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Design and Professional Practice 2

The Design and Development Process

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Aims and Objectives

The aim of this lecture is to provide you with an understanding of the Product Development Process.

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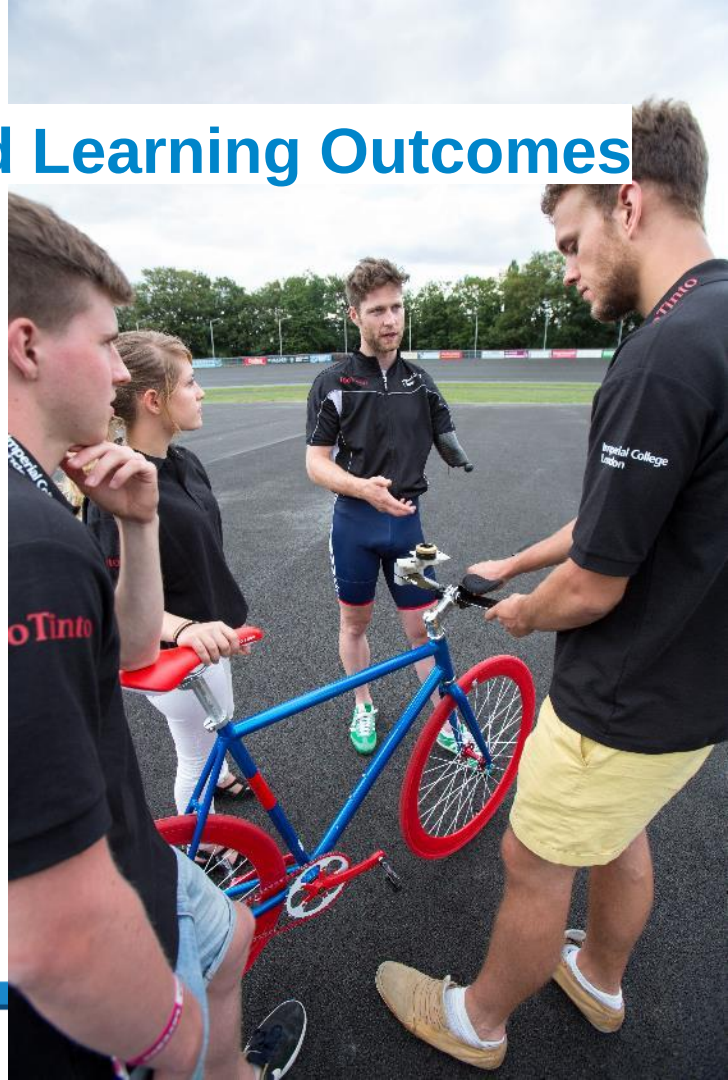
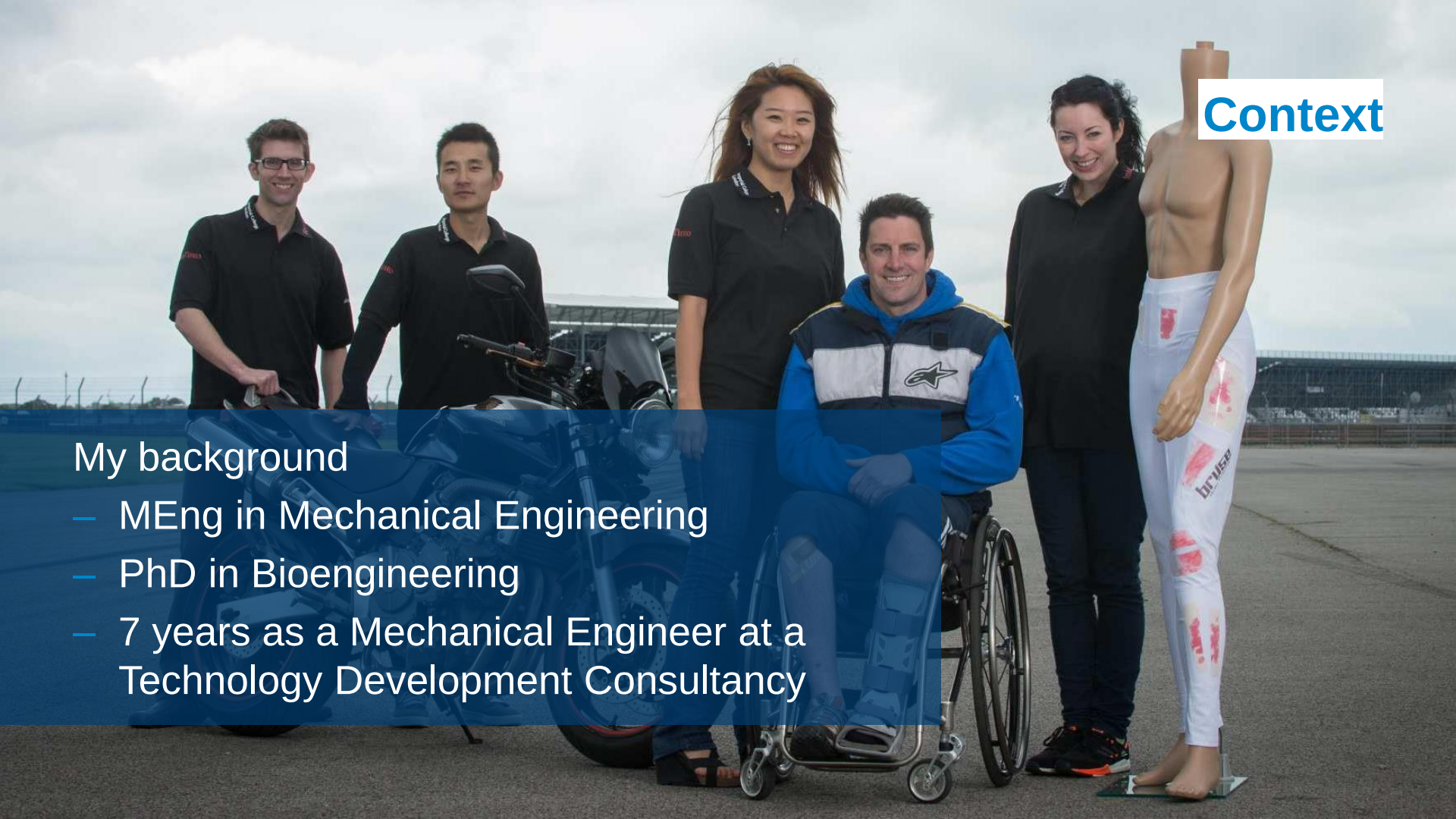
Intended Learning Outcomes

