Medical device regulation:
From a barrier to competitive edge

BUSINESS FINLAND

Tom Ståhlberg

17.9.2021, 9.30-11.30/12.30-14.30

RaLex Partners

From a barrier to competitive edge

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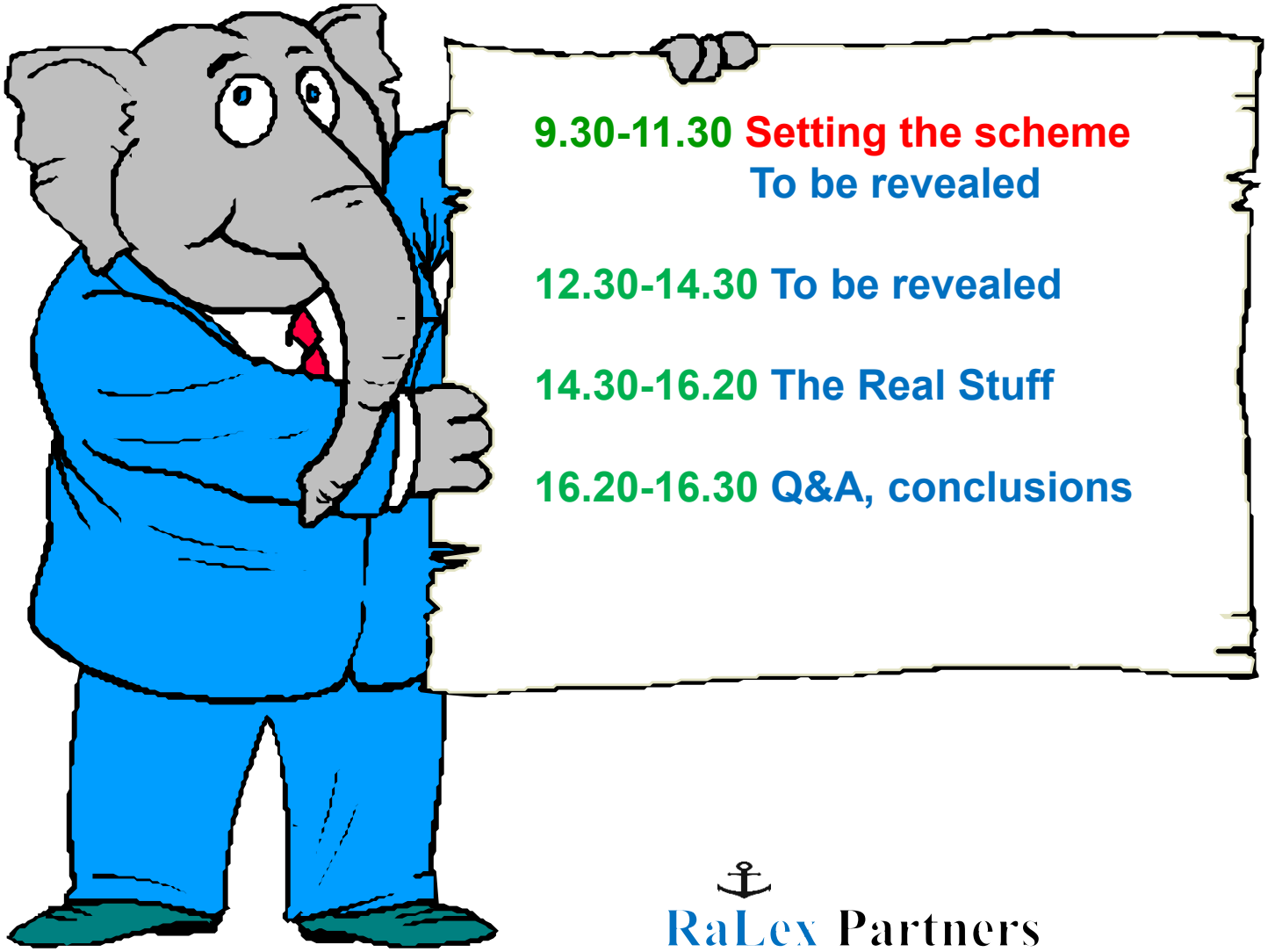

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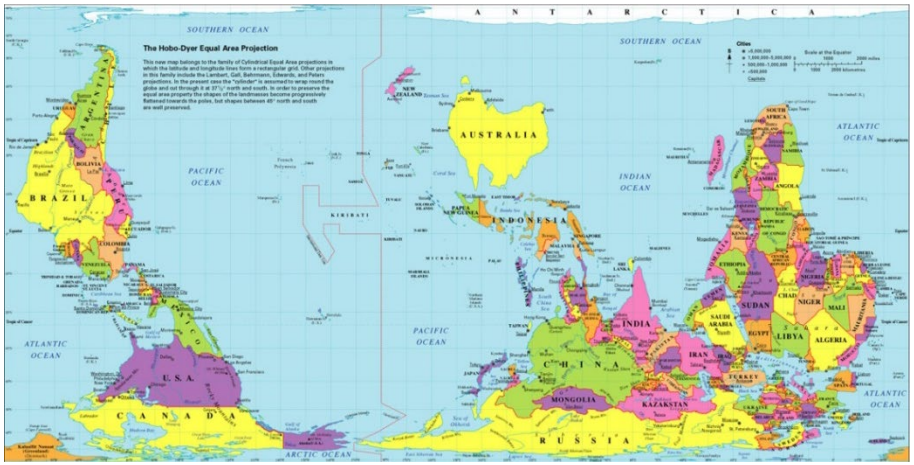
Medical devices must be safe and fit for their intended use

X

Breaking the barrier

CE



Regulatory barrier

Can we be smarter? Turning the barrier to our benefit?

Breaking the barrier

We have done it before!

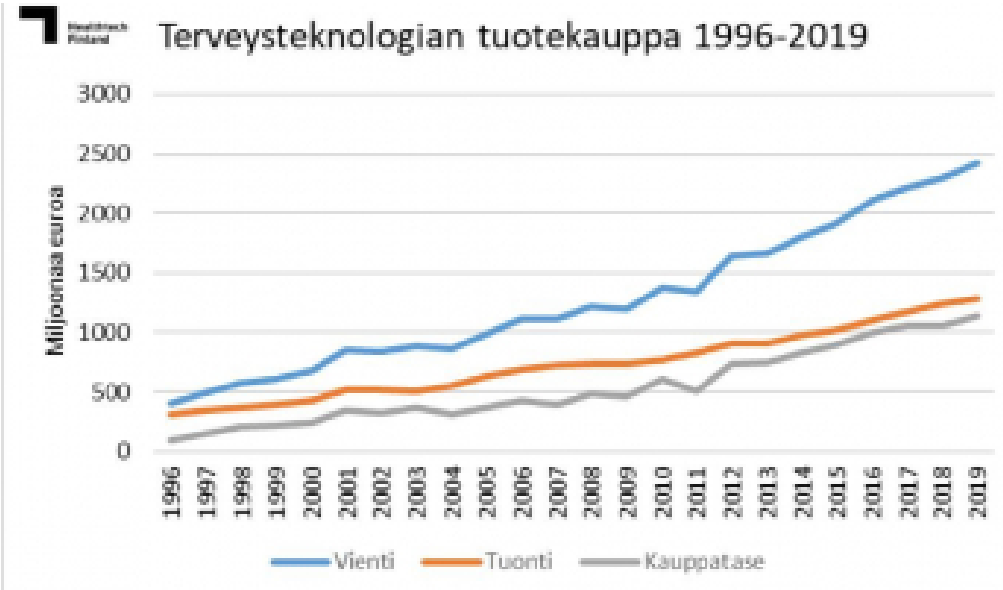
2 400 000 000

5,7 % growth

1 1000 000

trade surplus

About 420 companies



About 95 % of MDs exported from Finland

However, we could be better…

Turning the barrier to our benefit

Build on our ecosystem:
- Research
- Companies, Trade organizations
- Regulatory consultants
- Business Finland,
- Notified Bodies, FIMEA

Patient and MD user in focus: knowing the needs
From innovation technology to fulfilling medical needs
Marketing from Day 1! Because, country = RA, patient/user

From process approach to project approach

From QMS to MS, still ISO 13485 (with inbuild regulatory)
Regulatory from Day 1!

