

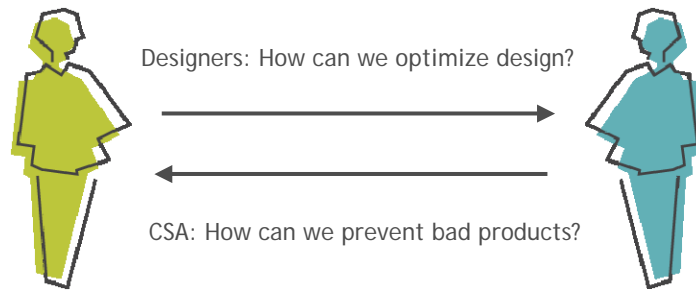


Universal criteria  
for the design of  
medical instruments

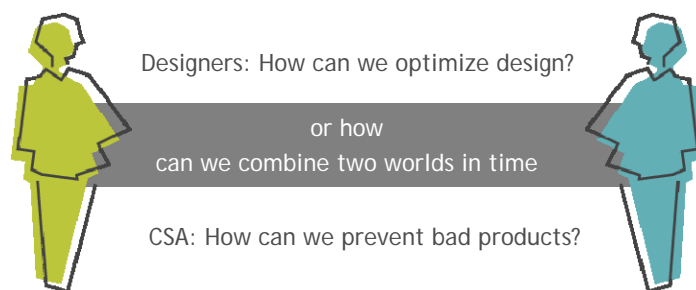
Ingeborg Griffioen



## Two questions



## Two questions





## Panton bv

Team creative experienced designers

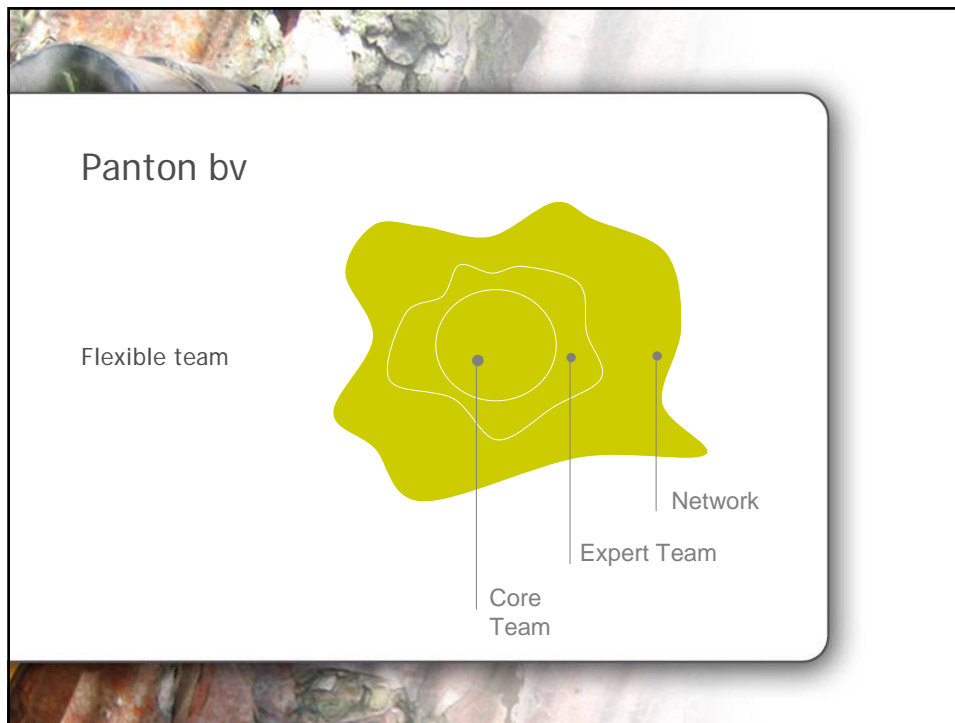
Mission: solve problems in health care

Strong focus on: usability & safety

How: design

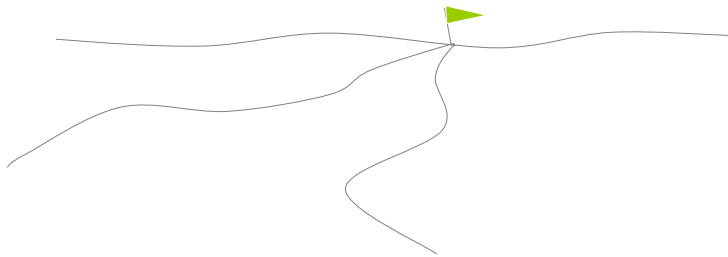
Products, process, communication





## Designer focus

Excel on  
A) Functionality  
B) Costs  
C) Timing



## Designer focus

A) Functionality  
technical feasible, ergonomics, design

B) Costs  
product costs and investments

C) Timing  
production, marketing, approvals, trade show

