
**T**he **E**uropean **A**ssociation **M**edical devices

**N**otified **B**odies

# Innovation for Safety: achievements and challenges
# A notified body perspective

Gert Bos
IMDRF-4 open session
Brussels - 13 nov 2013

# TEAM-NB


## Aims:

- Communication with
  - European Commission
  - Competent Authorities
  - Industry
- Promote technical and ethical standards
- Participate in improving the legal framework
- Contribute to harmonization
- Represent Notified Bodies

# Focus on expertise

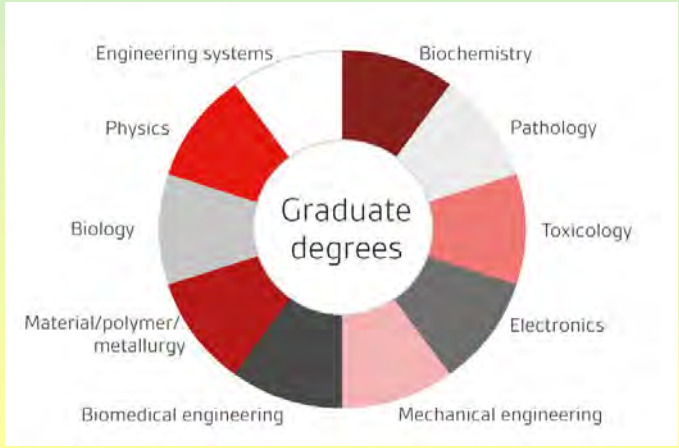
e.g. ORTHOPAEDIC & DENTAL

- Wide scope of devices

  Experienced staff

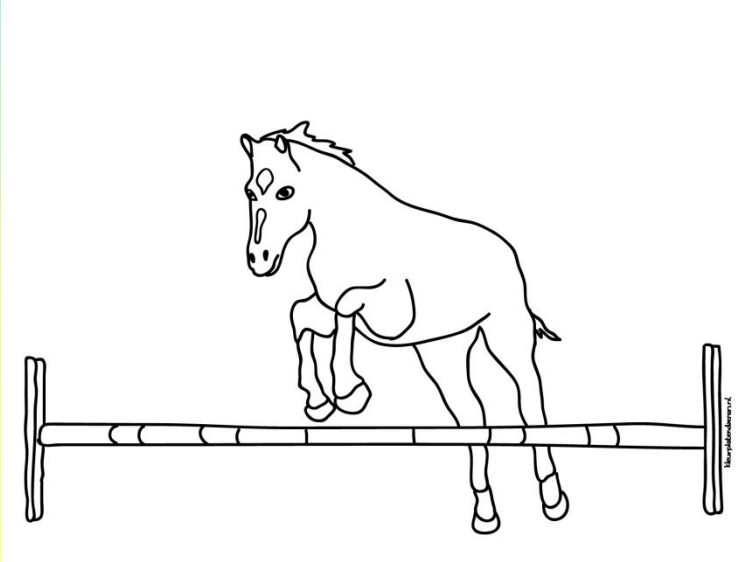
  – Industry, academia, RA
  – ~400 years experience
  – ~80 graduate degrees

- > 2000 certificates
  – >1000 Design Exam certificates
  – >600 DE certificates
    (Hips, Knees, Shoulders)

# Flexibility in thinking

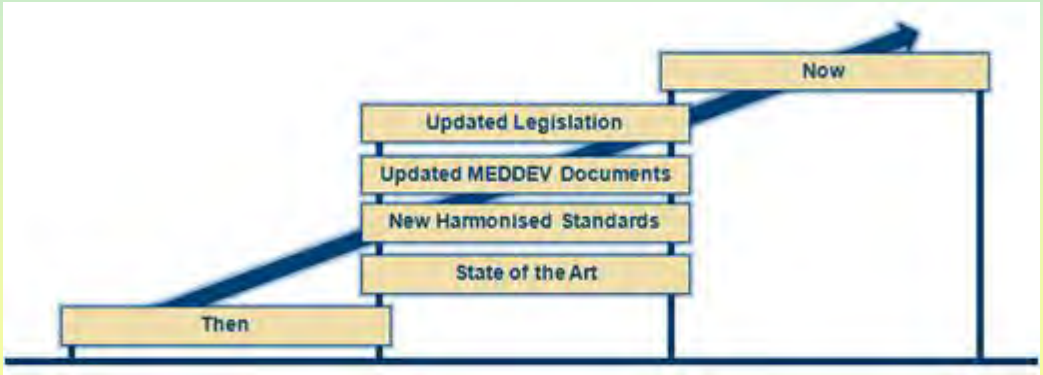
- ‘raising the standard’ still in our mindset
- Raising the bar