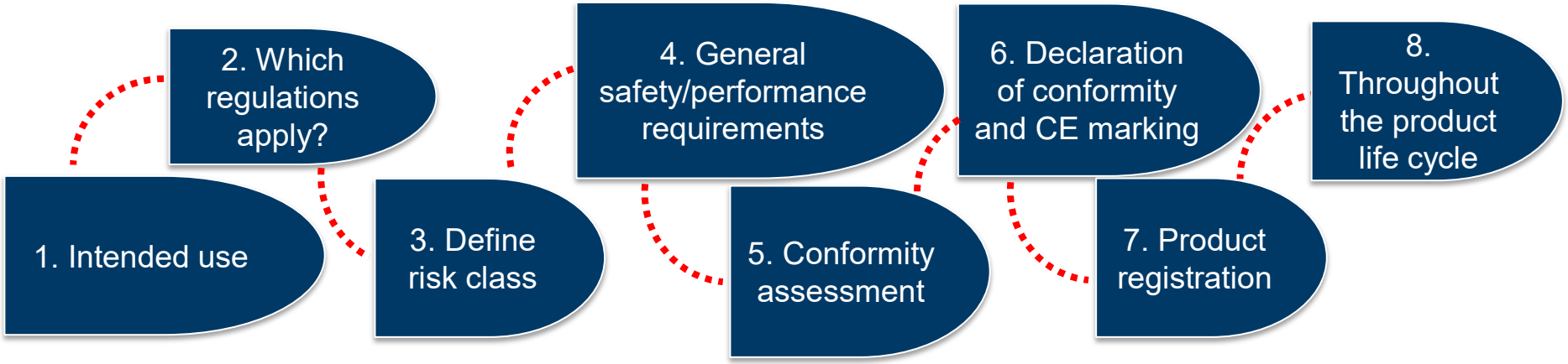
How can these goals be fulfilled?

Product specific path:
Fulfilling regulatory affairs demands (RA)

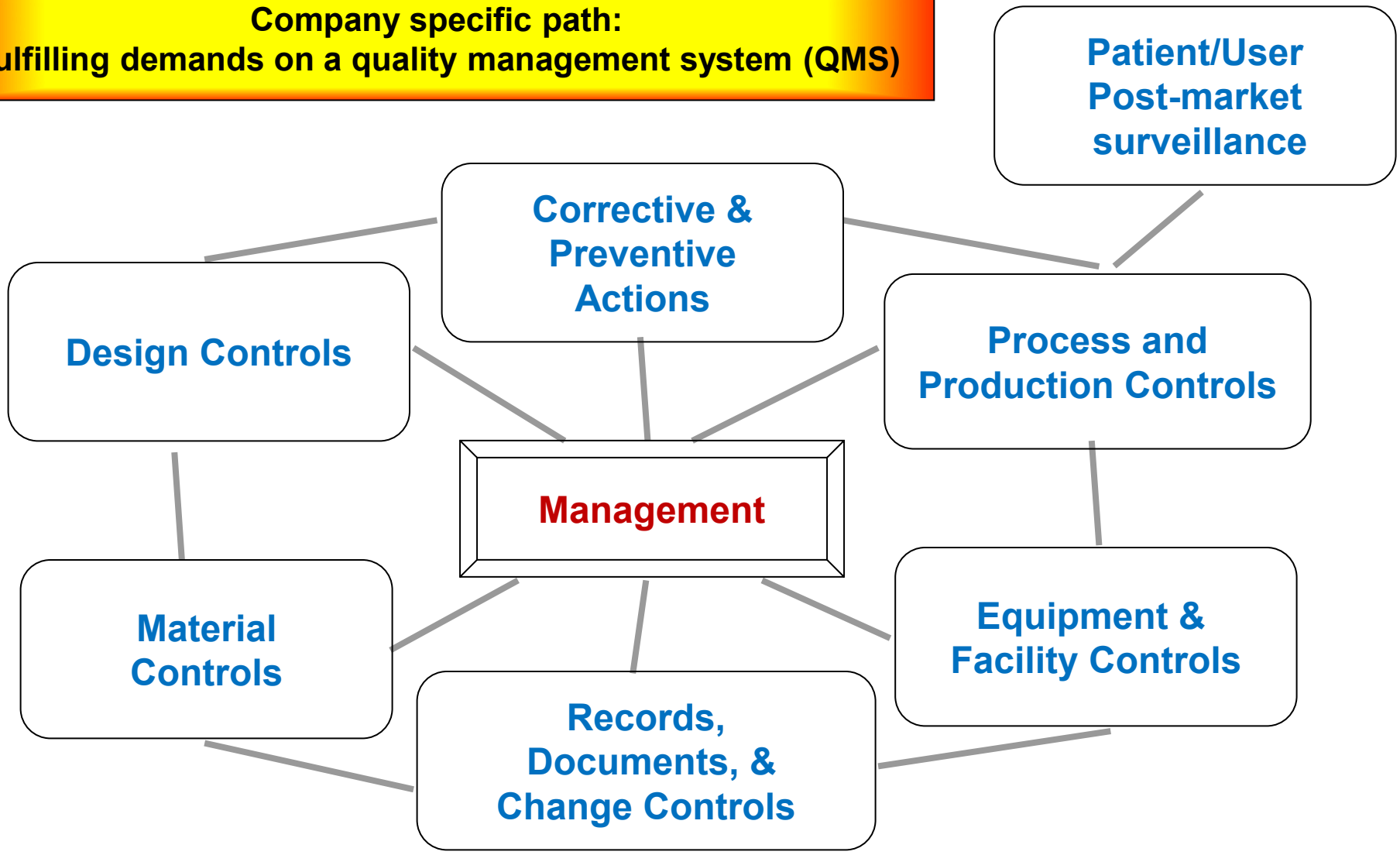
Company specific path:
Fulfilling demands on a quality management system (QMS)

Our compass:
Patient safety and MDs fit for their intended use

Product specific path:
Fulfilling regulatory affairs demands (RA)



Company specific path:
Fulfilling demands on a quality management system (QMS)



ISO 13485:2016 …for regulatory purposes

+ ISO 14971 Risk management

BUSINESS
FINLAND

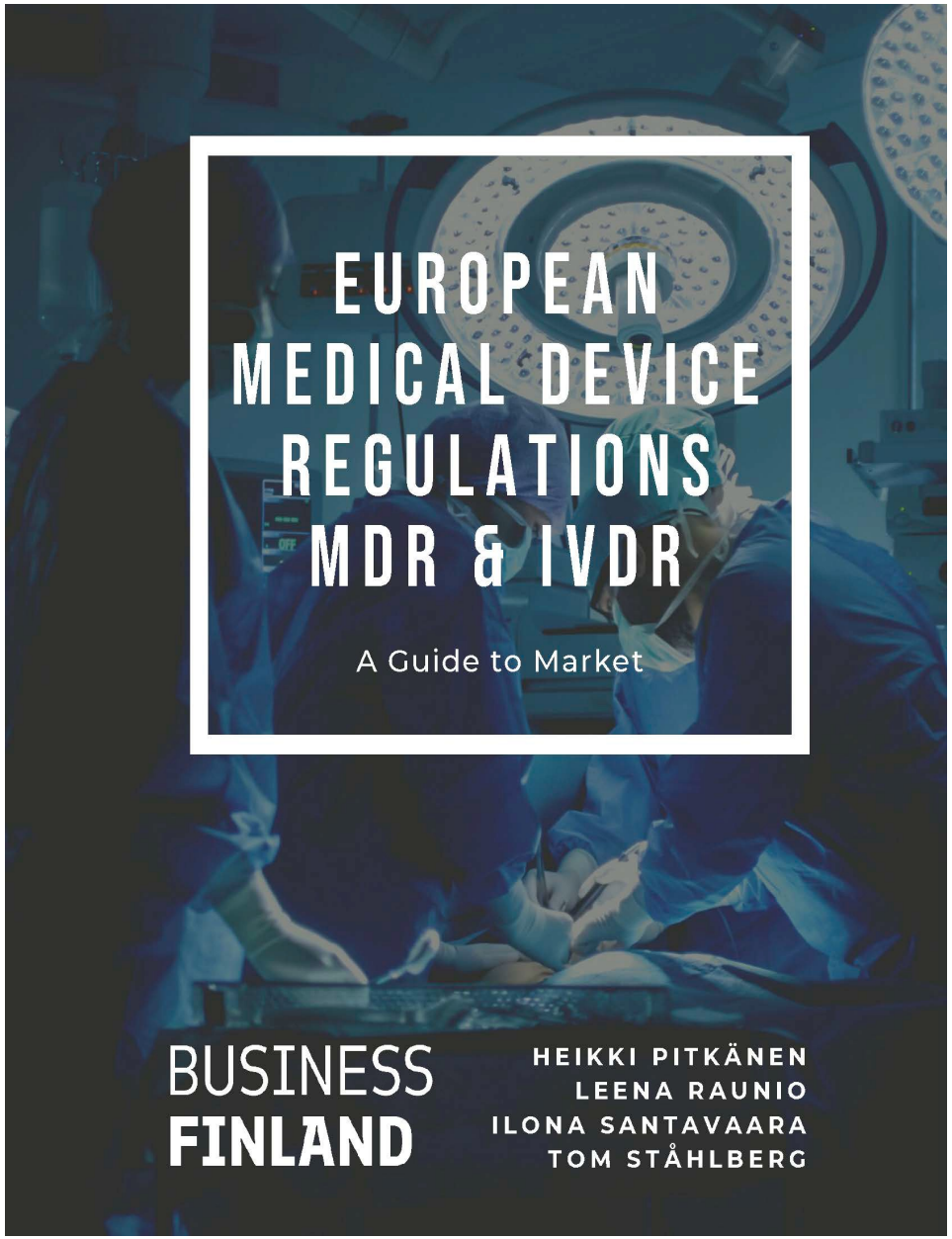
Heikki Pitkänen

Leena Raunio

Ilona Santavaara

Tom Ståhlberg

From Directives to Regulations



Be active

Ask questions!