## Designer focus

### A) Functionality

technical feasible, ergonomics, design

☑ *users love it*

### B) Costs

product costs and investments

☑ *feasible for supplier*

### C) Timing

production, marketing, approvals, trade show

☑ *beat competitor*

## Designer focus

### A) Functionality

technical feasible, ergonomics, design

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### B) Costs

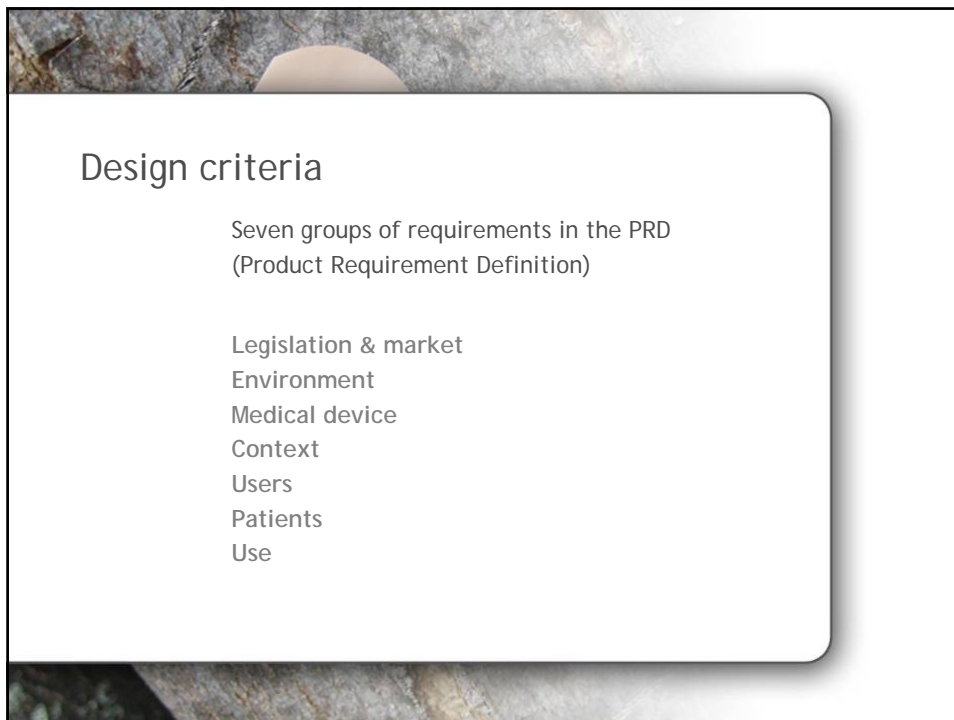
product costs and investments

☑ *feasible for supplier*


### C) Timing

production, marketing, approvals, trade show

☑ *beat competitor*








## Design criteria

Seven groups of requirements in the PRD  
(Product Requirement Definition)

- Legislation & market
- Environment
- Medical device
- Context
- Users
- Patients
- Use

