonomic office chair is designed to support the user's body correctly, reducing the risk of strain and injury during long periods of use.

5. Aesthetics

Aesthetics deals with the visual appeal of the product. A well-designed aesthetic can enhance user satisfaction and product desirability.

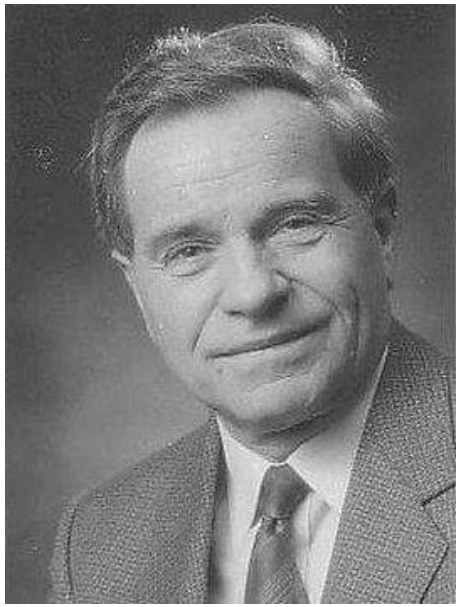
- **Visual Design**: Focus on elements such as color, shape, texture, and finish to create an attractive appearance.
- **Brand Identity**: Ensure the product design aligns with the brand's image and values, creating a cohesive and recognizable look.
- **Emotional Response**: Design to evoke positive emotions, making the product enjoyable to use and own.

Example: A sleek, modern design for a home appliance can make it an attractive addition to a kitchen, encouraging users to prefer it over less visually appealing alternatives.

Pahl and Beitz Design Model

- The Pahl and Beitz Design Model, developed by German engineers Gerhard Pahl and Wolfgang Beitz, is a systematic approach to engineering design.
- This model is widely recognized for its structured methodology, which guides the designer through a comprehensive process from problem definition to the final detailed design.
- It is particularly effective for complex engineering projects where rigorous documentation and thorough analysis are crucial.

Pahl



Beitz

Key Phases in the Pahl and Beitz Design Model:

1. Clarification of the Task

- Requirement Analysis
- Problem Definition
- Information Gathering

2. Conceptual Design

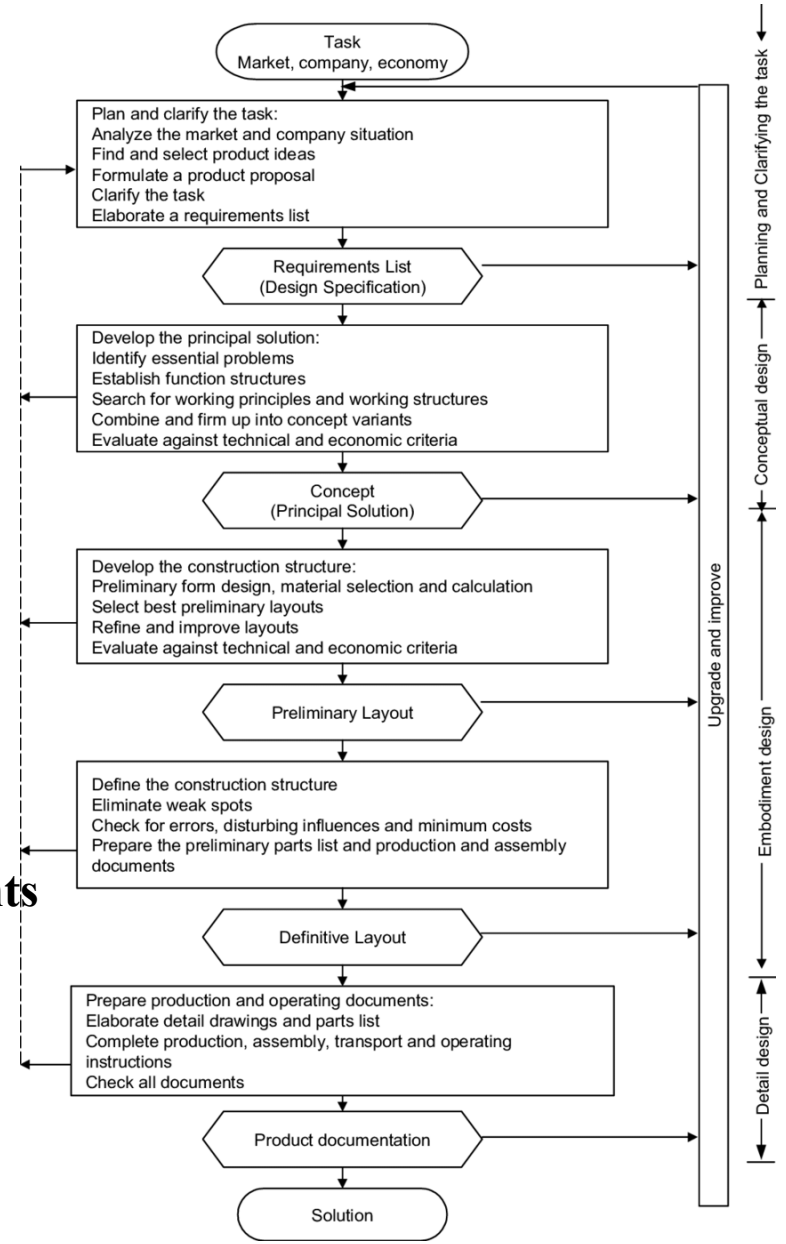
- Function Structure
- Concept Generation:
- Concept Evaluation and Selection

