Early-Stage Design Control for Device Development

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Trusted Solutions, Rapid Response

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Introduction

The purpose of this training session is:

Provide a general overview of Design Controls during Feasibility and Clinical Evaluation

Introduction

- David Rothkopf
- After Aerospace moved to Medical
  - Design engineer
  - Manufacturing Engineer
  - Operations/setting up new factories
  - Quality
  - Regulatory
- Started 4 Medical Device companies & two consulting firms
- As a consultant, we mostly work with start ups

Topics of Discussion

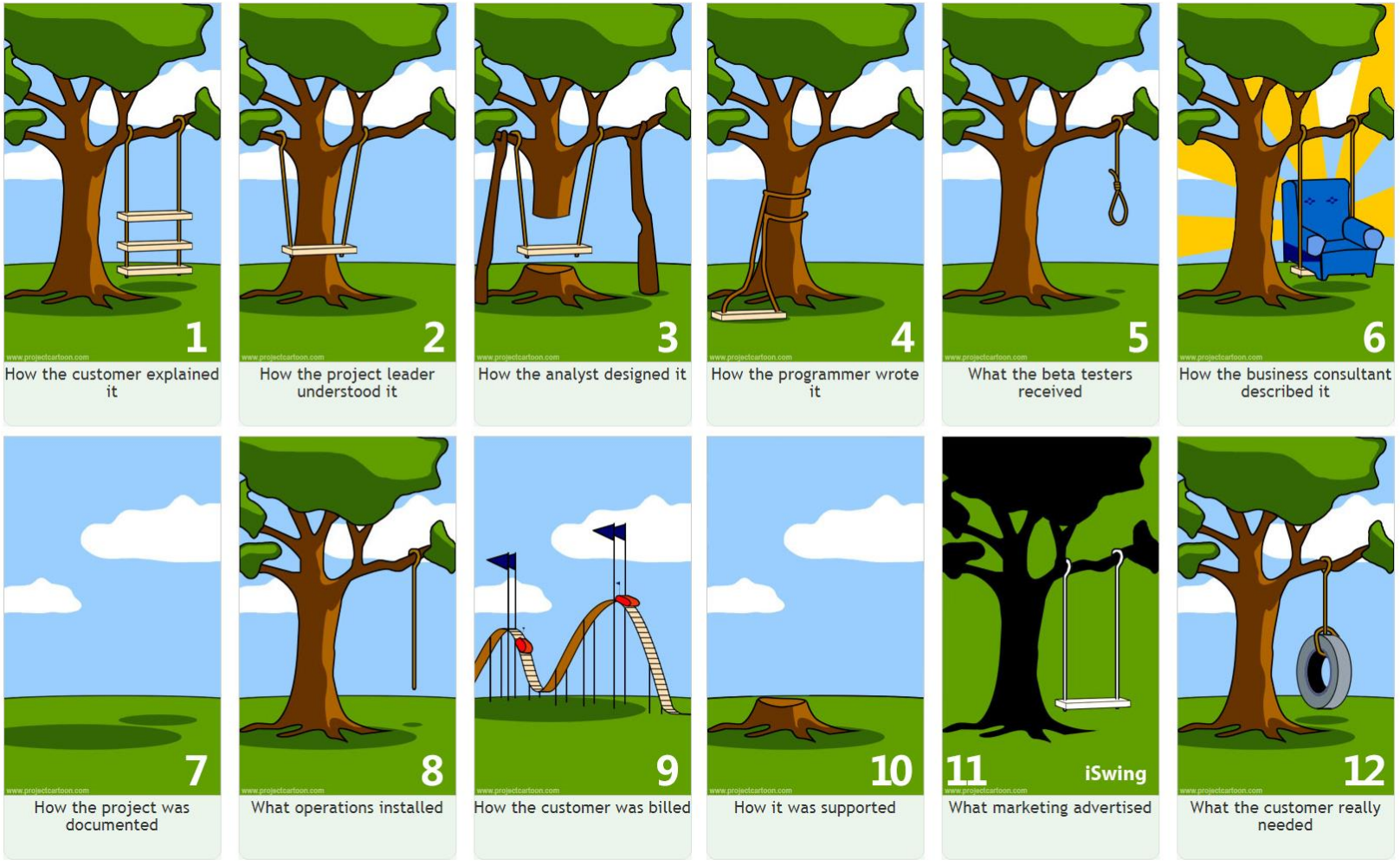
- General Comments
- Design Inputs
  - User needs
  - Problem solution
- Design Output
- Verification Documentation
  - Lot traceability
- Early feasibility Studies