Read the book (to be presented later on)

Disclaimer

I already have a clue about these things

– so it is totally your responsibility to learn and come aboard!

Breaks, about 10.30 and 13.30 (about 10 minutes)
Lunch break 11.30-12.30
Ending 16.30

From a barrier to competitive edge

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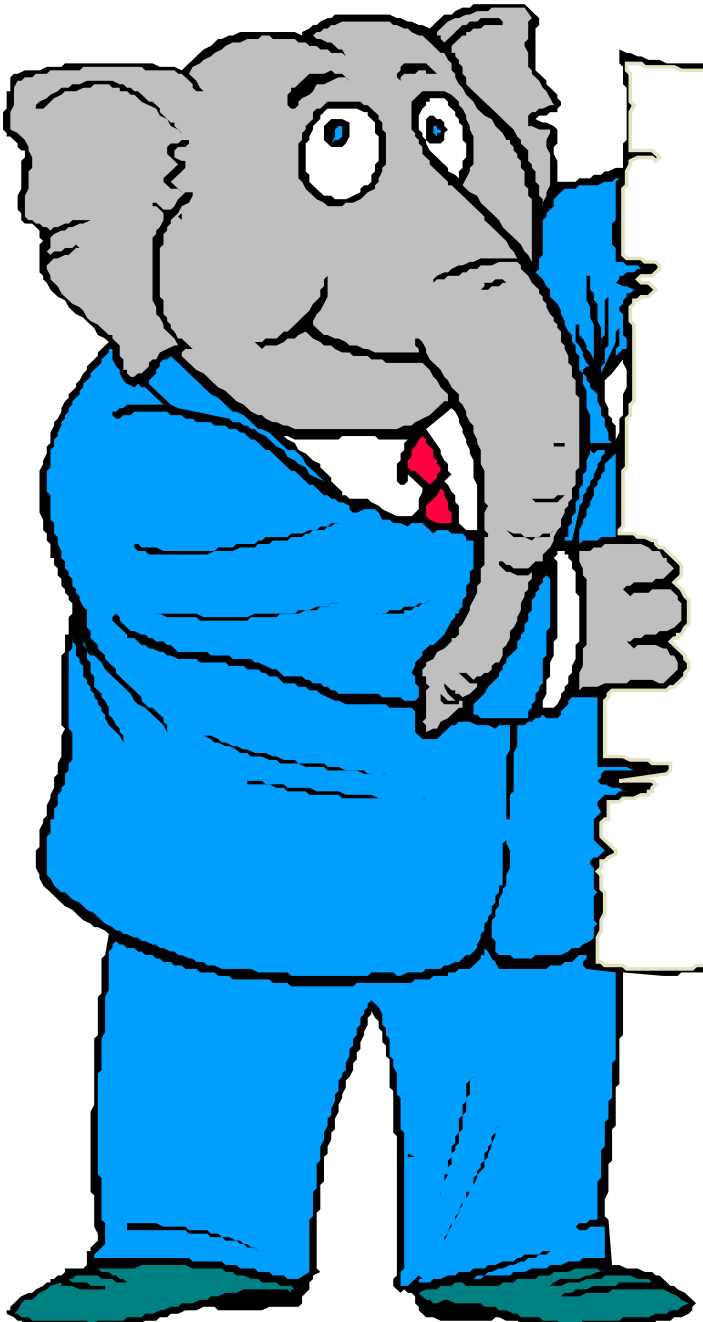

9.30-11.30 **Setting the scheme**

Post-market phase:

- MD on the market?
- Distributors? AR?
- CE: dealing with authorities?
- Rest of the world?
- Production and …?

12.30-14.30 **Pre-market phase:**

- Intended Use, risk classification
- Laws and standards
- GSPR and conformity
- Registration, Eudamed, UDI
- QMS: developing, obstacles

14.30-16.20 The Real Stuff

16.20-16.30 Q&A, conclusions

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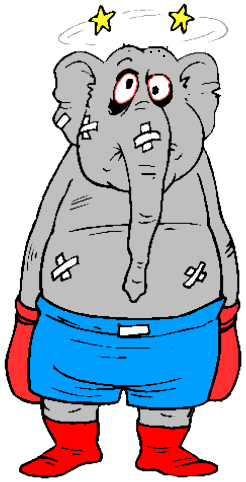
Who am I?

1.1.2019 Retired, still active
Own company, RaLex Partners



At PerkinElmer/Wallac Oy 1986-2012:
International marketing
Quality
Regulatory (Director, Regulatory Affairs & Compliance)

Healthtech Finland, Teknologiateollisuus
Director, Regulatory Affairs & Compliance, 2012-2019

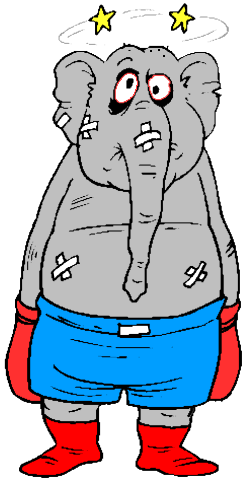
Clinical Biochemist from Åbo Akademi, M.Sc., 1988
Scientist: >30 scientific publications + >50 abstracts

Medical courses + worked within TY medical faculty
(clinical virology, Clinical microbiology)

Economical and management training internally and
Tampere Technical High School
Six Sigma Black Belt Training (Air Academy, USA)

Professional teacher, HAMK, 2009

Who am I?



ISO, CEN
CLSI
EDMA RA
EU WG
ABHS
Suomi-Venäjä RA
SGS-Fimko Sert. JR
Eurofins Expert Services Sert. JR
SFS yhteistyöelin
FinOHTA Advisory Board
Eri projektien Advisory Board
….

Conclusion: Eläkeläisukko saaristosta

From a barrier to competitive edge

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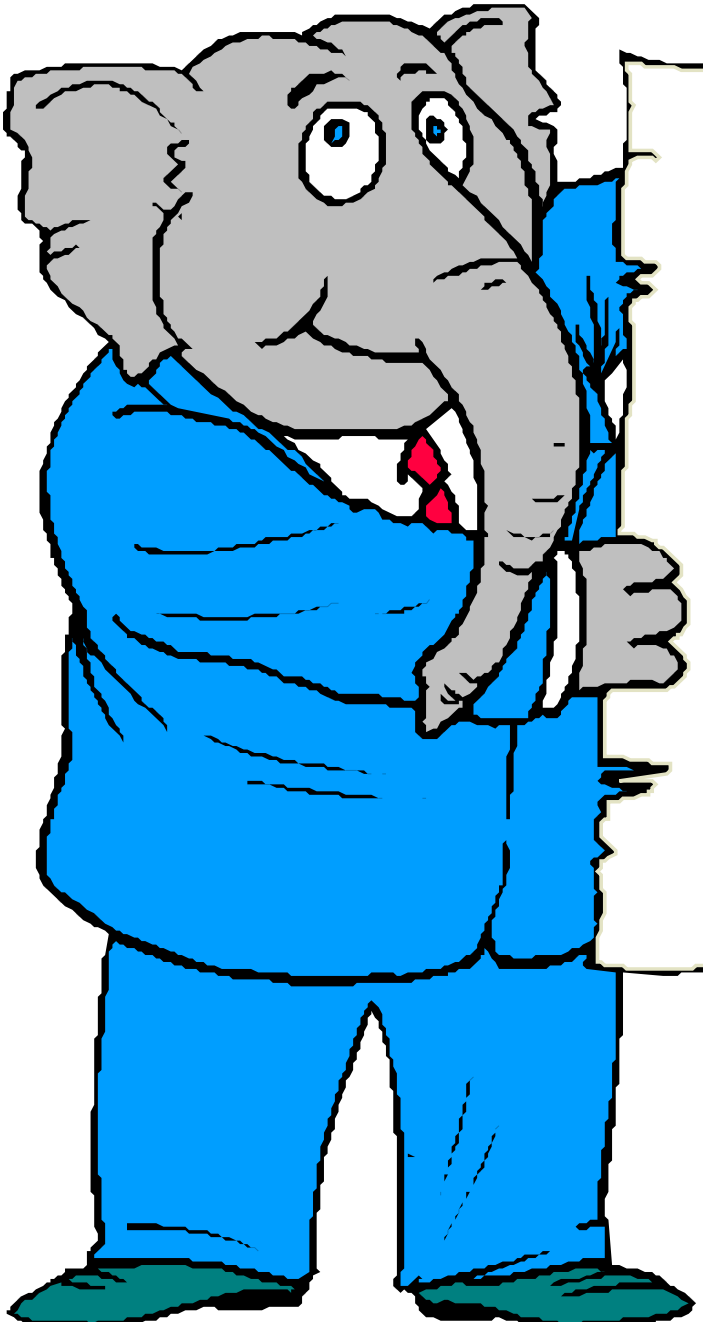

