

Development of Medical Devices:

*From idea to Innovative product*

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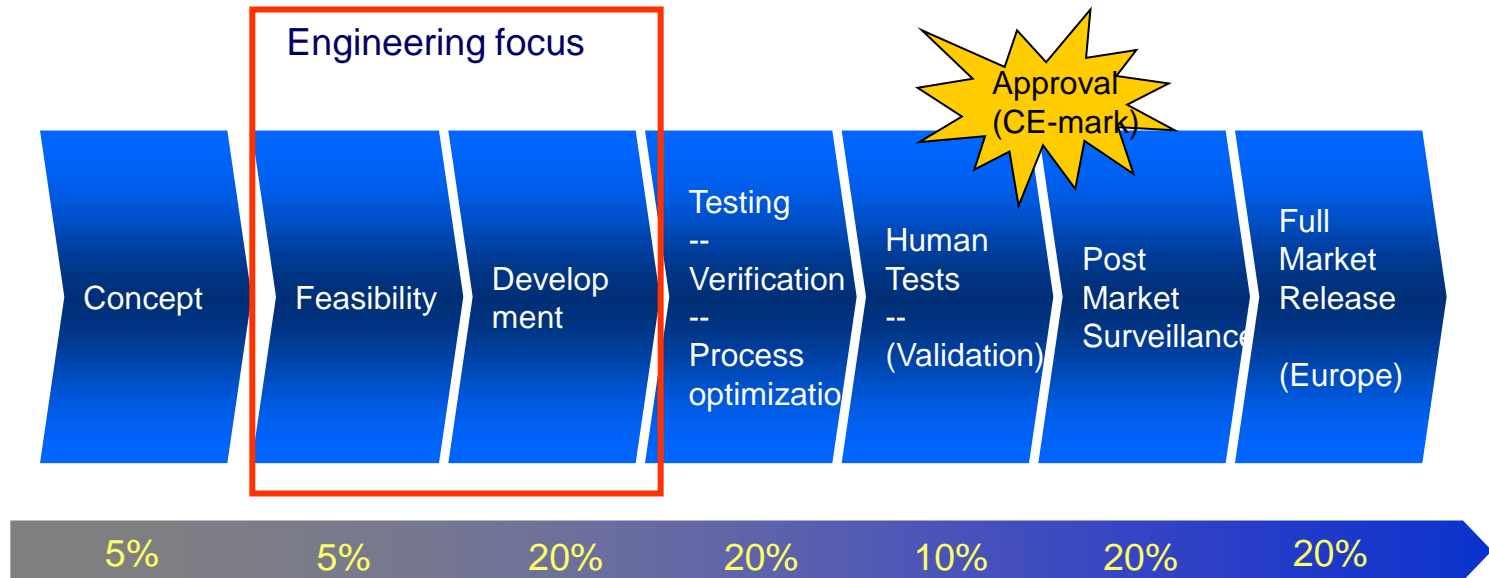


# A Biomedical Engineer speaking

- University Ghent
  - Electrical Engineer, Biomedical Engineer, PhD.
- Since 1996: small and large international corporations
- Medical devices for invasive cardiac and vascular therapies
  - High Tech and innovative
  - High Risk: Class III products
  - High added value
- Close interaction with physician and patient
  - Field Clinical Engineer
  - Manager Training Institute
  - VP Clinical and Regulatory



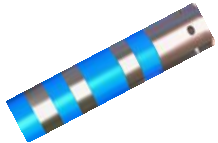
# From Idea to Product: The development cycle



## Absolute focus on

- Safety
- Reliable performance (EU)
- Effective performance (US)