- With mindset of generating standards, setting rules and expectation on changing requirements
- Focus on supporting initiation and revision NB-recs, TEAM-NB consensus, Code of Conduct, MEDDEVs, legislation in EU and beyond
- Case by case assessment based on regulatory, technical and clinical state of art interpretations

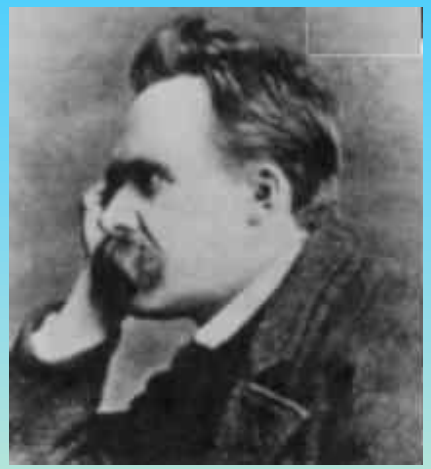
# Finding efficient pathways, identifying obstacles and hurdles






# Setting correct expectations

- Clear application reviews
- Early project reviews
- Pre-metings with drug agencies
- Pre-clearance with CA on borderline
- Modular review
- Regulatory strategy review
- Clinical strategy review



*There are no facts, only interpretations*
(Friedrich Nietzsche 1844 - 1900)

- Many external lectures on regulations and expectations

**Keep TALKING !! Don't assume, check !**

# Fast-track solutions – social changes …..

- **New** and **more communication** technologies used between stakeholders, database exchanges, automated workflows
- **Change in time perception** makes **timelines ever more demanding**

**Regular reviews** → **Fast-track reviews** → **Dedicated & On-site reviews** → **Regulatory & Clinical Strategy reviews** →

# regulatory environment that supports innovation

EU Commission

EU parliament






EU Council of Ministers

# Making inherently unpredictable process as predictable as possible

- Explain details
- Motivate to prepare
- Check for readyness

- DO IT transparently
- FOLLOW the RULES

**COMMISSION RECOMMENDATION**
**on the audits and assessments performed by notified bodies in the field of medical devices**

25.9.2013 EN Official Journal of the European Union L 253/27

RECOMMENDATIONS

COMMISSION RECOMMENDATION
of 24 September 2013
on the audits and assessments performed by notified bodies in the field of medical devices
(Text with EEA relevance)
(2013/473/EU)

POLICY & REGULATION

**Preparing for unannounced EU NB inspections – are you ready?**

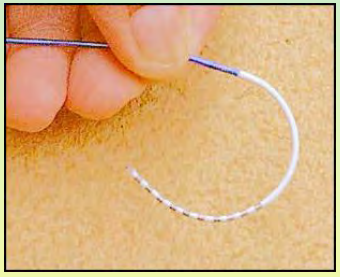
Unannounced visits from notified bodies are going to be part of life for medtech manufacturers in the EU. But do you know how you would cope if two inspectors walked through the door, expected your staff to host the visit and your testing equipment to be dedicated for their immediate use? Do you know what costs you would have to bear? Here, Gert Bos* and Françoise Schlemmer* of notified body association TEAM-NB explain why it is critical that manufacturers and subcontractors practice and validate protocols for hosting such visits

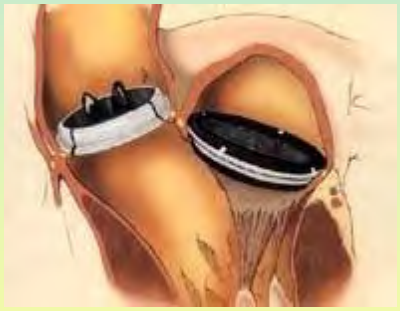
SCRIP Regulatory Affairs
October 2013

Clinica Medtech Intelligence

# support early access to innovative devices

## in the interest of patients





# OUR MISSION

In conclusion:

- With focus on *expertise* and
- *flexibility in thinking*,
- finding *efficient pathways*,
- *identifying obstacles and hurdles*,
- *setting correct expectations* and
- offering *fast-track solutions*,
- contribute to a regulatory environment that supports innovation rather than inhibits it, thereby making an inherently unpredictable process as predictable as possible to support early access to innovative devices in the interest of patients.

- *To ensure patient safety while supporting timely access to medical device technology globally.*
- *To provide our customers thorough, responsive, predictable conformity assessments, evaluations and certifications that are recognized and accepted worldwide.*

# Get your answers today !

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