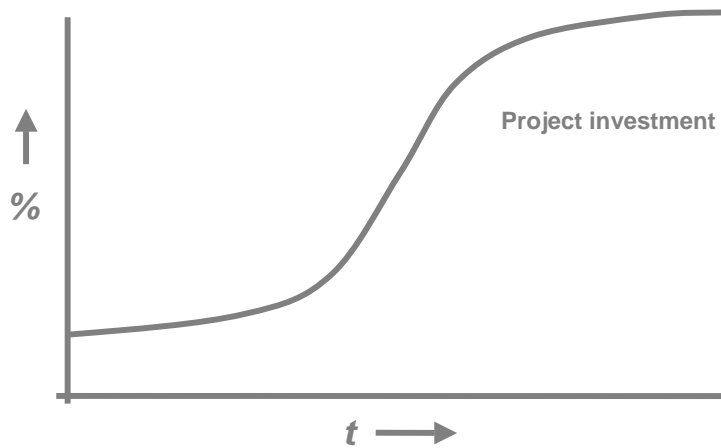


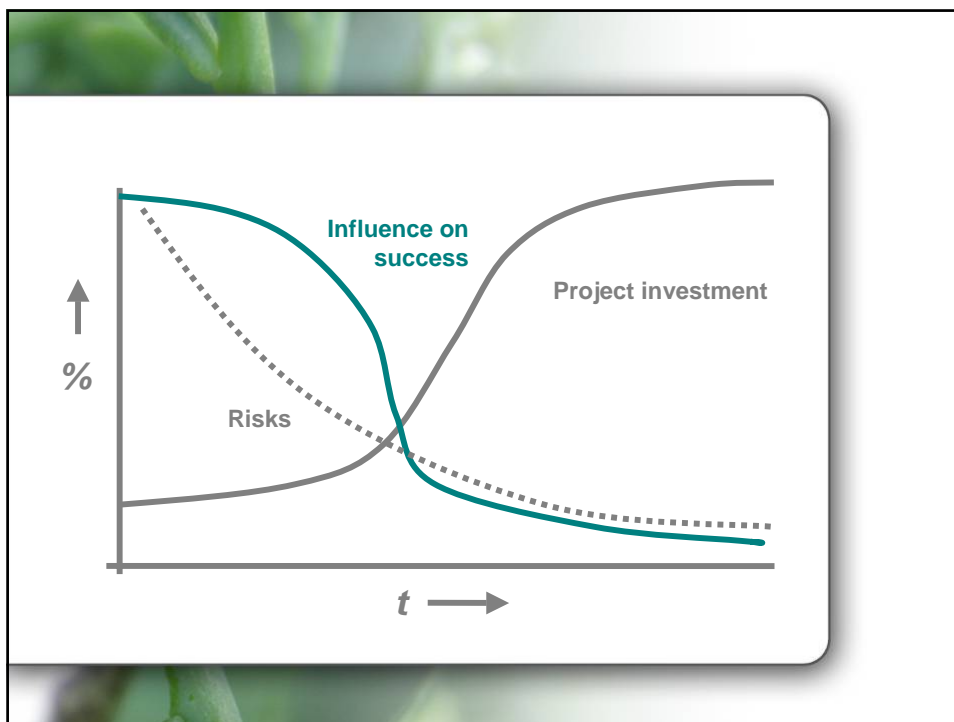
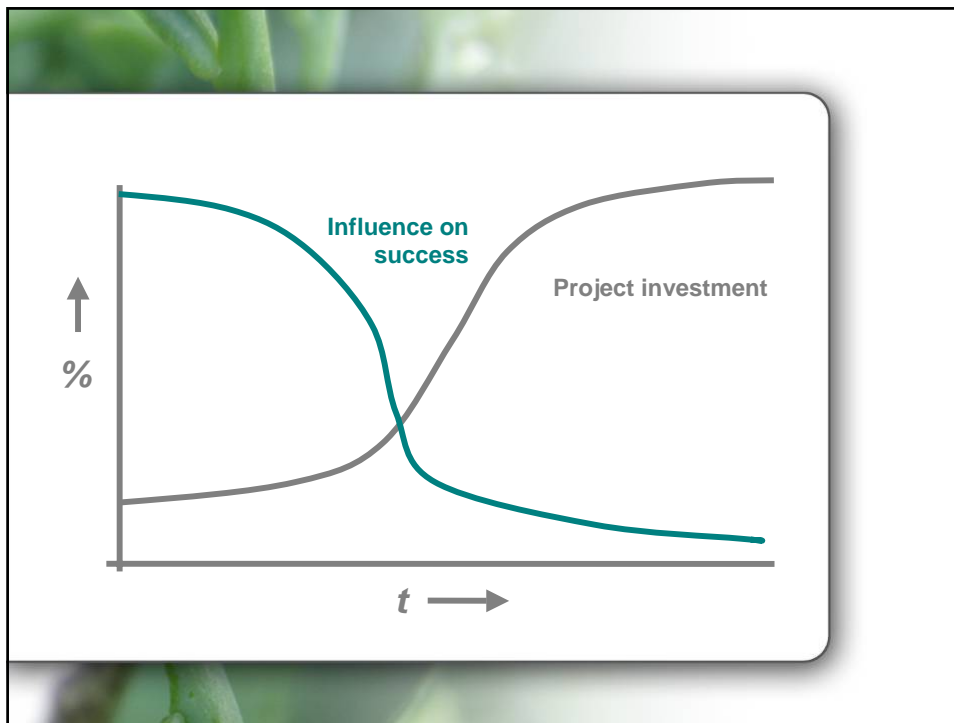
## Design process