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From process approach to project approach

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Regulatory from Day 1!

From process to project approach

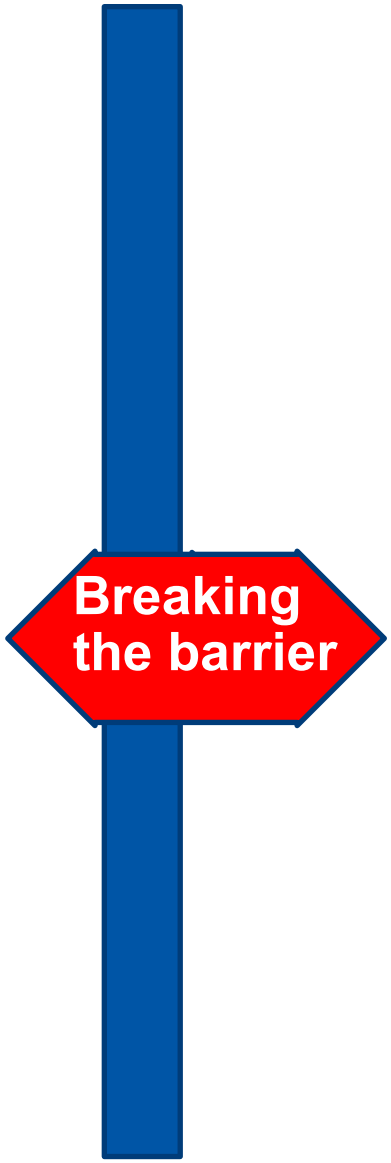
Process: going on “forever”
typically for research
unfortunately, also typical for many MD developing companies

Project: definitive starting and ending points
clear goal setting
needed for MD product development, otherwise you are “amateurs”

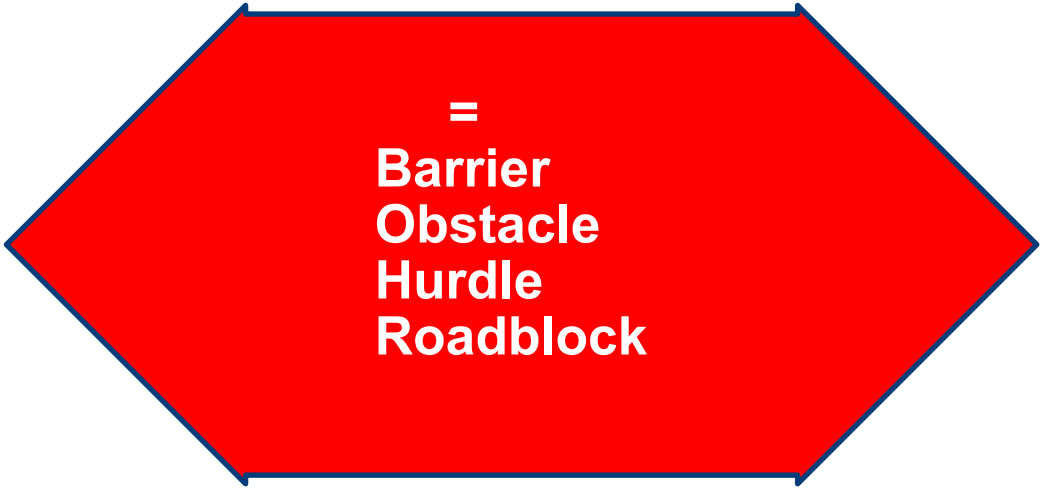
Would you start digging before you know what you will build?

Do not start from the technical idea, but from the patient need!

I will use this symbol, when pointing out barriers!



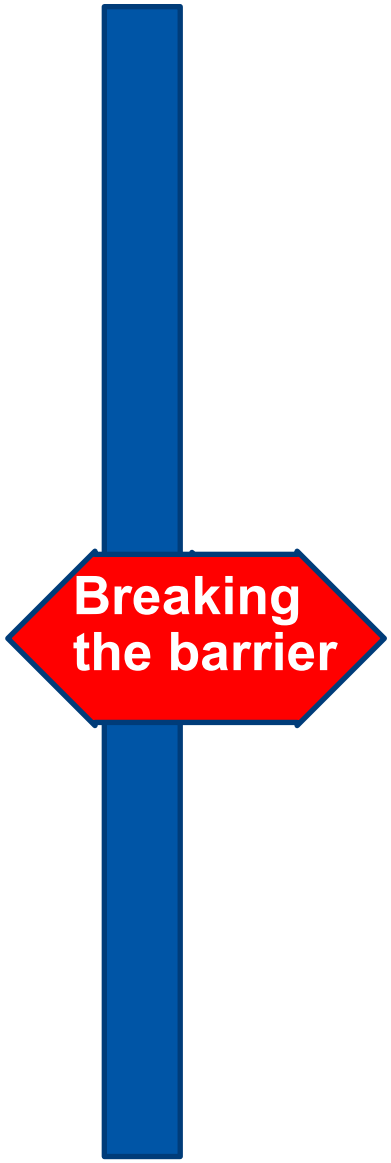
Sometimes just the symbol
Sometimes with text: the barrier/potential solution



I am not a besserwisser
I appreciate that some of you may know more
I do not try to insult you

But, I will be provocative!

Post-market phase: What will you face?



What medical need will our product fulfill?

How can we live up to safety and performance demands throughout the MD lifecycle (post-market surveillance)?

What to do if something goes wrong (vigilance)?

Needs to be considered already in the pre-market phase

We will meet the patient and users

Medical need
Our solution?

User
- Layman or professional?
- Usability

Can we even find them?
24/7

Finnish MD export

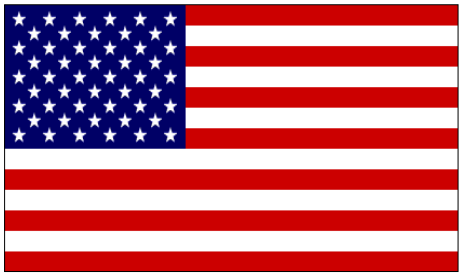
39 % USA

35 % Europe, most important

Germany, France and UK (Nordic countries as a sum)

9 % China

4% South-America
3% Australia, New Zealand
2% Russia
2% Canada
2% Japan
1% Middle East
4% Others



Regulatory harmonization efforts, but critical differences also medical care best practice and health care systems vary (HTA?) – you cannot extrapolate from one country to the other

Post-market surveillance

(60) ‘post-market surveillance’ means all activities carried out by manufacturers in cooperation with other economic operators to institute and keep up to date a systematic procedure to proactively collect and review experience gained from devices they place on the market, make available on the market or put into service for the purpose of identifying any need to immediately apply any necessary corrective or preventive actions;

Include in QMS
First plan in R&D

Article 83

Post-market surveillance system of the manufacturer

1. For each device, manufacturers shall plan, establish, document, implement, maintain and update a post-market surveillance system in a manner that is proportionate to the risk class and appropriate for the type of device. That system shall be an integral part of the manufacturer's quality management system referred to in Article 10(9).

2. The post-market surveillance system shall be suited to actively and systematically gathering, recording and analysing relevant data on the quality, performance and safety of a device throughout its entire lifetime, and to drawing the necessary conclusions and to determining, implementing and monitoring any preventive and corrective actions.