# A cycle with high impact....



## Ablation catheter

- 4-5 y
- 20-30M\$ (EU), +20M\$ US



## New therapy with implantable device: Cardiac Resynchronization Therapy

- 10-15 y
- 200-300M\$ (EU), + 70M\$ US

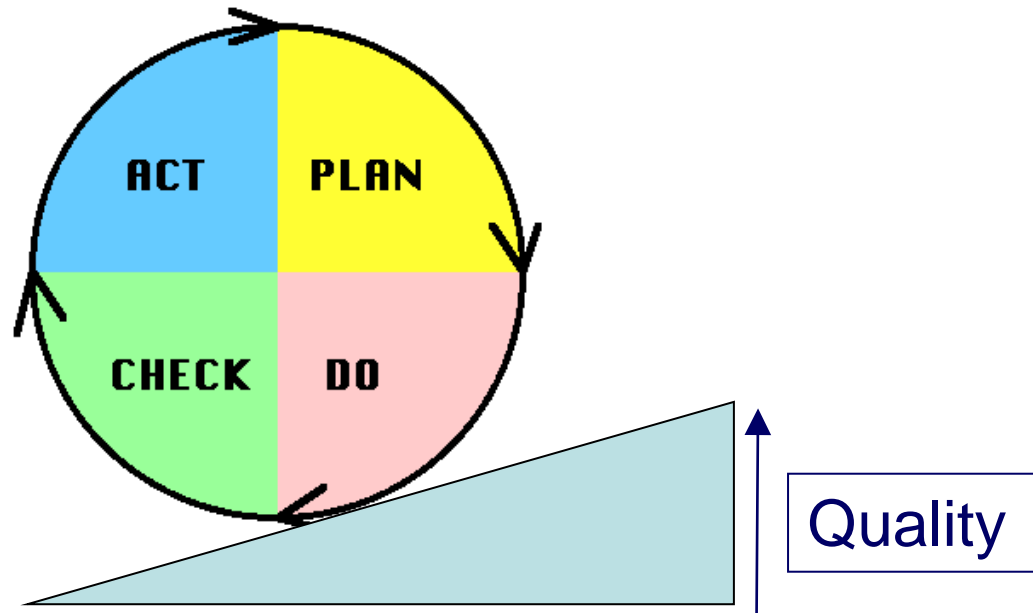
## Optimize development by

- Total Quality Management
- Risk Management
- Integrate Voice of Customer

# Quality and Safety

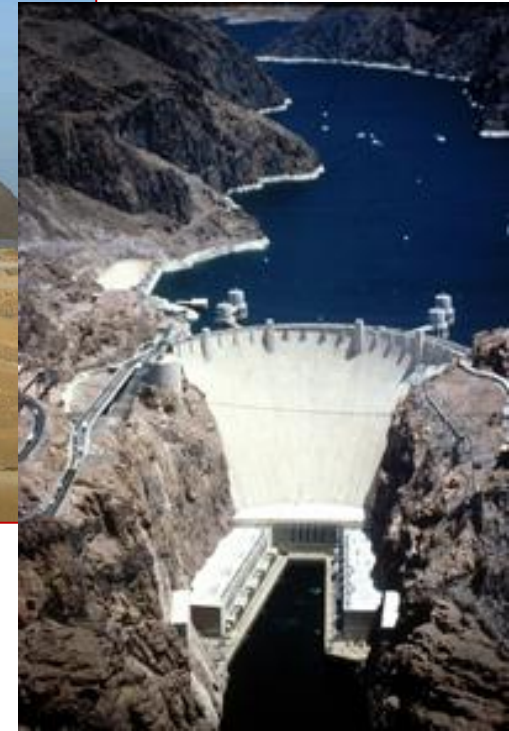
- Quality and safety rely on:
  - Total Quality Management, integrated in design
  - Standard Operational Procedures:  
*'Do what you say and say what you do'*
  - Version Control
  - Prospective Verification and Validation criteria
- ISO 13485: Quality Management System for Medical Device Companies
- Software: main source for safety alerts