By the end of this session, you should be able to explain the Product Development Process and be prepared to use it in your own project.



Context



My background

- MEng in Mechanical Engineering
- PhD in Bioengineering
- 7 years as a Mechanical Engineer at a Technology Development Consultancy

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Product Development Process

Project timeline and assignments track the general product development process

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Product Development Process

Understanding the user requirements and use environment:

- Background research
- Literature review
- User interviews
- Formative trials

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‘If all you have is a hammer, everything looks like a nail”

(Maslow, 1966, p15)

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Product Development Process

Understanding the user requirements and use environment:

- Background research
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Assignment:
Product Specification Document

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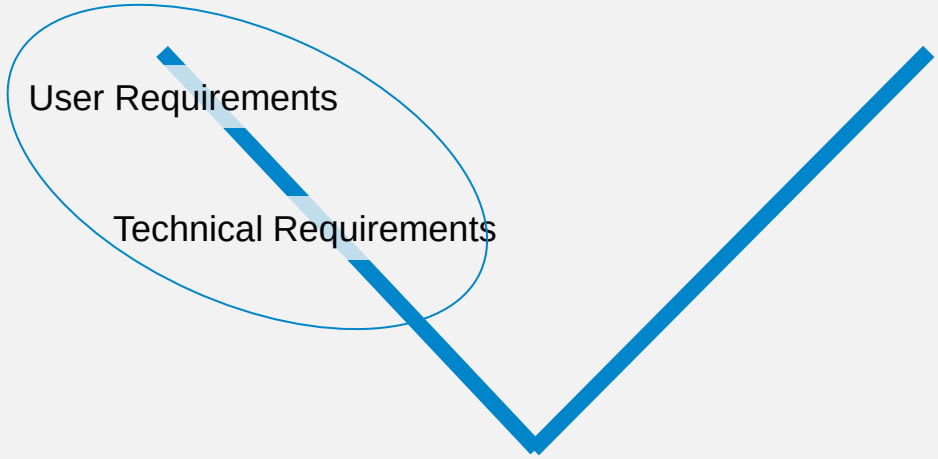
Product Development Process

The V-Model



1 Problem Definition

2 Concept Generation

3 Technical Development

4 Detail Design

5 Manufacture Realisation

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Product Development Process

User Requirements

4.0 System Features

4.1 The system will consist of two handheld devices, differing only by the size and arrangement of the electrodes. The primary device will consist of a more extensive number of electrodes and will be used to produce planes of coagulated tissue in highly vascular organs. The secondary device will be used to coagulate small vessels or areas of tissue that have not been coagulated by the primary device.

4.2 Each device's handle will be constructed from a medical grade polymer which will provide thermal and electrical insulation. The handle design will be comfortable and practical.

4.3 For the primary device, multiple electrodes will issue from the handle in an array that will be designed to coagulate a volume of tissue at depths of up to 20cm, with a length of more than 2cm and widths of 1 cm. Each volume of tissue will be coagulated in less than 5 minutes.

4.4 For the secondary device, electrodes will issue from the handle in an array that will be designed to coagulate tissue at depths of up to 5 cm , lengths of 2cm and widths of 1 cm. Each volume of coagulated tissue will be achieved in 3 minutes.

4.5 Both devices will be supplied sterile and for single use only.

4.6 Each alternate electrode on a device will act as the ground return for the active electrode; hence the RF energy will be delivered bipolar. This substantially reduces the measured impedance, allowing for a more efficient power delivery, and eliminating the risk of ground electrode burns.

4.7 The electrodes on each device will be made from a material that will provide mechanical strength compatible with multiple insertions into soft tissue without significant deformation of the electrodes. The electrodes will have suitable conductive properties. The electrodes will have a non-stick surface preparation to facilitate insertion and removal from the liver or other soft vascular tissue. The electrodes will be designed to allow easy insertion into soft tissue.

4.8 The devices will have cables and connectors for connection to an RF generator outside of the sterile field. The RF generator will supply the RF energy in the frequency range 200-800kHz to the electrodes. The device will operate with 200W generators such as the Radionic's RF generator.

Technical Specification

Device		A: Long Probe	B: Short Probe
Total Number of Needles		4	4
Needle Diameter	mm	2.0	1.5
Total Length	mm	210	70
Useable Needle Length below plate	mm	190	50
Insulated Length	mm	150	0
Non insulated (active) length (distal portion)	mm	40	50 (full length)
Arrangement of needle array		2 x 2 (2 pairs)	2 x 2 (2 pairs)
Separation to sideways neighbour (centre-centre)	mm	6.0	6.0
Separation to next pair (centre-centre)	mm	7.0	7.0

1 Problem Definitio

5 ufacture lisation

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Product Development Process

Generating a collection of potential solutions to meet the challenge:

- Ideation (thinking stuff up), Morphological Analysis
- Build upon research
- Sketches, mock-ups and simple prototypes
- Basic calculations
- Ranking of concepts

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Product Development Process

Progressing the chosen concept(s):

- Prototyping
- Simulation / Analysis
- Testing / Trials
- Design iteration
- Manufacturing options
- Understanding risks and ethics
- Costing

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Product Development Process

Final design lock-down:

- Design for manufacture and Assembly
  - CAD and 2D Drawings
  - Wiring diagrams
  - Coding
  - Material selection
  - Bill of Materials
- Evaluation planning