3. Data gathered by the manufacturer's post-market surveillance system shall in particular be used:

(a) to update the benefit-risk determination and to improve the risk management as referred to in Chapter I of Annex I;

(b) to update the design and manufacturing information, the instructions for use and the labelling;

(c) to update the clinical evaluation;

(d) to update the summary of safety and clinical performance referred to in Article 32;

(e) for the identification of needs for preventive, corrective or field safety corrective action;

(f) for the identification of options to improve the usability, performance and safety of the device;

(g) when relevant, to contribute to the post-market surveillance of other devices; and

(h) to detect and report trends in accordance with Article 88.

The technical documentation shall be updated accordingly.

(74 cont.) Relevant data and information gathered through post-market surveillance, as well as lessons learned from any implemented preventive and/or corrective actions, should be used to update any relevant part of technical documentation, such as those relating to risk assessment and clinical evaluation, and should also serve the purpose of transparency.

What is an incident in EU?

Death or serious injury which has happened or could have happened related to a deficient medical device

“serious deterioration in the state of health”
Permanent or transient injury

Predisposition to report!
Sometimes very restrict timelines! ”Normally” 15 days!

Also the users must report!!!

EU Vigilance

Incidents

Field Safety Corrective Action (FSCA)

- the return of a medical device to the supplier
- device modification
- device exchange
- device destruction
- retrofit by purchaser
- advice given by manufacturer

FSCA = worldwidely used ”recall”

Field Safety Notice (FSN)

May happen the day you launch the MD

From a barrier to competitive edge

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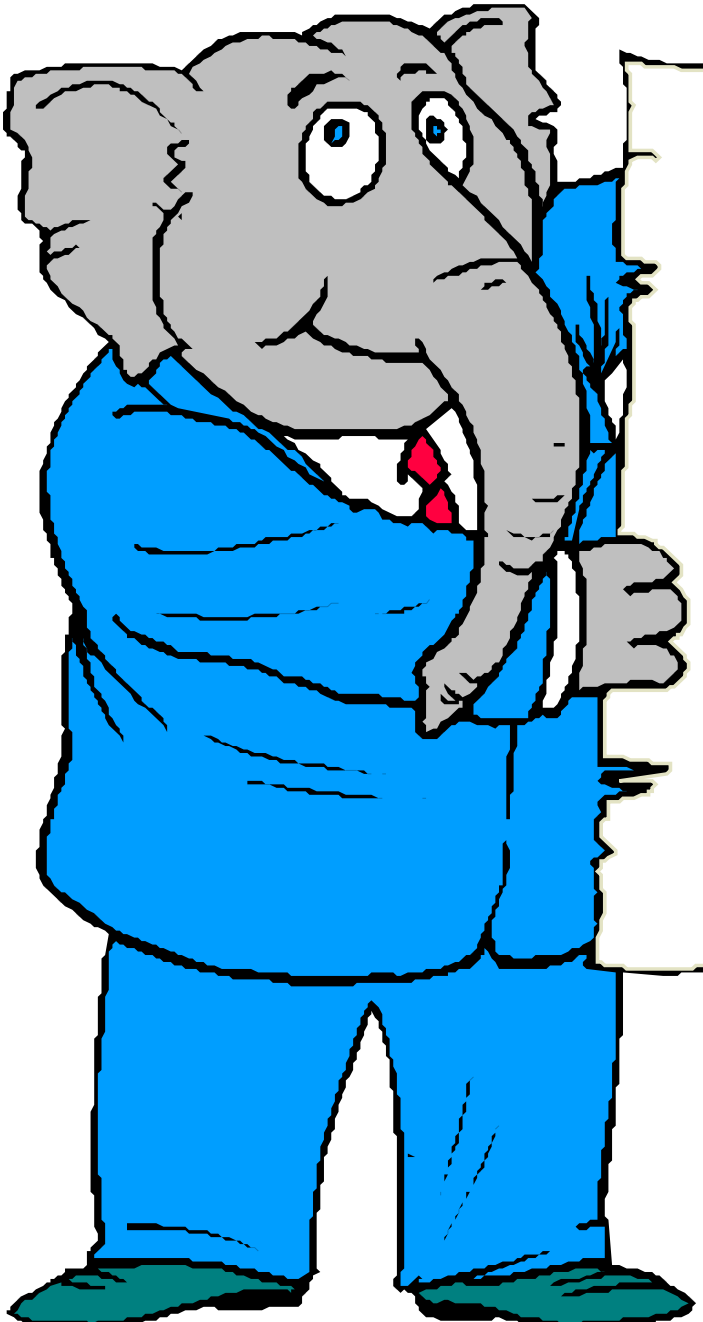

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Economic operators

The Directives does not recognize distributors, importers

Laki Terveydenhuollon laitteista ja tarvikkeista does recognize

Great improvement: responsibilities defined in MDR/VDR

MDR/IVDR

(28) ‘economic operator’ means a manufacturer, an authorised representative, an importer or a distributor; ’

Why?

To identify each parties particular responsibilities!

MDR and IVDR – Distributor and Importer

(27) ‘distributor’ means any natural or legal person in the supply chain, other than the manufacturer or the importer, that makes a device available on the market, up until the point of putting into service;

(26) ‘importer’ means any natural or legal person established within the Union that places a device from a third country on the Union market;

General obligations both similar and different!

Article 13

General obligations of importers

Article 14

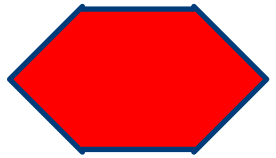
General obligations of distributors

Authorised representatives, article 11 (both MDR and IVDR):

verifying that products meet CE requirements
keeping relevant documentation
verify that the product has been registered (in Eudamed)
strict role in complaint handling, CAPA, incidence reporting

This is also almost identical for importers

Barriers related to distributors, importers, ARs?



"No" customer will find you only because you think you have the best medical device in the world

It takes time (actually extremely long time):

To find and qualify a distributor (importer, AR)

To develop the legal contracts (also registration)

To train and motivate the distributor

To develop a service network

(own daughter sales company? Sometimes internet sales)

Should you start by first (while developing your own product) to market medical device(s) from another country?!!

From a barrier to competitive edge

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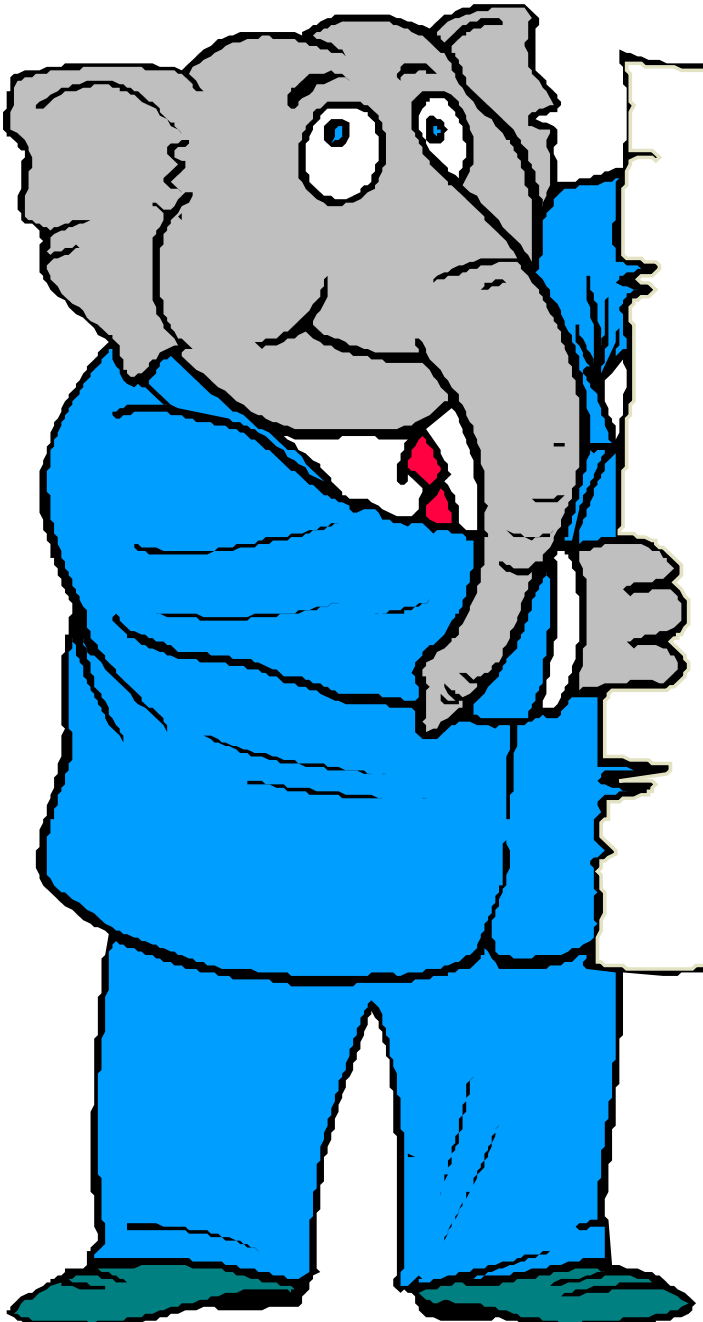