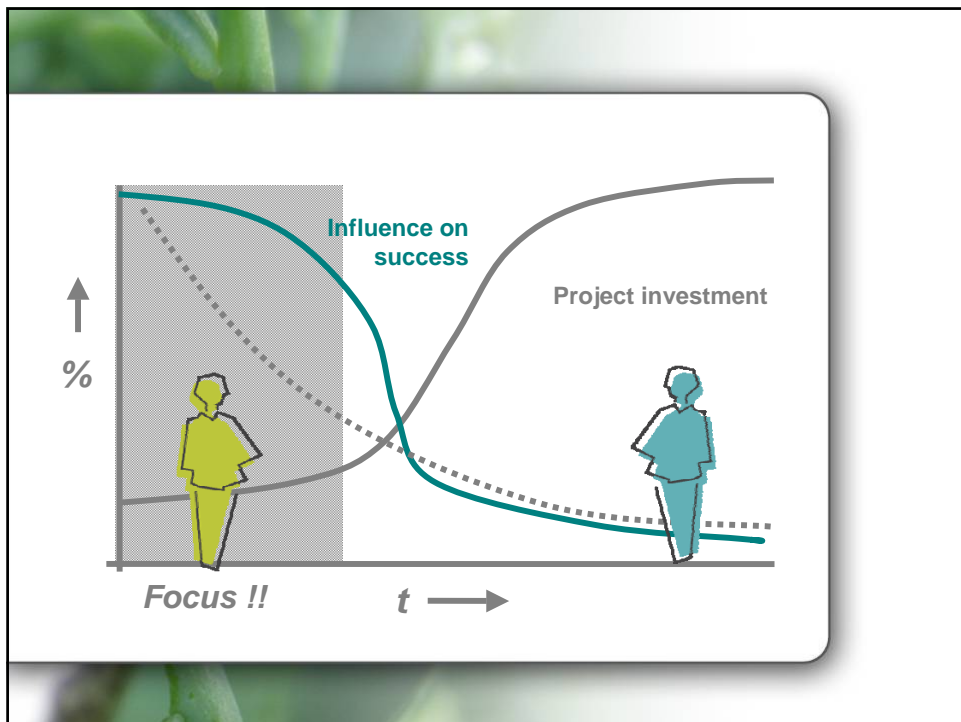
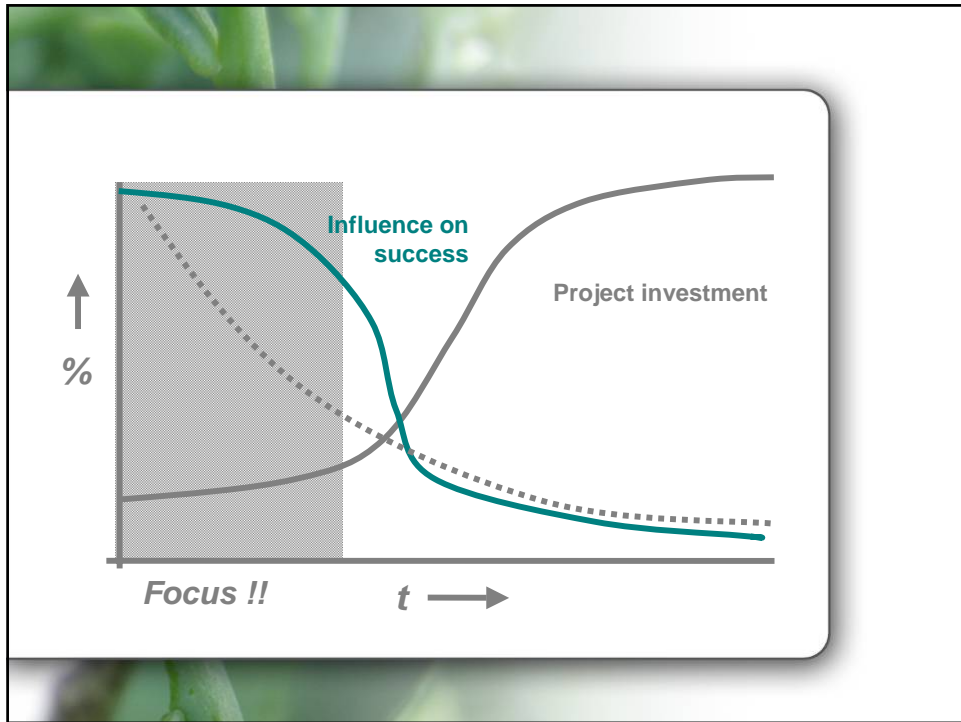


