Designing Safety Critical Medical Devices

Sebastien Cuvelier Mussalian

Summary

Team Consulting, Who we are, What we do?

Case Study:

- Normothermic Liver Perfusion System
- Class III Investigative Device

A bright idea that works

Intellectual property, business plan & funding

Product design lifecycle

Regulatory framework

FDA submission recommendation

The importance of human factors

Medical system architecture

Team Consulting – Who are we, What we do

Helping to create products that enhance lives

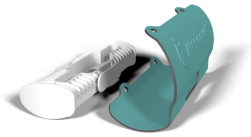
Team Consulting - Why Us

Injectors

Inhalers

Nasal drug delivery

Dermal



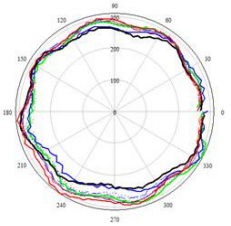
Dispensing and packaging

Compliance monitoring

Diagnostics

Medical technology

Research instrumentation



Metrology

Surgical

Implantables

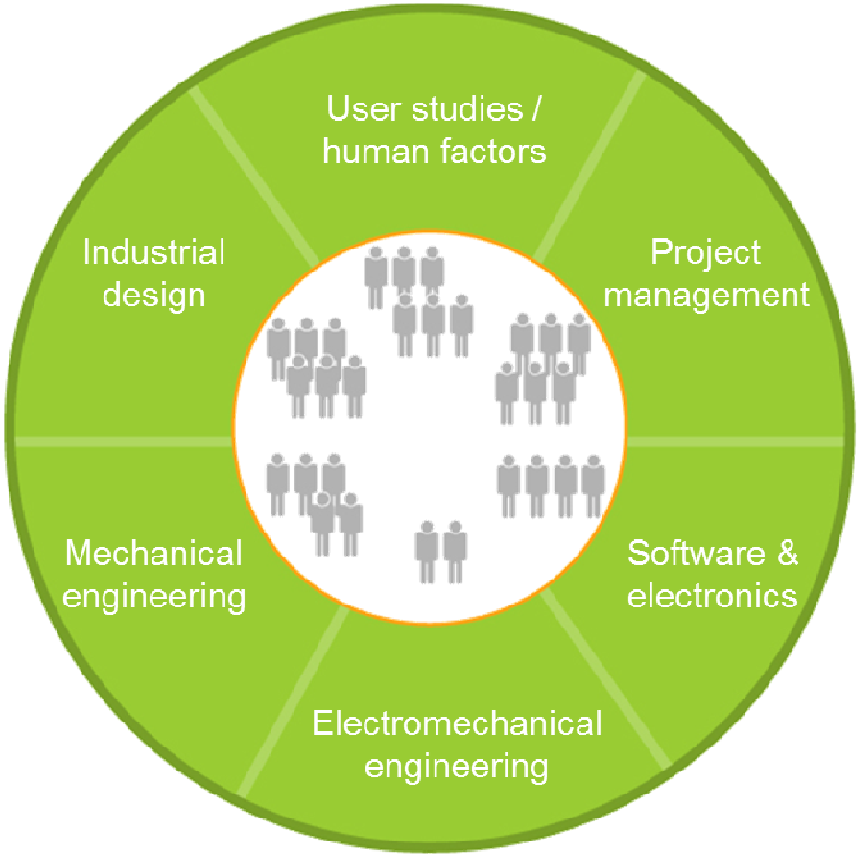
Regenerative medicine

Optyse

Services

Team Consulting – Our Team

Our 40+ staff working **seamlessly** together



…so you benefit from our **combined** experience

… to create the **right** product

Team Consulting - Established & Global

- Established 1986, based in Cambridge UK
- Working with global client base
- Leading healthcare entirely focused in lifesciences

ISO: 13485 2003
9001 2000

Case Studies

Regenerative Medicine:

Normothermic Liver Perfusion System

Regenerative Medicine:

Normothermic Liver Perfusion System

Medtech: Class III Investigative Device

A bright idea that works

Intellectual Property

Business Plan

Project Brief

Quote & proposals

Funding

Product design lifecycle

Requirements definition

Understand & share what is already known, workshop and research to fill in any knowledge gaps