3. Embodiment Design

- Preliminary Layout
- Material Selection
- Detailed Design of Subsystems
- Evaluation and Optimization

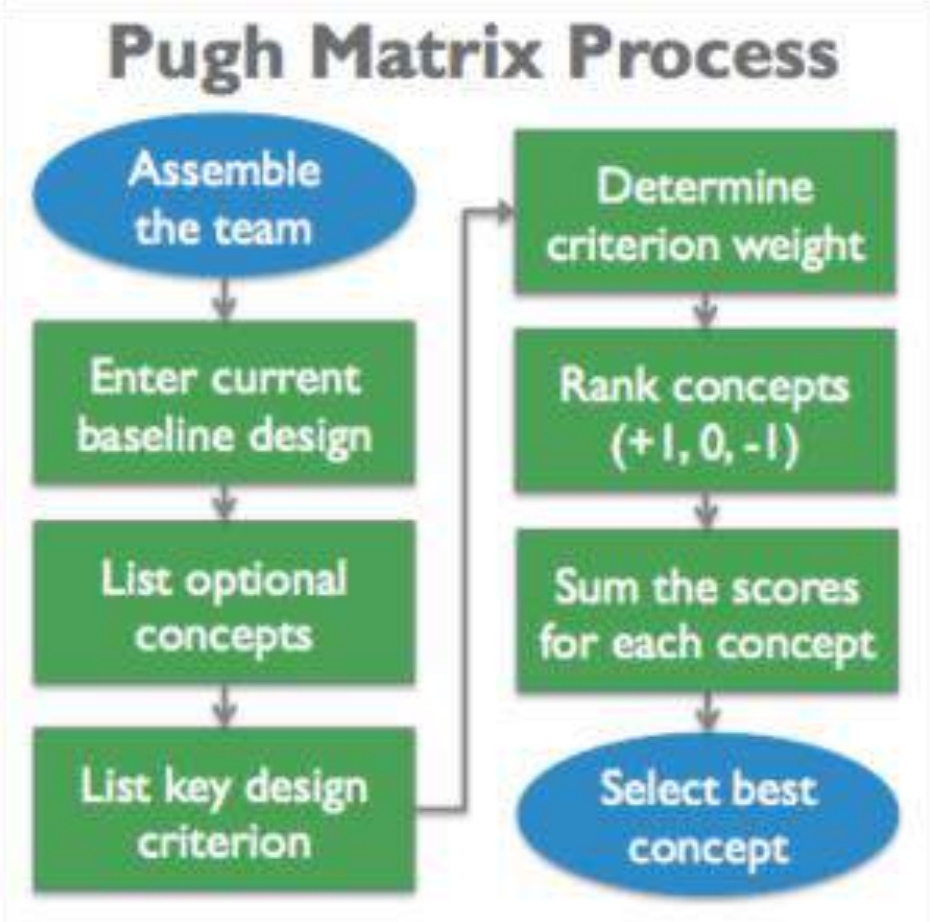
4. Detail Design

- Final Layout
- Standard Parts and Components
- Production Documentation
- Testing and Validation



Pugh's Design Model

- Pugh's Design Model, also known as the Pugh Matrix or Decision Matrix Method, is a structured approach to concept selection that helps in comparing multiple design alternatives against a set of criteria.
- This model was developed by Stuart Pugh and is particularly useful in engineering and product design.
- The primary goal is to evaluate and select the best concept through systematic comparison and iterative improvement



