I aim to show how to achieve conceptually robust products through trade-off avoidance.
PRODUCTS MARKETED IN 165 COUNTRIES

AFFILIATES IN COUNTRIES 77

R&D CENTRES IN CHINA, DENMARK, UK AND US

EMPLOYS APPROXIMATELY 41,400 PEOPLE

STRATEGIC PRODUCTION SITES IN BRAZIL, CHINA, DENMARK, FRANCE AND US

SUPPLIER OF NEARLY HALF OF THE WORLD’S INSULIN

DKK 111.8 BILLION IN TOTAL REVENUE

APPROXIMATELY 210,000 SHAREHOLDERS

28,000,000 PEOPLE USE OUR PRODUCTS
Device R&D
What we do

1. Support the drug pipeline with delivery systems
2. Mostly focus on mechanical, disposable devices
3. Ensure manufacturability
4. Mitigate almost all conceivable risk scenarios
prefilled devices

When developing injection devices, properties such as **accuracy**, **size**, **manufacturability**, **mechanical efficiency** and **functional sequencing** are key.
Why contradictions?
Keeping the competitive edge
MORE functionality

- Functions
  - Cost/complexity
  - Lead time

++ Functions
++ Cost/complexity
++ Lead time
Challenges in robust design

When marketing wants more features, one either:

1. **More** functional requirements
   1. Increases the functionality driven by each part
   2. Improves complex verification requirements

Production wants less complexity — one must:

1. Reduce the amount of operating states and reliance on
   2. Avoid sensitivity
   3. **More** second order phenomena and interaction effects
early advanced analyses

complex assembly sequence

inaccuracies we couldn't explain

unforeseen friction

stiff springs and high forces

new pen - new problems
Robust by design or by tweaking?

Evaluate robustness
- Evaluate robustness
- Develop solution
- Concurrent optimisation
- Decomposition of contributing effects
- New issue created
- Contradictions Analysis
- Robust Design Day 17
The information incongruity
How do you imbue robustness early?

Methodology and approach

Why and how does it work?
Trade-offs
The influence of contradictions on medical devices

FR2
E.g. Regret torque
force/speed

Min. acceptable force
Beyond this limit, the
pen will not be able
to maintain a dose
setting

Acceptable range for
FR1
Acceptable range
for FR1 + FR2
Acceptable range
for FR2

Parameter variation

DP
E.g. Spring
stiffness

Min. acceptable force
Beyond this limit, the
pen will not be able
dose, due to friction

Contradictions Analysis – Robust Design Day 17
Types of functions

- **Min is best**: Mostly related to noise
- **Nom is best**: Mostly relates to accuracies
- **Max is best**: Mostly related to reliability, UX, and output functions
Influence of parameters
Qualitative assessment of DP

2  Highly positive influence
1  Contributing positive influence
0  Nominal/unknown influence
-1  Detrimental influence
-2  Highly detrimental influence

These are used to assess the severity of trade-offs between functions
**Negative relation**

**Limiting relations**

**Positive relations**

**Functional interrelations**
Procedure
Identifying and quantifying trade-offs

1. Identify functional requirements
2. Classify FRs and identify involved parts/
3. Identify involved design parameters
4. Assess influences of DPs and resulting contradictions
5. Identify root cause and perform redesign

Prototype or analyse the effect
Issue reduction
Iterative Pareto approach

<table>
<thead>
<tr>
<th>Issue no.</th>
<th>Criticality</th>
<th>Work required</th>
<th>Level at milestone</th>
</tr>
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<tbody>
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Contradictions Analysis – Robust Design Day 17
Some examples

The cause and influence of a contradiction
Leadscrew vs. rack and pinion

Why one is better than the other

FR1: Mechanical efficiency

FR2: Accuracy efficiency

DPs: Thread diameter, pitch, thread angle, axial play, radial play, secondary bearing diameter, leader height
Leadscrew vs. rack and pinion
Why one is better than the other

FR1: Mechanical efficiency
FR2: Accuracy efficiency

Which is best?

DPs: Module, pressure angle, bearing diameter, pitch diameter, rack support, backlash/axial play
Example
A slip-clutch driven gearbox

Functions:
Transfer rotation in one direction only, prevent overload, change state to reset mechanism
Contradiction
A slip-clutch driven gearbox

Functional requirements

FR1: Accuracy (nom is best)
FR2: Slip clutch disengagement accuracy (nom is best)
FR3: Mechanical loss (rotational) (min is best)
FR4: Return mechanism accuracy (nom is best)
FR5: State change force (min is best)

Critical design parameters:

<table>
<thead>
<tr>
<th>FR1</th>
<th>DP1</th>
<th>DP2</th>
<th>DP3</th>
<th>DP4</th>
</tr>
</thead>
<tbody>
<tr>
<td>DP1: Spring stiffness</td>
<td>0</td>
<td>2</td>
<td>-2</td>
<td></td>
</tr>
<tr>
<td>DP2: Spring pretension</td>
<td>2</td>
<td>2</td>
<td>1</td>
<td>0</td>
</tr>
<tr>
<td>DP3: Contact diameters</td>
<td>-2</td>
<td>-2</td>
<td>-2</td>
<td>2</td>
</tr>
<tr>
<td>DP4: Tangential play in tooth interfaces</td>
<td>0</td>
<td>2</td>
<td>0</td>
<td>-1</td>
</tr>
<tr>
<td>FR5</td>
<td>-2</td>
<td>0</td>
<td>2</td>
<td></td>
</tr>
</tbody>
</table>
Issues

Parasitic loads on gearbox

Stiff spring needed to provide return and slip-clutch functionalities

Variable efficiency between states

Substantial play requirements
Solution
A slip-clutch driven gearbox

A radial system - In essence, the force loop has been changed, and the functionality redistributed
Typical causes

1. **Excessive integration** of functions in single parts
2. Opposing or unintended **load paths**
3. Contradictions when changing from one **functional state** to another
4. **Asymmetry** - e.g. eccentric loads, improper moment balancing
5. Opposing stiffness requirements between directions – **aspect ratio**
6. Inherent trade-offs in **energy converting interfaces**
Uses and experiences
Prioritisation of analyses
Contradiction driven redesign
Successes and impact

The 2nd design performs better, on numerous parameters:

1. Degree of contradiction reduced by more than 30 % (despite new functionality and increased analysis detail)
2. Three parts removed (12.5 %)
3. Static strain on engine reduced from 6 % to 0.5 %
4. Contributors to activation force reduced by 30 %
5. Drive train friction reduced by 27 %
6. 25 tolerance and kinematic analyses removed through design
7. Most DfMA issues removed
Solving contradictions

1. Change the distribution of functionality on parts – *change the concept*

2. Reorient a functions axis of operation – *change the kinematic intent*

3. Introduce or remove parts – *differentiate or integrate functionality*

4. Decrease the severity of the trade-off – *optimise the design*

5. Find and exploit nonlinearities – “*invent*”
To sum up

Trade-off avoidance

achieve conceptual robustness early

reduce complexity

improve nominal performance
Thank you!

Interested? Feel free to contact me:
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