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From EU directives to regulations

Directive 93/42/EEC on Medical Devices
Directive 90/385/EEC on Active Implantable MD

Directive 200747/EC
Amending…

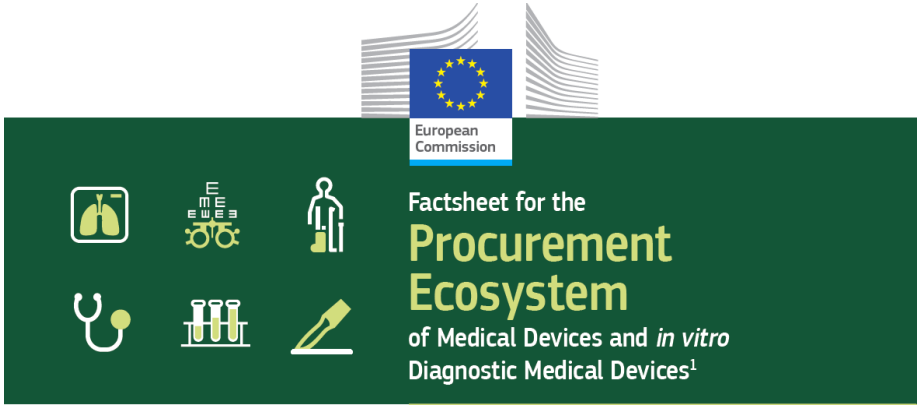
Regulation on MD
2017/745

Directive 98/79/EC on IVD MD

Regulation on IVD MD
2017/746

Transition period:
MDR to 26.5.2021
IVDR to 26.5.2022

Check and keep continuously an eye on EU website!



Will it be a scandal?

The MDR transition period ended 26th May, 2021

Only about 27 % of the MDs were ready!

The transition periods were used by the EU Commission to get their acts together (the goal is not yet reached!)

IVDR transition period ends May 2022 = about 242 days (17.9.2021)

Sweden estimated 17 000 assays, in all EU only 6 IVD notified bodies

What does this mean in practice?

During the transition period, products certified under the Directives and products certified under the Regulations will coexist on the market. Both will have equal status under the law, and no discrimination in public tenders may take place.

IVDD and MDD products can still be sold

Gap analysis
Implementation
NB certficate
Registration
IVDR
<26.5.2022

Grace period for some products

If valid certificates and NO significant changes
Can be produced/sold

<26.5.2024

If valid certificates and NO significant changes
Can be sold by distributor

Max 26.5.2025

Valid certificates?
No significant changes!

Will EU regulations be understood worldwide?

European Commission

Factsheet for Authorities in non-EU/EEA States

on Medical Devices and *in vitro* Diagnostic Medical Devices[1]

EU legislation - are there national obstacles?

Regulations adopted as such in all member states at the same time, i.e. May, 2017

I.e. when a product is registered e.g. in Finland it has free access to all EU… at least almost

Certain aspects mentioned in the regulations may be complemented by national requirements – be aware of these!

e.g. HE67/2021 in Finland

Most important is the possible (and in many countries very likely) language requirements

Others may be: fees, ”listing” requirements, penalties

Sometimes, these may be difficult to monitor as the requirements are available only in the local language

Finnish legislation on medical devices

Be aware!

HE 67 2021

Termi muuttuu ”lääkinnällinen laite”
Kieli: Suomi, Ruotsi tai Englanti sallittu (Huom.! Eri sääntö eri dokumenteille)
Kertakäyttötuotteiden uudelleenkäsittely ei sallita
PRRC – kansallinen tulkinta vaatimuksista
Hyvä hallinto ja virkavastuu - myös ilmoitetulle laitokselle
Kiellettyjä markkinointitapoja
Ammattimainen huolto ja asennus
Tarkennuksia: kliiniset tutkimukset ja suorituskykytutkimukset
Tarkennuksia: oma laitevalmistus
Tarkennuksia: FIMEAn velvollisuudet
Poliisin virka-apu, ulkopuolisen asiantuntijan käyttö, valehenkilöllisyys
Rangaistuskeinot ja valvontamaksut

FIMEAlle oikeus antaa tarkentavia määräyksiä, esim.:
yksilölliseen käyttöön tarkoitetuista laitteista
tiettyjen asiakirjojen saatavuudesta

EU legislation - are there national obstacles?

HTA (Health Technology Assessment) may be of huge importance when considering public procurement

EuNetHTA, but also internationally
May be critical national variations (e.g. Germany, France)

EU Competent Authorities

Webinar 9.11.!

In Finland FIMEA

You will see them:

- **when registering (but, gradual change to Eudamed)**
- **through their market surveillance**
- **through their nomination and scrutiny of the Finnish notified bodies (NBs)**
- **If some other CA has informed them about your problems**
- **In vigilance situations**
- **Good internet-pages!**

Weakness: rather small organization
Strength: efficient, rather pragmatic, easy to approach

The competent authoriy is there to keep you under control and safeguard that medical devices are safe and fit for their use

- they are not allowed to help you by consultations!

EU Notified Bodies Part I

Nominated by a competent authority after a EU level joint assessment
Specifically for the Directives and/or the Regulations
Specific responsibilities defined in the Regulations and acts as ”semi-authorities”

From an international perspective a very unique approach – in all other countries everything is handled by the authorities themselves

Available NBs are listed by EU:
https://ec.europa.eu/growth/tools-databases/nando/index.cfm?fuseaction=directive.notifiedbody&dir_id=34

Presently, only 22 for MDR and 6 for IVDR (in reality 22 different ones, as some have both competencies)

Note: The nomination is related to certain product families and to certain horizontal technical competence – make sure that the one you want to choose has the right competence. The competence can also be restricted by excluding higher risk class(es).

Check your product(s) vs. the NB competencies!

EU Notified Bodies

NBs and the post-market phase:

- Renewal of certificates, follow-up audits, unannounced audits
- Be aware of: initially detailed scrutiny of one product, next time another product!
  - QMS (including the EU regulatory demands!)
  - Product(s)
- Post-market surveillance reports
- Vigilance situations

Nominated in Finland:

Eurofins Expert Services
SGS Fimko

EU authorities – how to deal with them?

Be straightforward, honest and transparent!

Be aware of that neither the CA nor the NB can be consultative

Be ready!

Remember that you have to interprete the MDR – provide justifications for your decisions and possible exclusions

Provide justifications for also rather self-evident decisions or exclusions – it is not their duty to guess why you have done something in a particular manner or why you have omitted something!

I will complement this when we talk abou the pre-marketing phase!

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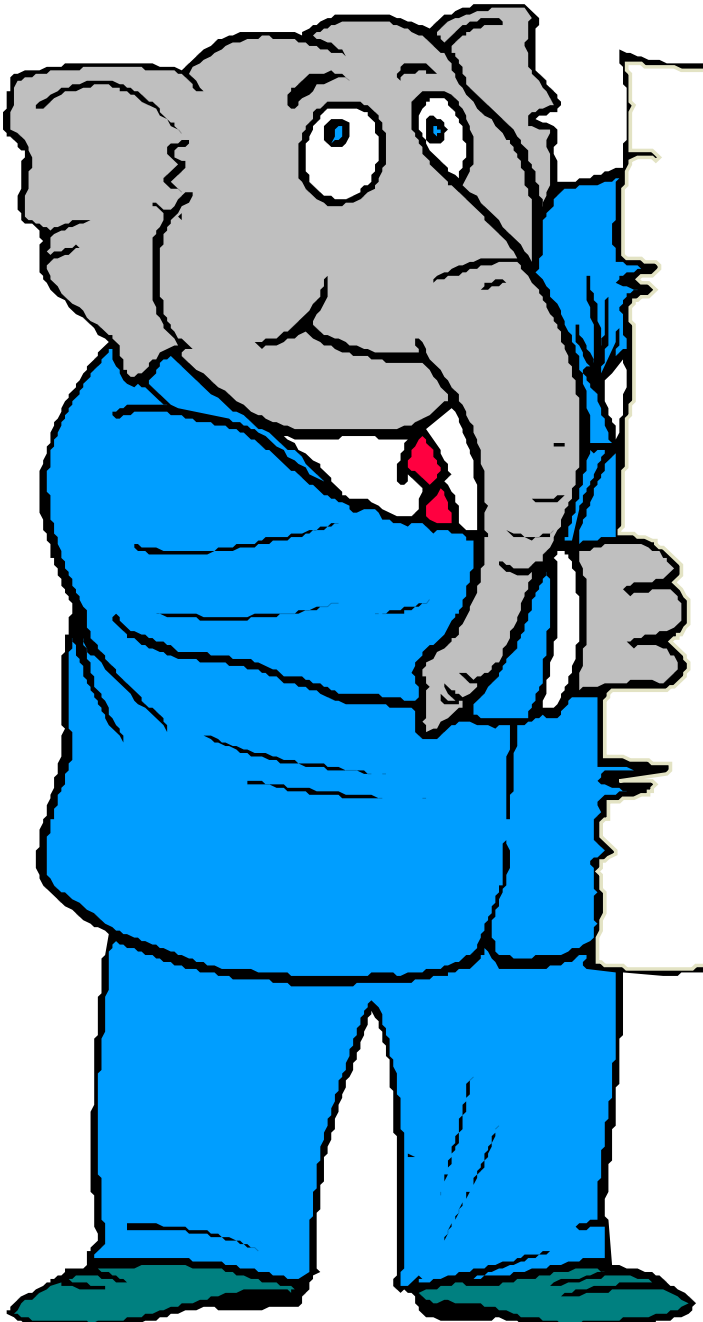