# The Deming cycle: Total Quality Management

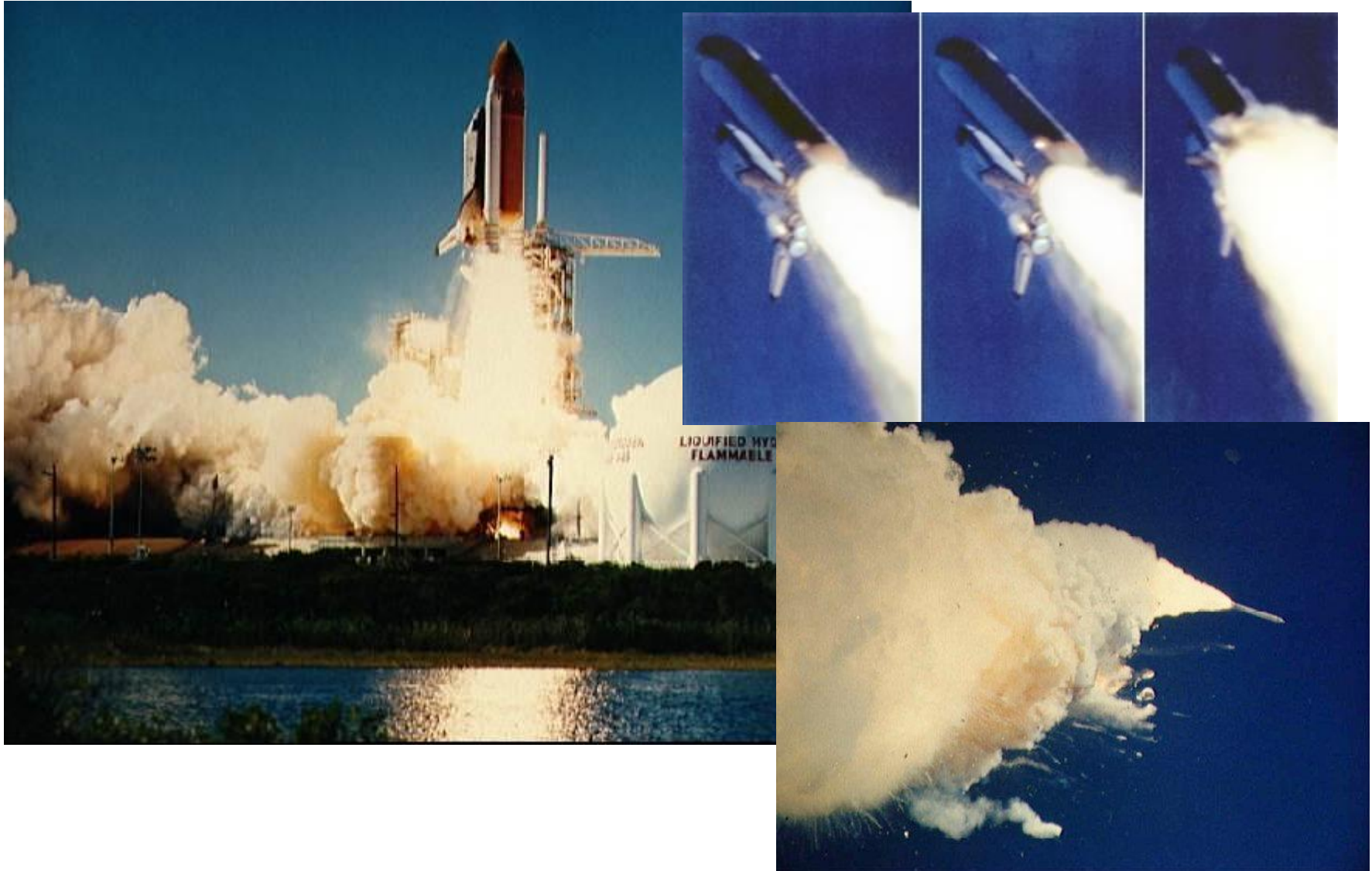


Plan – Do - Check – Act

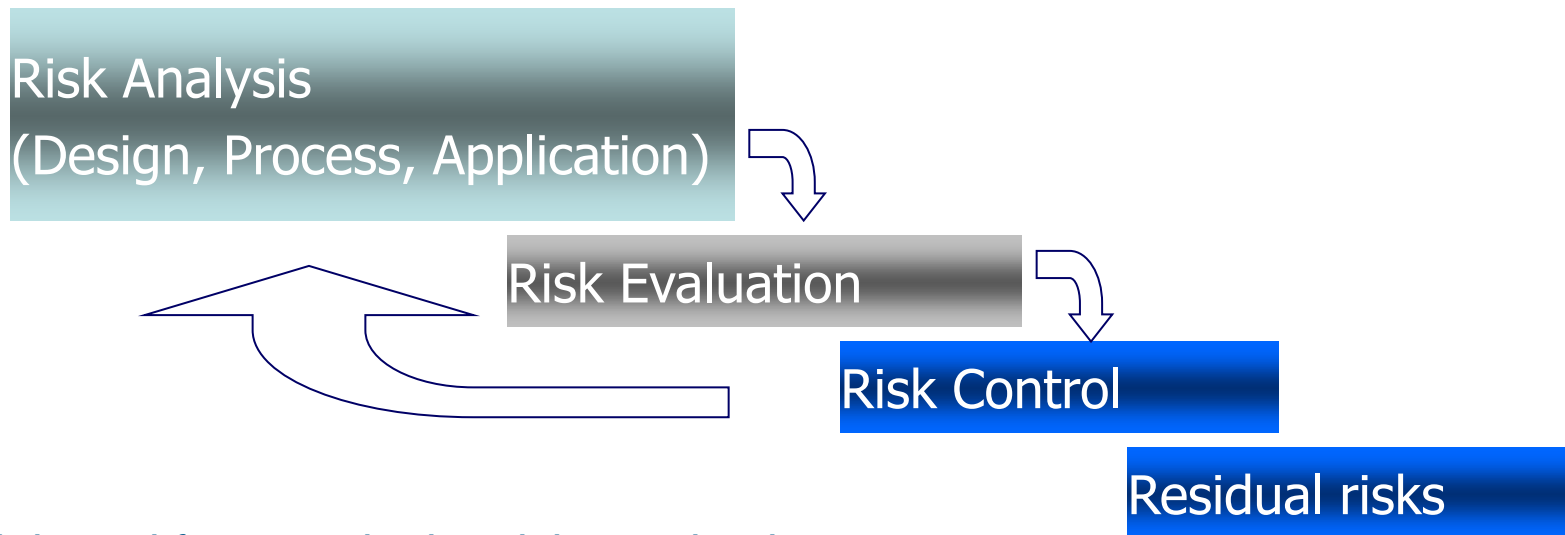
# Risk Management: a new concept ?



# No compromise to Risk Management

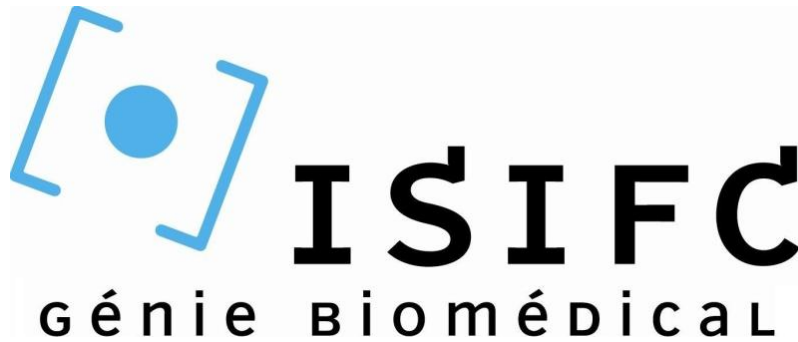


# Risk Management for Medical devices: ISO 14971



- Main tool for quantitative risks evaluation
- Continuous input from
  - Customer: user feedback
  - Engineer: Design and Process Failure Mode Analysis
- Risk management for Medical Devices is required by
  - ISO 14971
  - European Medical Device Directive
- Risk Management is strongly driving updates of technical standards
  - Technical descriptive → design responsibility
  - Leaves creativity while reducing risks

# QA and Reg: An academic challenge



Institute for Biomedical  
Engineering -- Besançon (F)