Key Phases in the Pahl and Beitz Design Model: Conti…

Key Steps in Pugh's Design Model:

1. **Generate Alternatives**
2. **Select Criteria**
3. **Create the Matrix**
4. **Scoring**
5. **Evaluation**
6. **Iterative Refinement**

1. . Generate Alternatives

- **Concept Generation**: Begin by brainstorming and generating multiple design concepts.
- These alternatives can be derived from creative thinking, benchmarking existing products, and combining different ideas.
- The goal is to explore a broad range of possible solutions.
- **Multidisciplinary Input**: Involve team members from different disciplines (engineering, marketing, user experience, etc.) to ensure a diverse set of ideas.

Key Phases in the Pahl and Beitz Design Model: Conti…

2. Select Criteria

- **Criteria Definition**: Define the criteria against which the design alternatives will be evaluated. These criteria should be relevant to the project goals and can include factors such as performance, cost, usability, manufacturability, safety, and regulatory compliance.
- **Weighting Criteria**: Optionally, assign weights to each criterion based on their relative importance. This helps in prioritizing critical aspects of the design.

3. Create the Matrix

- **Matrix Setup**: Create a matrix with the design alternatives listed along the rows and the evaluation criteria listed along the columns.
- **Baseline Concept**: Select a baseline concept (usually an existing product or a reference design) to serve as a benchmark for comparison. This is placed as the first column in the matrix.

Key Phases in the Pahl and Beitz Design Model: Conti…

4. Scoring

- **Score Assignment**: For each criterion, assign a score to each design alternative relative to the baseline. The scoring typically uses symbols such as:
  - **"+" (plus)**: The alternative is better than the baseline for that criterion.
  - **"0" (zero)**: The alternative is equivalent to the baseline for that criterion.
  - **"-" (minus)**: The alternative is worse than the baseline for that criterion.

5. Evaluation

- **Summarize Scores**: Sum the scores for each alternative to get an overall score. This helps in identifying the strengths and weaknesses of each concept.
- **Rank Alternatives**: Rank the design alternatives based on their total scores. The alternative with the highest score is generally considered the best option.

Key Phases in the Pahl and Beitz Design Model: Conti…

6. Iterative Refinement

- **Analyze Results**: Review the scores and identify areas where leading concepts can be improved. Look for opportunities to combine the best features of different alternatives.
- **Refine Concepts**: Modify the design alternatives based on the analysis and repeat the evaluation process. This iterative refinement helps in converging towards an optimal design solution.
- **Consensus Building**: Engage stakeholders to review the results and reach a consensus on the best alternative. This ensures buy-in from all relevant parties.

Example of a Pugh Matrix (portable blood glucose monitor)

Imagine a company is designing a new medical device, such as a portable blood glucose monitor. They have generated three design alternatives (A, B, C) and selected the following criteria for evaluation: Cost, Accuracy, User-Friendliness, and Battery Life. Here's how the matrix might look:

In this example, Alternatives A and C both have a net score of +1, indicating they are both better than the baseline in different ways. Further analysis and refinement would be needed to choose the best option.

Criteria	Baseline (Existing Device)	Alternative A	Alternative B	Alternative C
Cost	Baseline	-	0	+
Accuracy	Baseline	+	0	+
User-Friendliness	Baseline	0	+	-
Battery Life	Baseline	+	-	0
Total Score (+)		2	1	2
Total Score (-)		1	1	1
Net Score		+1	0	+1

List of Online Resources

1. https://nptel.ac.in/courses/127106136
2. https://archive.nptel.ac.in/courses/127/106/127106010/
3. https://onlinecourses.swayam2.ac.in/nou24_bt07/course (Imaging Devices)
4. https://onlinecourses.nptel.ac.in/noc22_cs39/preview

Important Questions

1. What is the definition of a medical device, and what are its primary purposes?
2. What are the key stages in the design life cycle of a medical device?
3. What are the main components and significance of man-machine dialogue in medical device design?
4. How does industrial design contribute to the development of medical devices?
5. What are the core principles of user-centered design, and why are they crucial for medical devices?
6. What are the five elements of successful design, and how do they apply to medical devices?
7. How does cognition impact the design of medical devices, and why is it important?
8. What is ergonomics, and how does it relate to the design of medical devices?
9. What are Pahl and Beitz's design models, and how are they applied in the context of medical devices?
10. What is Pugh's design model, and how does it facilitate decision-making in the design process?