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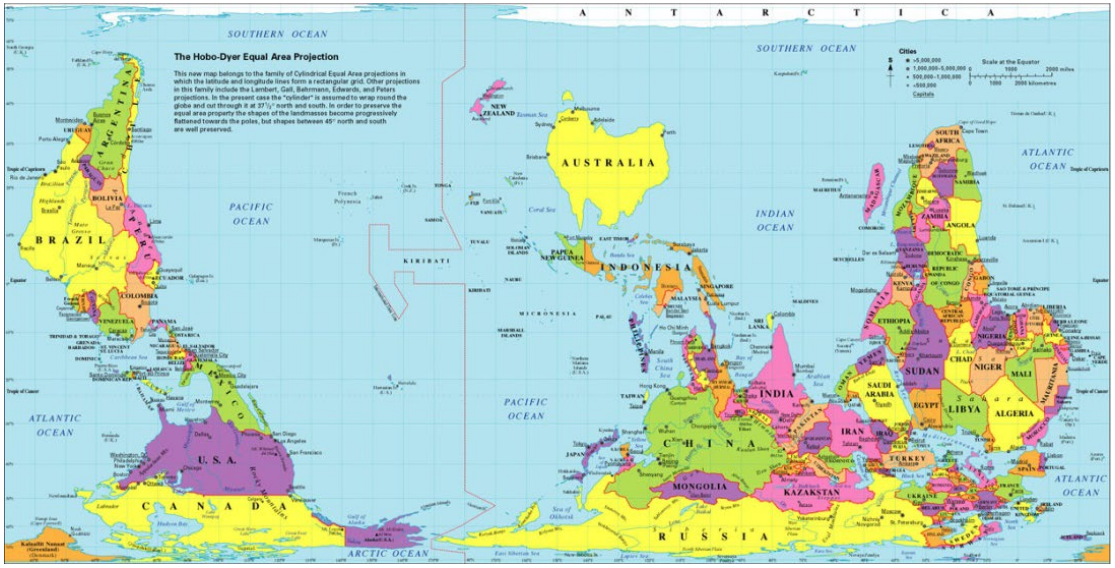
EU from a larger perspective, corrsponding worldwide

UK, no longer a part of EU

UKRP = UK Representative Person

Mika Reinikainen, Abnovo Ltd, in UK: chairman of both the EU AR and UKRP organizations!

MD/IVD – Not only EU! always global approach needed



Non-EU RA known by a few within some companies! Few consultants have experience!

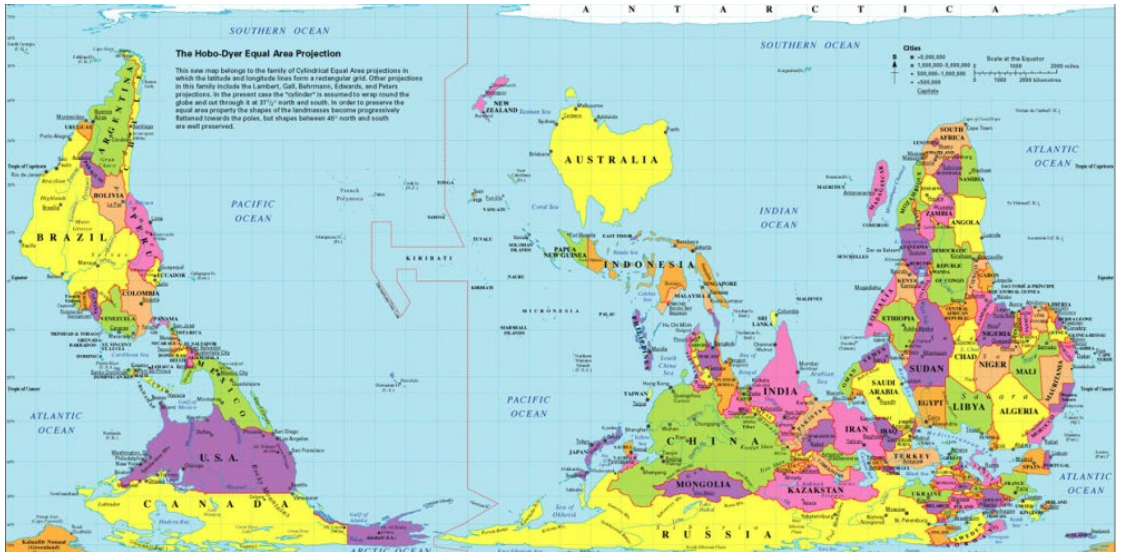
The most critical regulatory drivers: in common worldwide

We are influencing on the life and health of human beings:

Safe

Fit for their intended use

Our products and services must fulfill these demands 24/7!



But, in reality huge differences!

Harmonization efforts:
GHTF/IMDRF
Standardization

Some countries still without MD legislation (but, may be Indirectly covered by demands on EU Free Sales Certificate)

You have to know specifically the national demands in the countries you have chosen in your marketing strategy!

Also, these regulatory requirements must be captured in your QMS and technical documentation

Also authorities from these countries may come and inspect you
E.g. US FDA
MDSAP (Australia, Brazil, Canada, Japan, USA)

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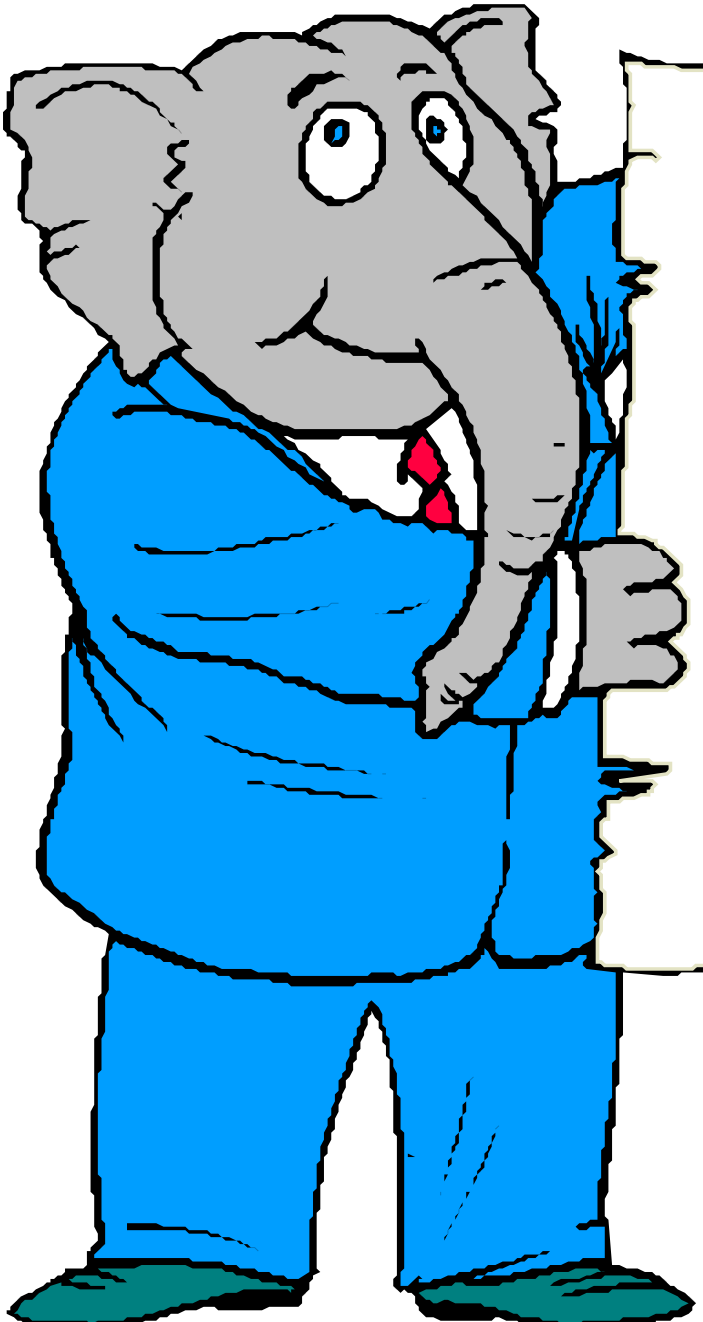