General Comments

- Design Control is like planning & completing a trip
- It is the documented manifestation of scientific method
  - Identify the problem statement (user need)
  - Provide a hypothesis (inputs/outputs) to solve the problem statement
  - Check for risks (risk management)
  - Test the hypothesis (verification and validation)
  - Document conclusion and implement (transfer)

- For medical devices – very broad term
  - Anything that does not use chemical reaction

Why Design Control is needed

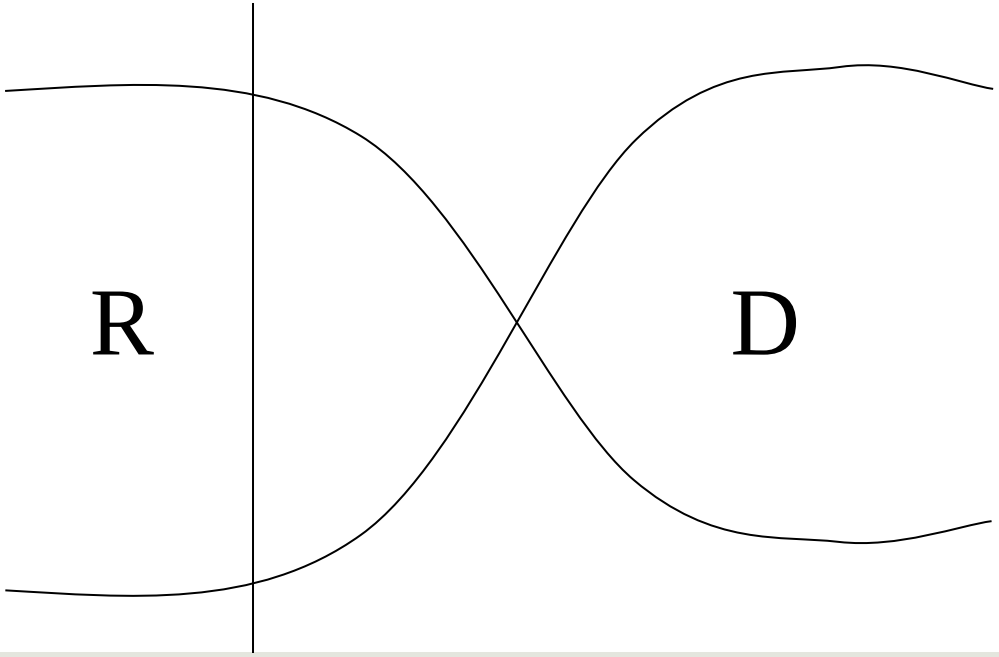


General Comments : Design Controls

- Applicability - FDA
  - All Class III and Class II medical devices
  - Some Class I - including any device automated with software (including MDDS)
- Applicability – EU MDR/IVDR, ROW with defined approval processes (e.g. China, Brazil, Australia, etc.)
- Applicability – ISO
  - All medical devices

Design Control

- So when does Design Control begin
  - Technically the legal requirement for Design Control is right after feasibility, requirements are started