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Product Development Process

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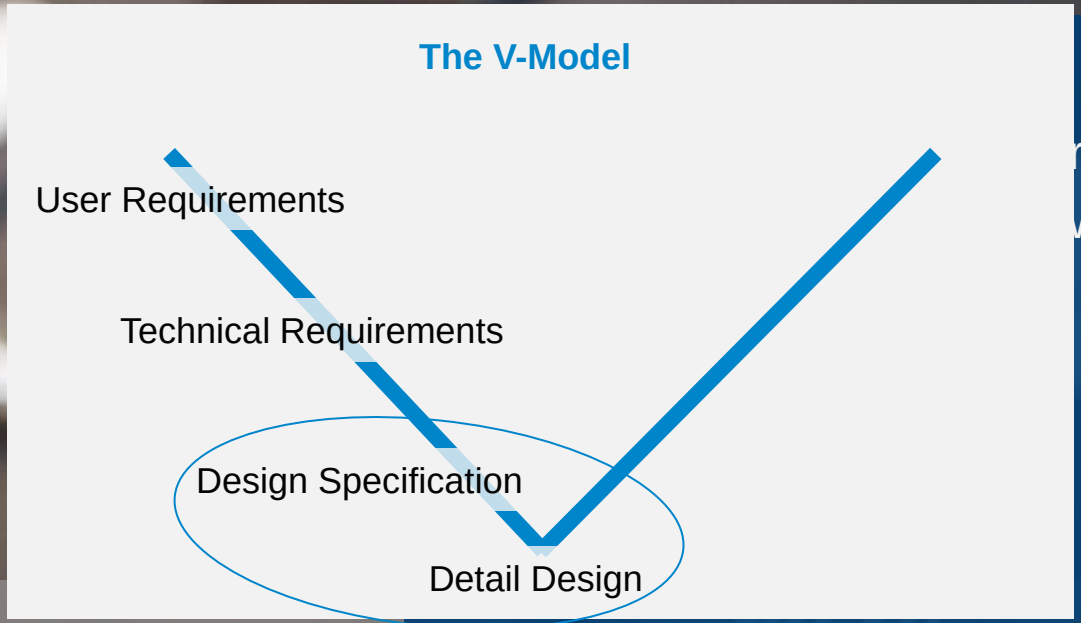
vings



1 Problem Definition

2 Concept Generation

3 Technical Development

4 Detail Design

5 Manufacture Realisation

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Product Development Process

Assignment:
Group Presentation

Final design lock-down:

- Design for manufacture and Assembly
  - CAD and 2D Drawings
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  - Coding
  - Material selection
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Product Development Process

Manufacture and assessment:

- Manufacture
- Assembly
- Testing and Evaluation
- Demonstration
- Report
- Recommendations

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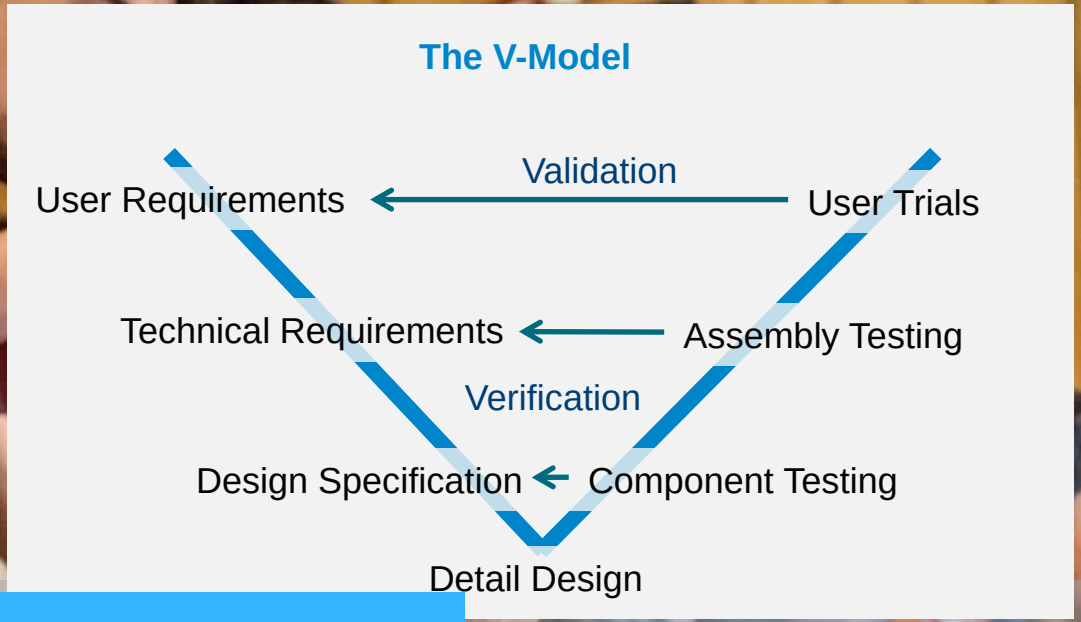
Product Development Process