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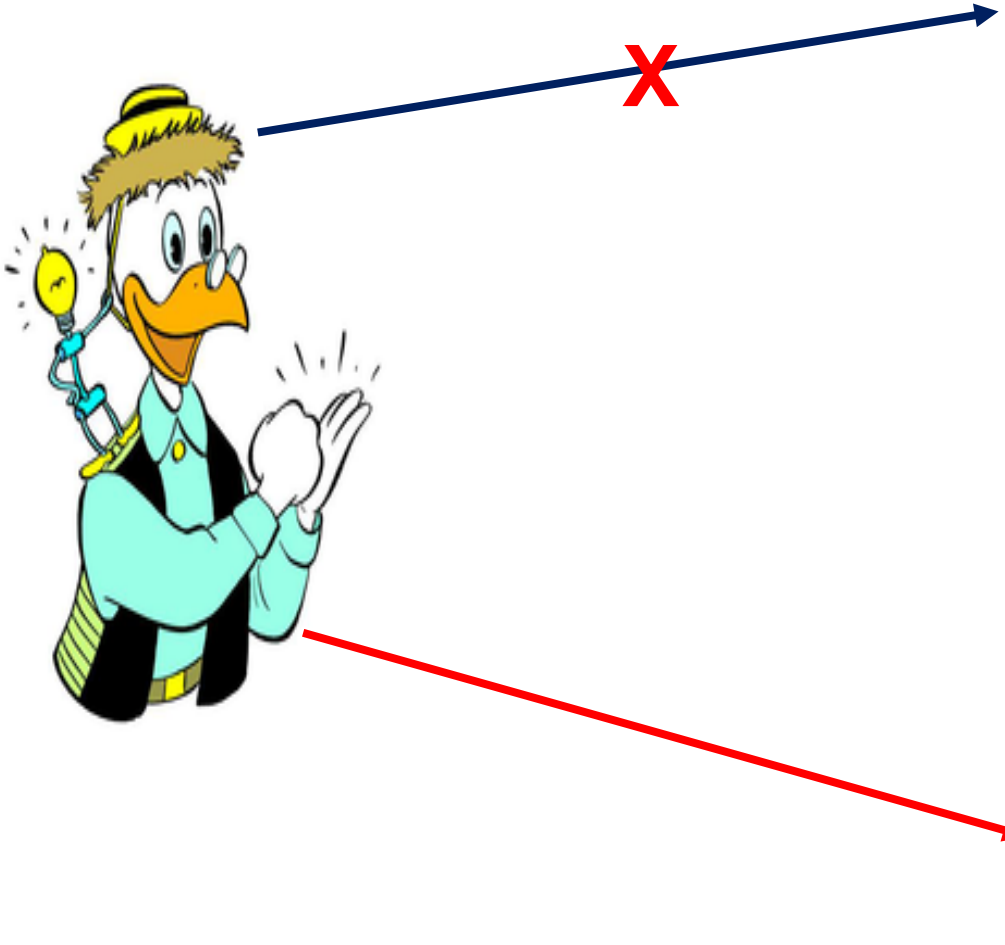
Product development is not aiming at a functioning prototype



X Huge amount

…but, to be able to produce a huge amount of lots or individual medical devices in a consistent manner

Why the post-market phase must be considered from Day1?

The technical solution may be your most important asset
Unfortunately, by far the biggest mistake ever is to build your work around the technical solution!

You cannot glue the post-market phase onto the pure development activities at a late stage – then you wlll never be successful!

Clinical landscape

Marketing landscape

Regulatory landscape

Business landscape

Production

Sales network

Your solution

Benefit > risks!
State of art?

Conclusions?

The project goal must be crisp and clear from Day 1!

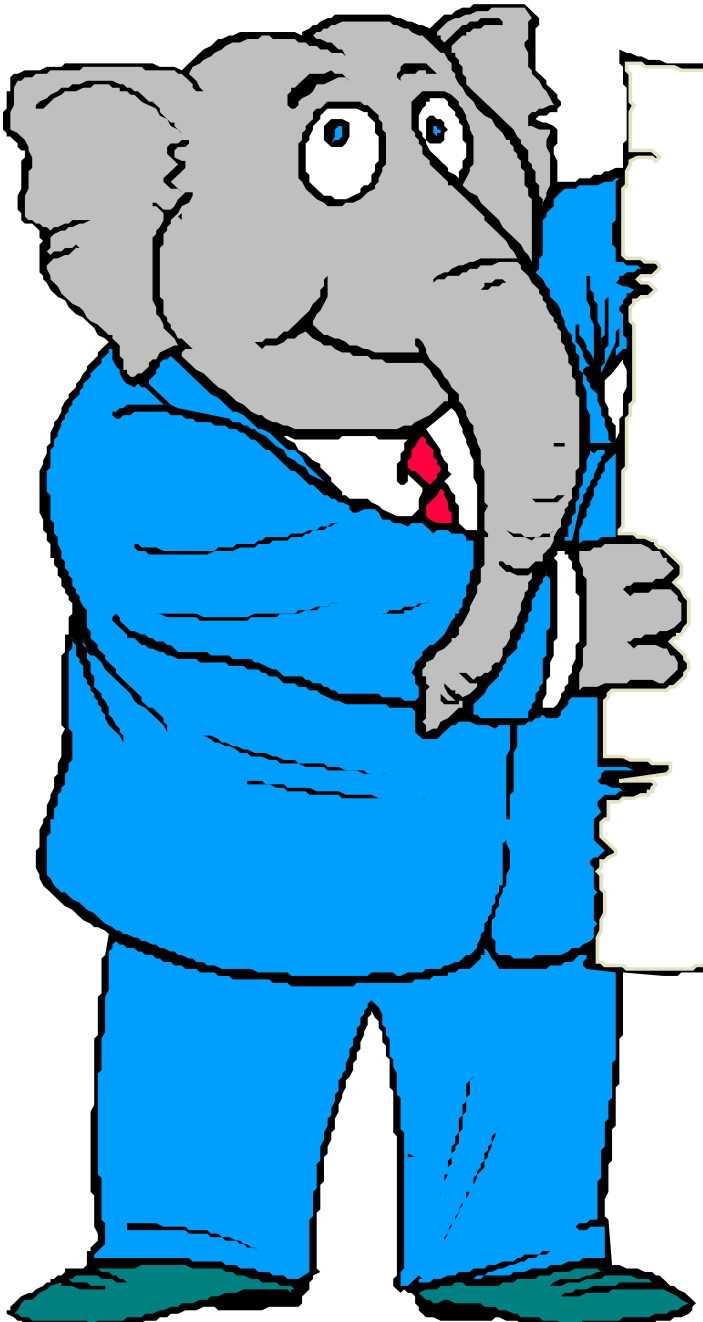
Link firmly your technical solution to a thorough understanding of selected patient groups in selected countries and deep understanding of their needs

Create a regulatory strategy build upon the marketing strategy within the chosen business strategy

Make sure that your documentation not only gives firm proof that the product is safe and efficient, but
also that you can ´consistently keep it safe and efficient by making sure that all other aspects of the company is prepared for this!

From a barrier to competitive edge

BUSINESS FINLAND



9.30-11.30 Setting the scheme

Post-market phase:

- MD on the market?
- Distributors? AR?
- CE: dealing with authorities?
- Rest of the world?
- Production and …?

12.30-14.30 **Pre-market phase:**

- Intended Use, risk classification
- Laws and standards
- GSPR and conformity
- Registration, Eudamed, UDI
- QMS: developing, obstacles

14.30-16.20 The Real Stuff

16.20-16.30 Q&A, conclusions

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