Focus on Quality and  
Regulatory Affairs



**Biotika®:** Virtual company with very real  
biomedical products

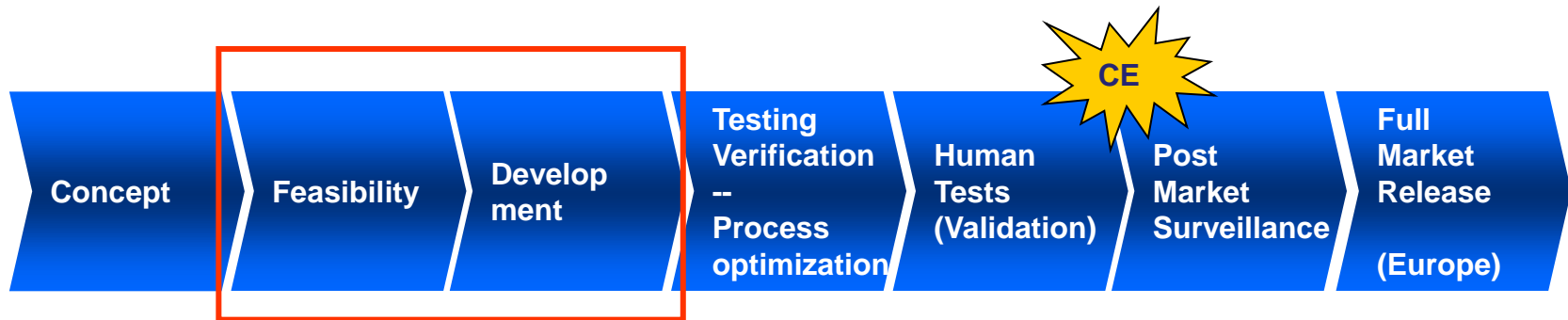
- Students learn to organize a company
- Full process of designing and launching  
biomedical products to the market.

## Mission

- Set-up Quality Management System (ISO 13485)
- Conduct bench tests, *in vivo* tests and clinical study
- Create Technical Files, resulting in CE-mark



# A great day: market approval



A new dimension in the cycle: **The customer**

- Physician
- Patient
- Health care system
- Reimbursement
- Insurance company
- Regulatory bodies
- ....

## *The customer is always right (the customer is King)*

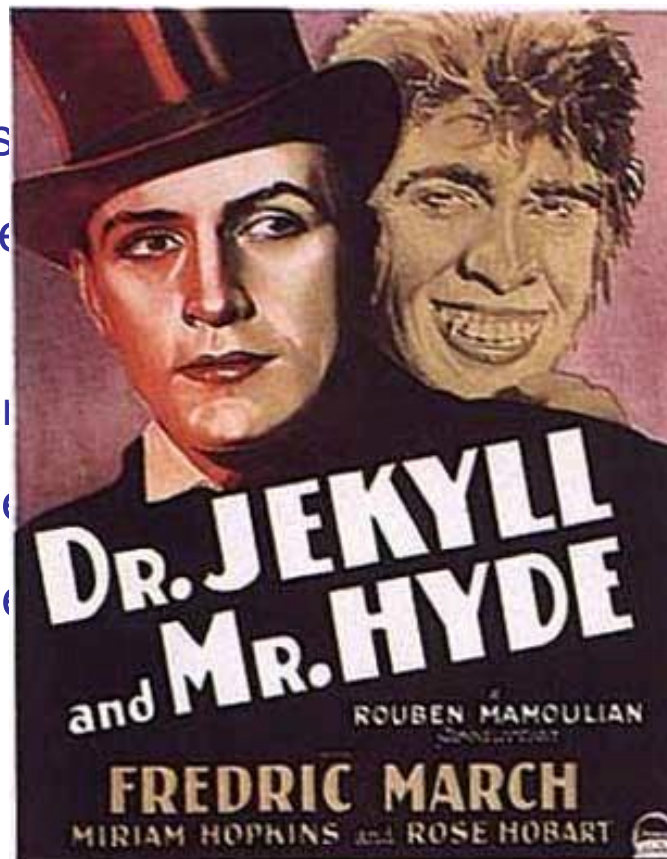
We are all customers

What type of King are we?

- Arrogant
- Critical
- Gentle, with understanding

When being developed

When being developed  
as an engineer?



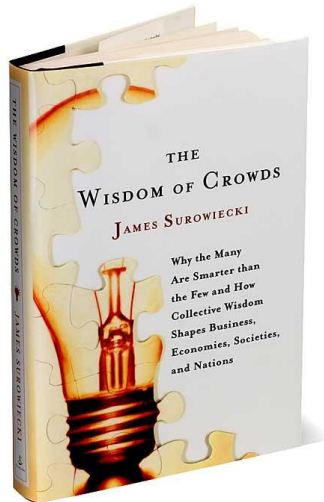
What is the viewpoint?

Is the customer or the engineer?