Concept generation

Create possible solutions

Proof of principle

Ensure the solutions work technically and with users

Detailed design

Translate concepts into manufacturable designs

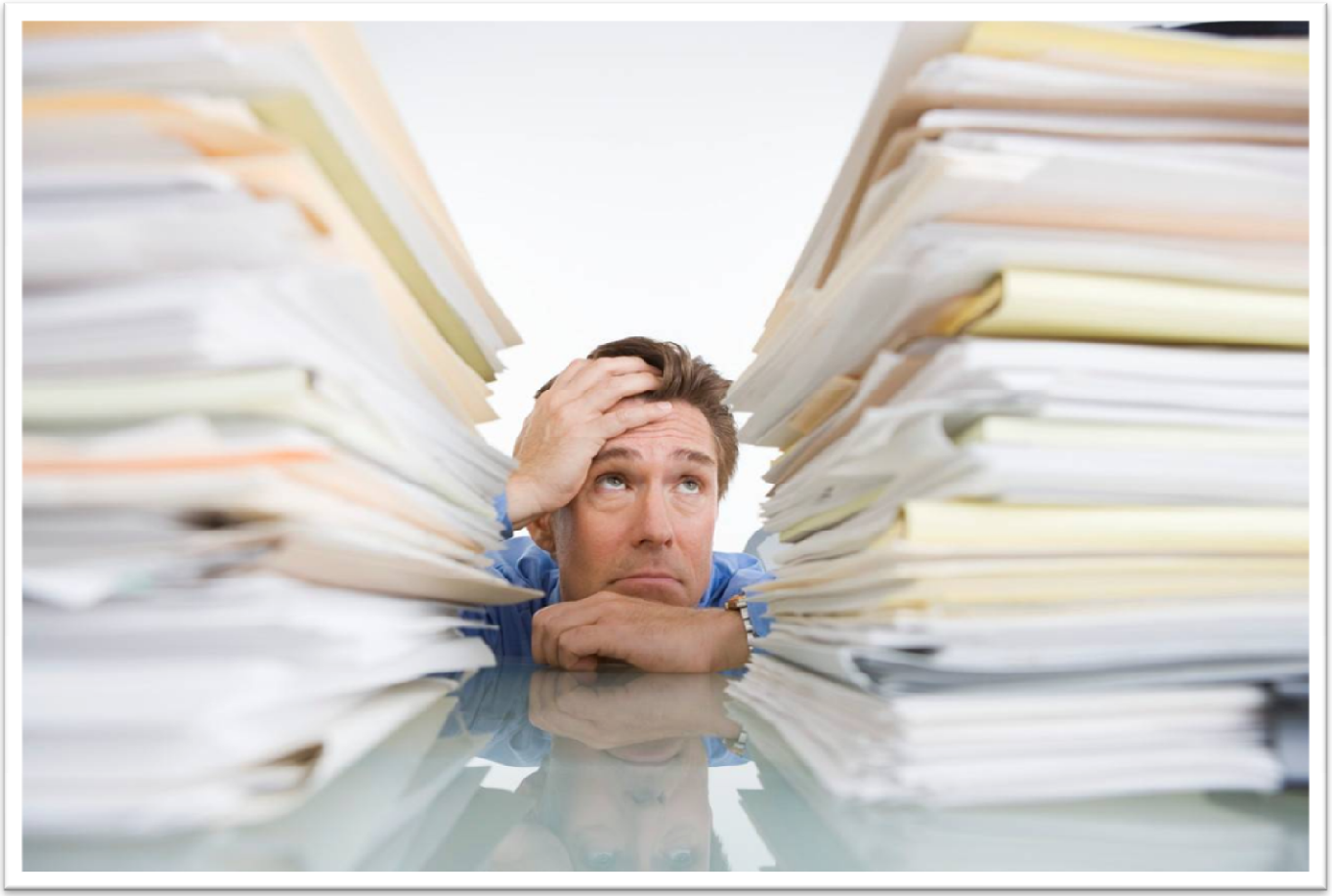
Manufacture / testing support

Ensure design intent and program requirements are followed

Regulatory Framework

- US & EU Framework
- 510k vs. PMA, 90d vs. 1yr
- Define your medical classification
- Build your Design History File
- Use of requirement tracking system and test procedure
- Risk mgt file (60601 3rd ed)
- Beware of SOUP
- Design for clinical trials

FDA submission recommendations



The importance of human factors

HE 75 … new AAMI standard
ISO 62366

User Research

- Who is my end user?
- What functions do users need?
- What do they want it to look like?
- Does it fit with my regulatory approval?

Usability Research

- Can they use the functions?
- What kind of user interface?
- Does it fit with my regulatory approval?
- Exploratory Research & Statistical Research

Medical system architecture

Safety critical medical functions

User focused functions

Export

If you have any questions please contact us

Tel: +44 (0) 1799 532768

Email: **scm@team-consulting.com**

Thank you...

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