Design Input

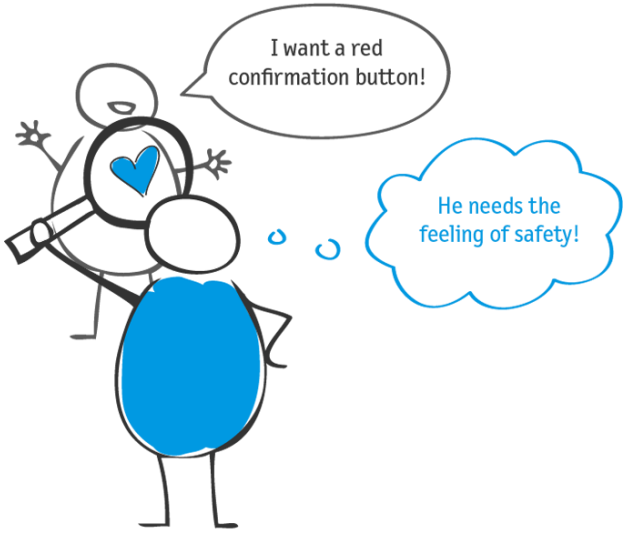
- WHY ARE YOU DOING THIS
- What is the problem your solving?

- Document user and patient needs (relate to intended use/indications)
- Define design requirements

- Does not have to be complete but you should write them down

User Needs – Why are you doing this

- Who…
  - …is going to use it?
- What…
  - …do you want the device to do?
  - …important attributes or features should be considered?
  - …type of procedures will the device be used for?
  - …other products or devices will it interact with?
  - …Skills/ Credentials does the user need?
- When…
  - …will it be used?
- Where…..
  - … Where will it be used? Special requirements for IVD products, CLIA, Point of Care, OTC,
- How…
  - …will the user interact with the device?
  - …often is the device used? Once? Repeatedly?
  - ….will data be stored, delivered, interfaced, reviewed



Design Input

- ALL the requirements needed to build the product
  - Standards
  - Specification
  - Measurable
  - Alarm
- Agile development
  - Identify the requirements you know, TBD the rest
  - Go back and add more requirements
  - Explain with as much detail so engineers know what you want

Design Control Flow - Software

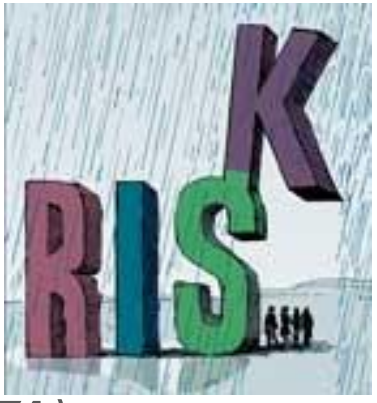
- IEC 62304:2006 Medical device software – Software life cycle processes
- Basically Mini waterfalls
- MUST start very early or else retrospective

Human Factors

- Start early
  - Design usability into the product not after it has been designed
  - Create story board, use cases, process flows
  - Macroscopic and user perception

- Reduce User Errors – stupid proof
- Use-related hazards
- Increase communication between the user and device
- **IEC 62366-1 2015** Application of Usability Engineering

Risk Management



- In Feasibility – Just think about risk
- No need to formally do anything yet

- ISO 14971: 2019 and TIR24971 (Guidance on 14971)
- Use risk analysis to determine

  the testing and statistical sample sizes

Human Factors

"A common mistake that people make when trying to design something completely foolproof is to underestimate the ingenuity of complete fools"

Douglas Adams

Design Output

- Technical conversion of design inputs
- Examples
  - Specifications, Drawing, Schematic
- Again not formal
- Maybe some level of revision control??
- Maybe just something like an engineering notebook

- Get suppliers involved early

Preliminary Design Verification

- Confirm that **design output meets the design input**
- May involve:
  - Animal tests
  - Cadaver study
  - BEP – Biological Evaluation Plan
  - Phantom testing (imaging, implant)
- Record how you made the parts
- Write down acceptable criteria and results
- Trace the materials used
- Record testing conditions so its repeatable

Early Feasibility Studies

- Enrolling a small number of subjects
- After animal studies
- Evaluate device design concepts
- Test for clinical functionality and maybe safety
- May lead to device modifications

- Design control is legally not needed but the information required is same as information required for design control
- IDE or IRB

Early Feasibility Studies

- For example: for most IDE studies and IRB studies
  - Description of the device – intended use
  - Clinical objective – Investigational plan
  - Prior investigations
  - Safety/risk information
  - Product development
- This is all information that also goes in a design file and will be asked by FDA

Questions

Thank you!

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