# The wisdom of the customer:

- Quality definition
- Ease of use – Usability (IEC 62633)
- Risk Management: Application Failure Modes

*Listen to the customer !!*



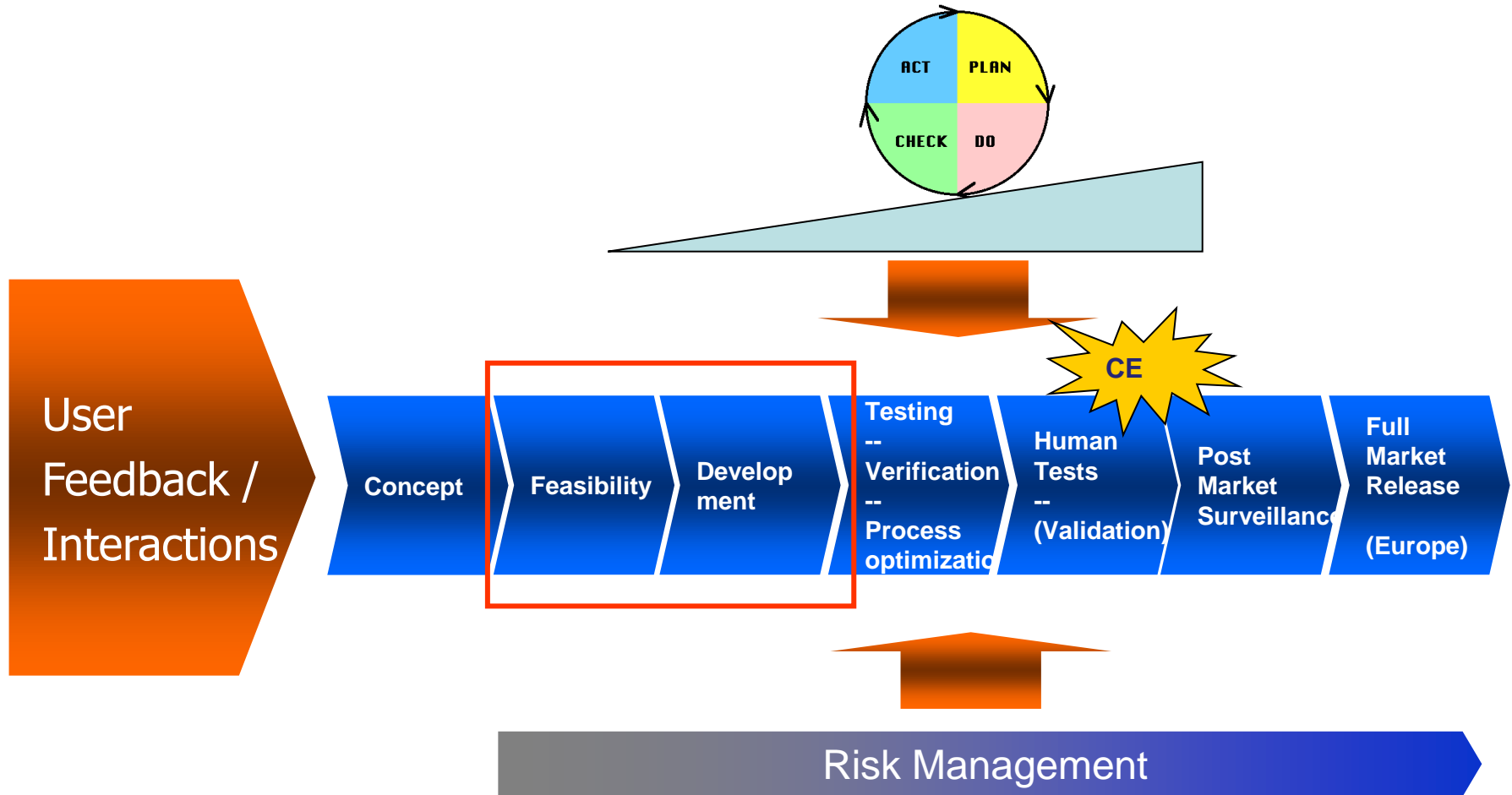
The Wisdom of Crowds:

*“A group of (divers) individuals has always more intellect than one expert”*

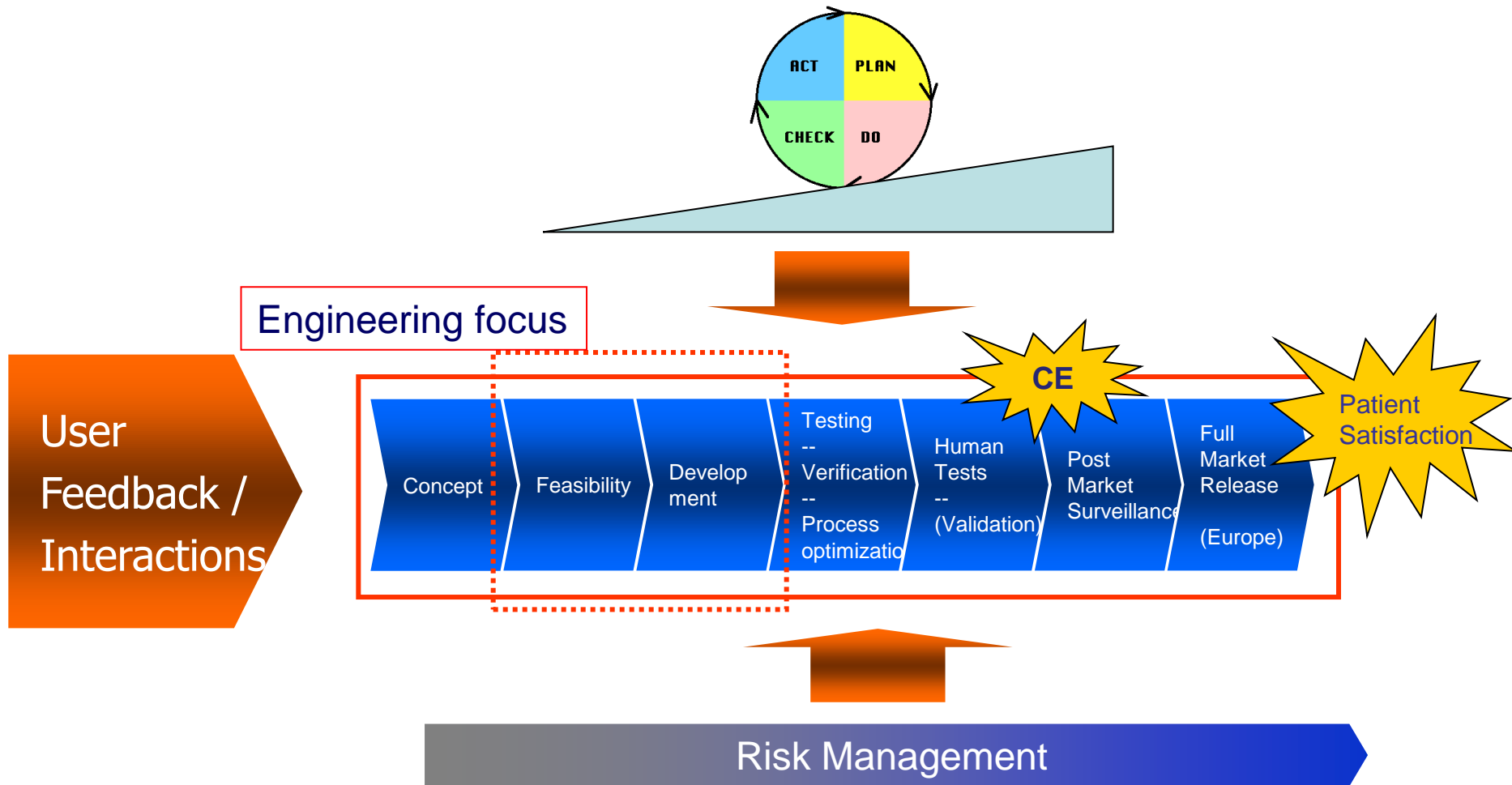
*Aristoteles, 4<sup>th</sup>c BC*

**Development of the device: start from the end !**

# High quality design requires ongoing user input

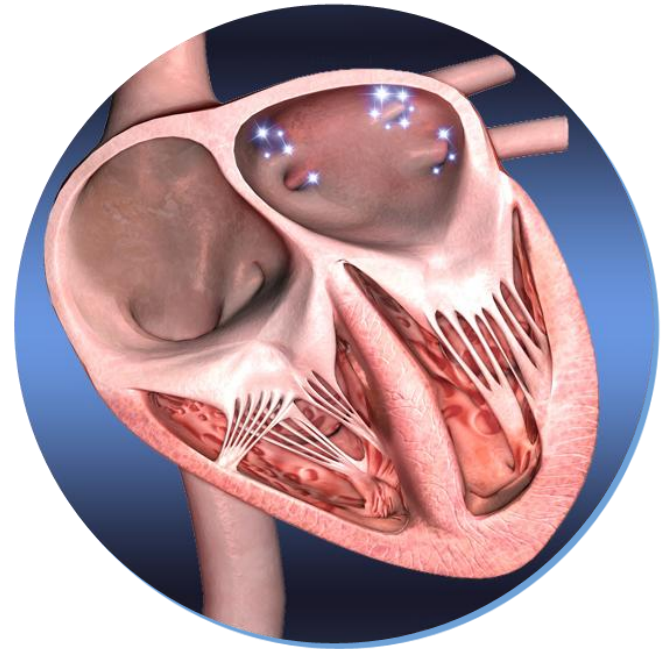


# Path to full customer satisfaction expands the engineer focus

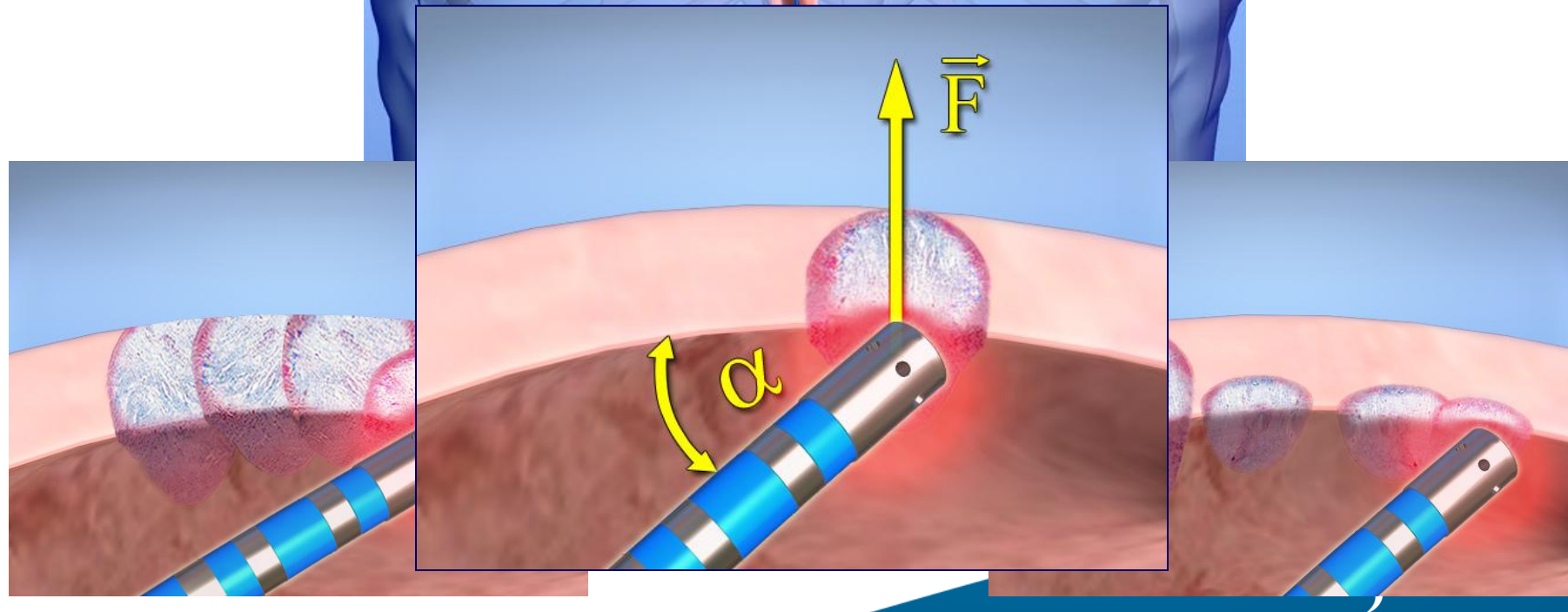