Validation:
Are we building the right product?
Verification:
Are we building the product right?

3 Technical velopment
4 Detail Design
5 Manufacture Realisation

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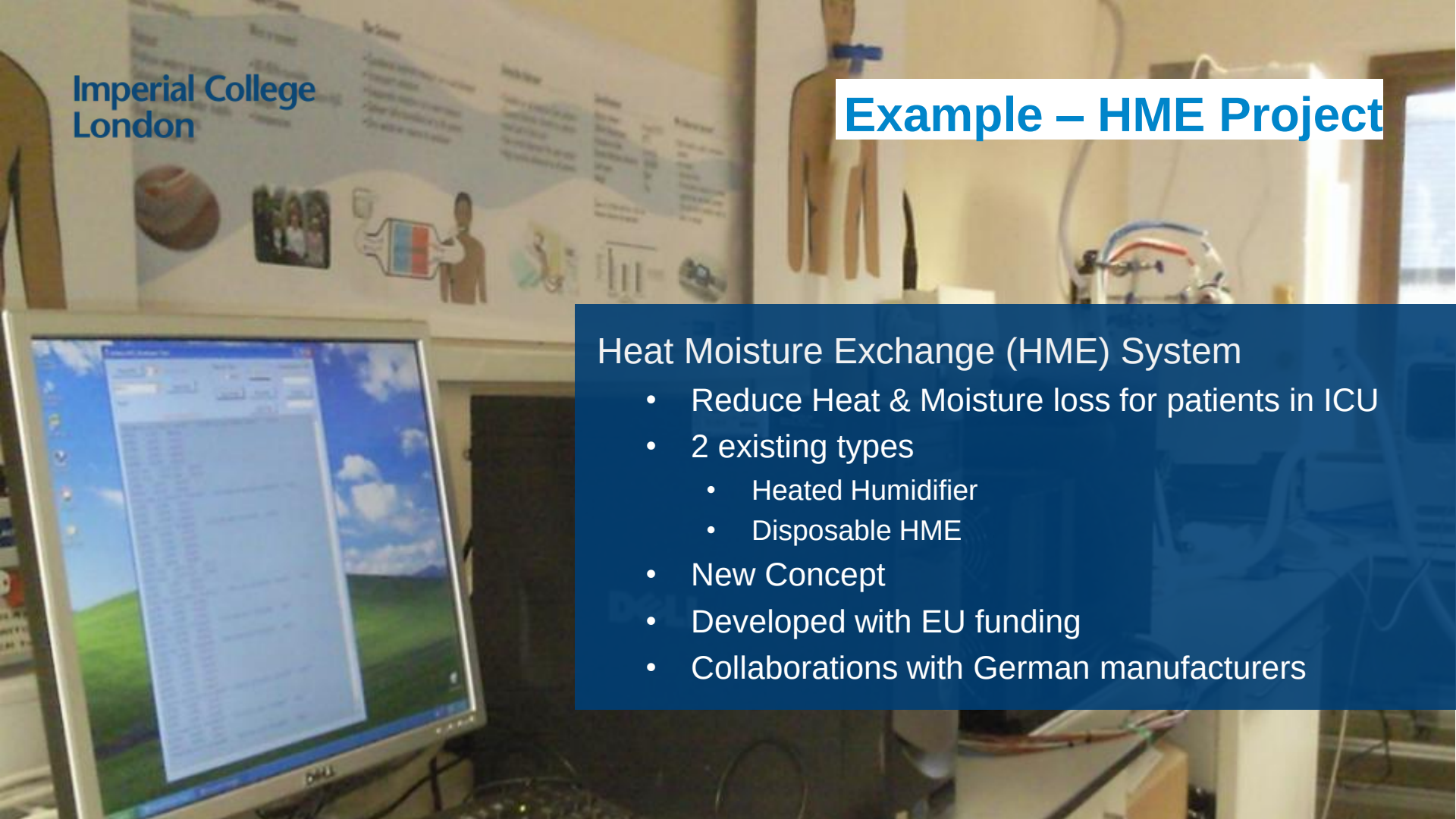
Product Development Process