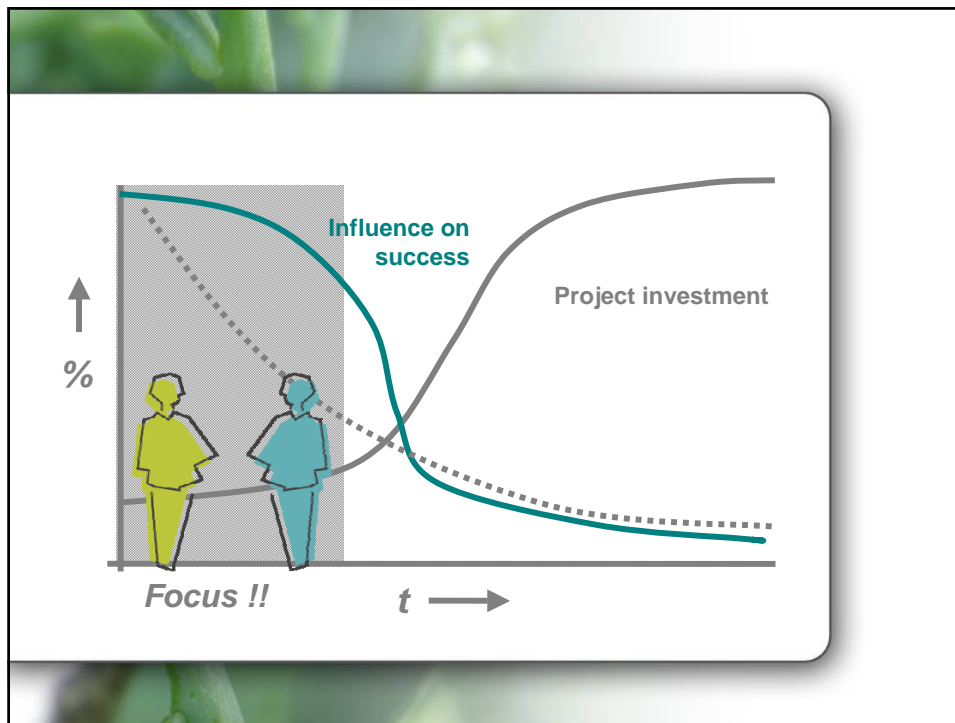
## Design process

Universal process  
Managing risks  
According to standards  
and quality systems  
  
Still creative ?!?!









## Design process

In the first phases:  
Room for creativity  
Feedback welcome  
There's a lot to consider simultaneously

Make the best decisions  
As a multidisciplinary team  
At organized design reviews



Design reviews

- Meetings between two phases to
- Eliminate wrong decisions ASAP
- Use preliminary results
- Check with PRD

Multidisciplinary team

## Design reviews

Analysis	→ PRD, FMEA
Idea phase	→ sketches
Concept definition	→ early models
Testing	→ test results
Design phase	→ drawings
Engineering	→ new models
Testing	→ test results
Sourcing	→ BOM
Production test	→ FOT, SOT
Certification	→ DHF, TCF
Production	→ products

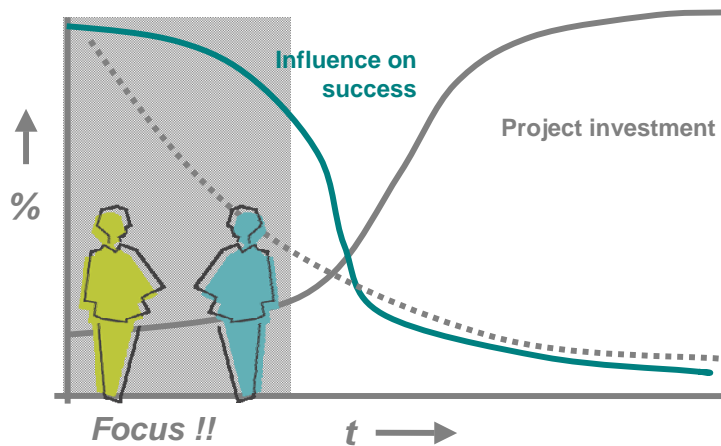
## Design reviews

Analysis  
Idea phase  
Concept definition  
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Design phase  
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## Bridging the gap

- I] Open the closed doors of both worlds
- II] Improve education



## Bridging the gap

I] Open the closed doors of both worlds



**Designers:**  
Invite CSA at reviews  
Team up creativity

**CSA:**  
Make designers understand application  
Scenarios  
Open innovation desk



## Bridging the gap

II] Improve education

**Designers + CSA:**  
Give lectures  
Create manual for designers





## Conclusions

- Improving & feedback is only feasible at start
- Feedback on preliminary results
- Focus on total result
- Open doors
- Plan reviews together
- Educate

## Conclusions



Designers !?

## Conclusions

Berwick (IHI) says  
improve healthcare by:  
Focus on the problem  
Gain knowledge  
Co-operate

## Conclusions