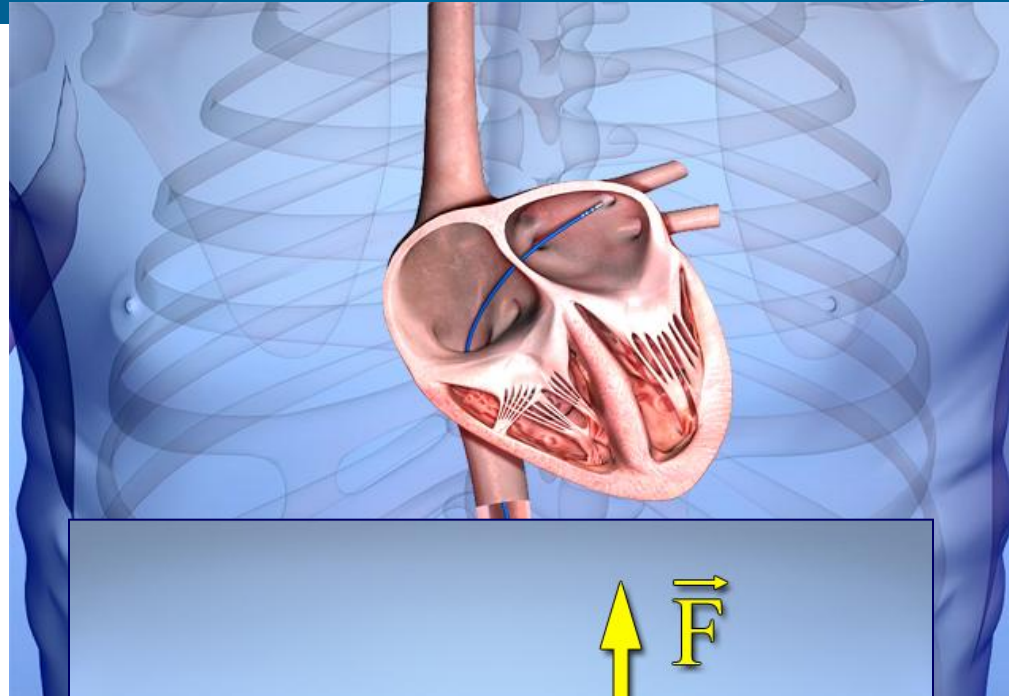


# Ablation catheter for treating Atrial Fibrillation

- Fibrillating of atria → no normal cardiac contraction
- Primary prevalence > 6M
- Impaired Quality of Life
- 2 x higher mortality rate
- 2.5 x higher stroke risk\*
- Standard therapy:
  1. Medication
  2. Ablation