Assignments:

Poster
Demonstration Day
Final Report

Manufacture and assessment:

- Manufacture
- Assembly
- Testing and Evaluation
- Demonstration
- Report
- Recommendations



Example – HME Project

Heat Moisture Exchange (HME) System

- Reduce Heat & Moisture loss for patients in ICU
- 2 existing types
  - Heated Humidifier
  - Disposable HME
- New Concept
- Developed with EU funding
- Collaborations with German manufacturers

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Example – HME Project

Problem Definition

- Basic objectives
- Clinical indications
- Interdisciplinary review panel (surgeons, engineers, etc.)

Commercial Aspects

- Consider the market
- Business model
- Market research / feasibility study

Project Planning

- Project management
- Milestones
- Risk management plan
- Resources (financial and human)

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Example – HME Project

Regulatory Requirements

- Classification
- Global standards

Design Requirements

- Requirements capture
  - Surveys
  - Interviews
  - Usability tests
  - Competitor analysis
- Product Specification Document (PSD)
  - User Requirements Specification
  - Technical Requirements Specification

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Example – HME Project

Regulatory Requirements

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- Intended performance
- Design attributes
- Materials
- Design evaluation
- Manufacture
- Testing
- Instruments required
- Sterilization
- Packaging
- Information to be supplied by the manufacturer

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Example – HME Project

Concept Design

- Concept generation (brainstorms etc.)
- Simple sketches
- CAD models
- Analytical calculations
- Manufacture consultation

Detail Design

- CAD models and engineering drawings
- Materials specification
- Tolerance stacks
- Inspection requirements
- Design for Manufacture and Assembly (DFMA)

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Example – HME Project

Concept Design

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Design Reviews

- Required at each stage of the development
  - Evaluate design requirements
  - Assess capability of the design
  - Identify problems

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Example – HME Project

Design Verification

- Checking the design meets the requirements
- Finite Element Analysis (FEA)
- Computational Fluid Dynamics (CFD)
- Risk Analysis
  - Failure Mode Effect Analysis (FMEA)
  - Fault Tree Analysis
- Prototyping
- Engineering Demonstrator
- Lab testing

Verification:
Are we building the product right?

Example – HME Project

Manufacture

- Manufacturing processes
  - Repeatable and reliable
  - Suitable for volumes
  - Suitable for material requirements
- Sterilisation
- Labelling
- Packaging
- Printing
- Instructions

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Example – HME Project

Design Validation

- Mechanical testing of prototypes
- Clinical safety evidence
- Clinical investigation
  - Ethics committee approval
- Sterilisation validation

Validation:
Are we building the right product?

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Summary

- To design a product successfully you need to understand the problem it is trying to solve.
- Product development is a convoluted and iterative process and you need to be flexible in your approach.
- You Verify you design against Technical Requirements but you Validate against the User Requirements.

For more information read A Brief Guide To ISO 13485's Design Controls In Medical Device Development (meddeviceonline.com)