# Atrial Fibrillation (AF) treated by Percutaneous Catheter Ablation (PCA)



# TactiCath: First Endosense product

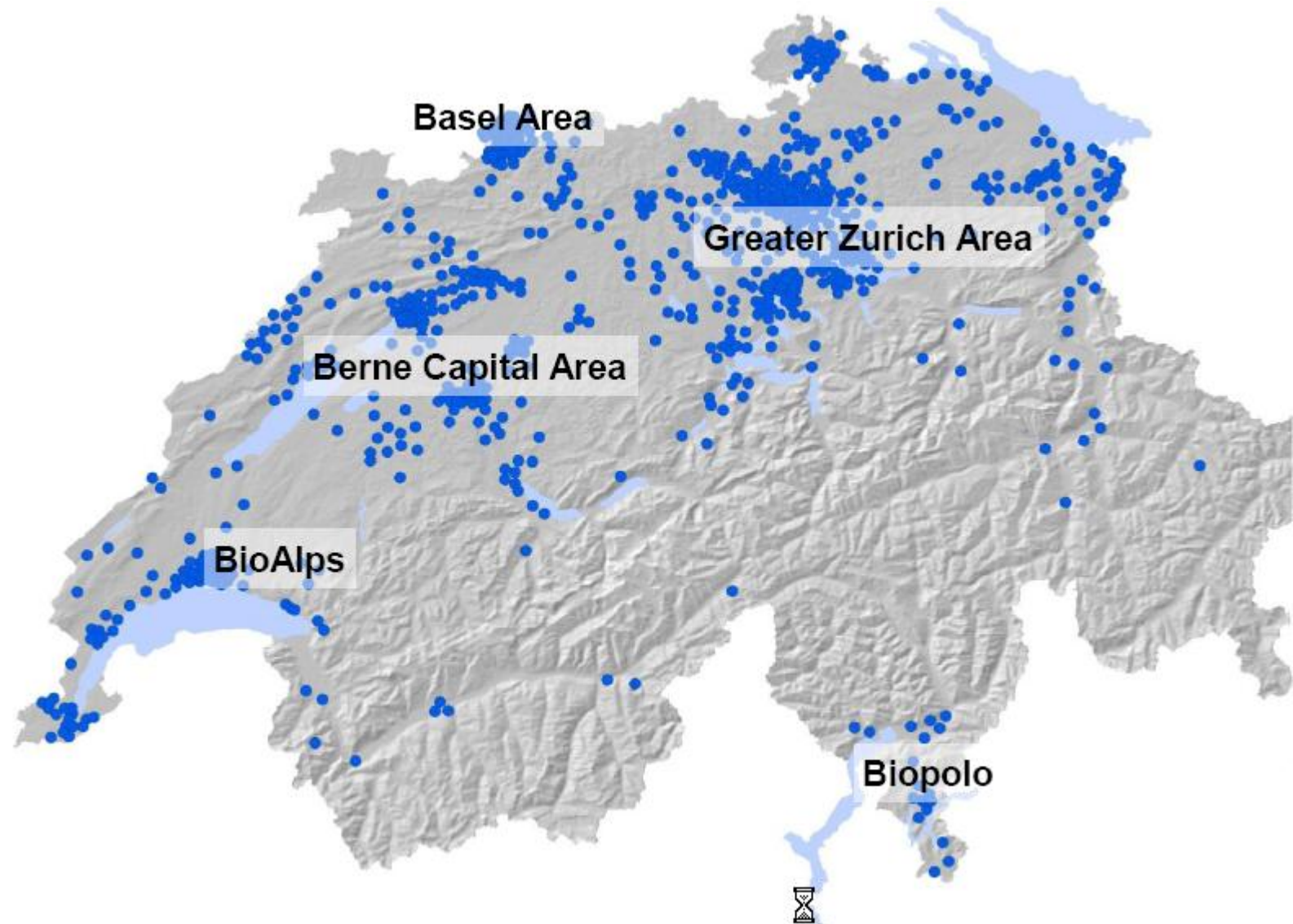
- 
- Start-up company, founded 2003, Geneva, CH
  - **TactiCath™** - first force sensing ablation catheter
  - Sales distribution through established partner: Biotronik
  - Preparing clinical study in US (FDA)
  - Funding: Venture Capital (\$20M in 2005, \$36M in 2009)
  - The only European company dealing with A-Fib (over 30 companies in US)

# Innovative product development: environmental needs

- High – tech environment
- High level education
- Tradition of High-added value
- International orientation
- Language skills
- Highly skilled (specialized) professionals
- Financing of high risk initiatives
- Easy supply of high quality technology and services
- Critical concentration of all those capabilities ('Valley')

Should be a future for Flanders ...

# Concentration Medical Device Cies (700)



● Location of medical technology manufacturers and suppliers; n = approx. 700

# Conclusion 1

Medical Device development is great !

- High Tech
- High added value
- High personal satisfaction

If you have the skills of implementing

- High Quality demands
- Thorough Risk Management
- Close customer interaction

# Conclusion 2

Flanders has the potential to be a place for  
Medical Device development

- No need for natural resources
- High Tech development
- Need for highly skilled personnel
- High value added services and high tech production
- Need for critical mass of capabilities

*Thank you*

# About GENEVA



- Populations: 185'000
- International: 40 % of residents in Geneva come from outside Switzerland
- Hosts over 300 international leading organizations.
- Third European financial centre after London and Zurich
- Eight world's most important financial centre, ahead of Frankfurt and Sydney
- Third-highest quality of life of any city in the world

Geneva is a **COMPACT METROPOLIS**

# International Organizations

- United Nations
- United Nations High Commissioner for Refugees (UNHCR)
- United Nations High Commissioner for Human Rights (UNHCHR)
- World Health Organization (WHO)
- International Labour Organization (ILO)
- World Intellectual Property Organization (WIPO).
- World Trade Organization (WTO)
- World Economic Forum (WEF),
- International Federation of Red Cross and Red Crescent Societies (IFRC),
- International Organization for Migration (IOM)
- International Committee of the Red Cross (ICRC).
- European Broadcasting Union (EBU)
- CERN (European Organization for Nuclear Research)

