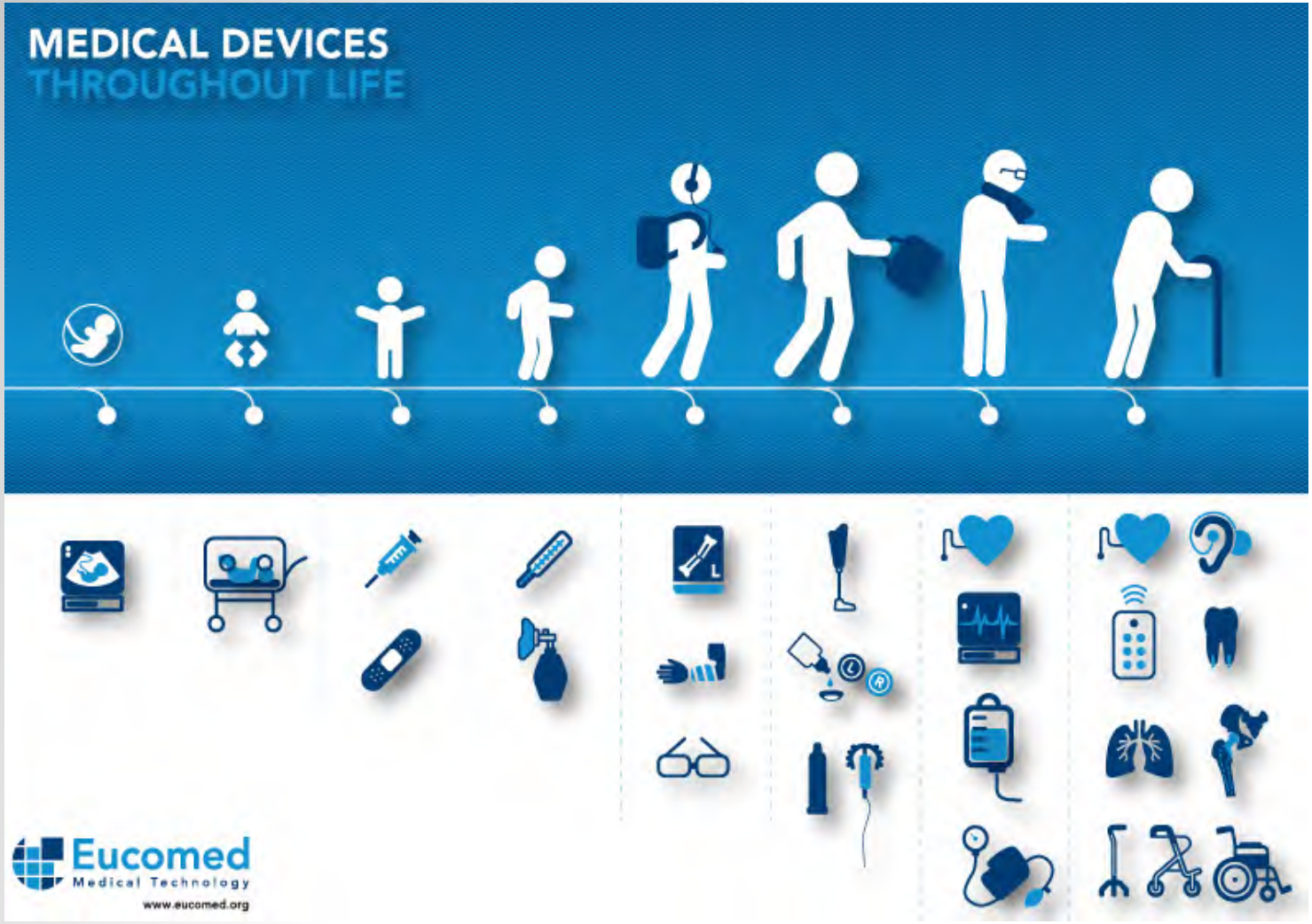
Changes in regulatory landscape

Evolution of the Medical regulatory context and the main impacts

Monthey – October 13rd 2016

medídee®

Medical devices throughout our lives



Source: Eucomed

medídee®

Today **Directives**: Medical Devices

AIMDD

Active implantable Medical Devices Directive

90/385 CEE

MDD

Medical Device Directive

93/42 CEE

IVDD

In Vitro Diagnostics

Directive

98/79 CE

Tomorrow **Regulations**: Medical Devices (Q1-2017)

MDR

Replacing

93/42 EEC

90/385 EEC

IVDR

replacing

98/79 EC

medídee®

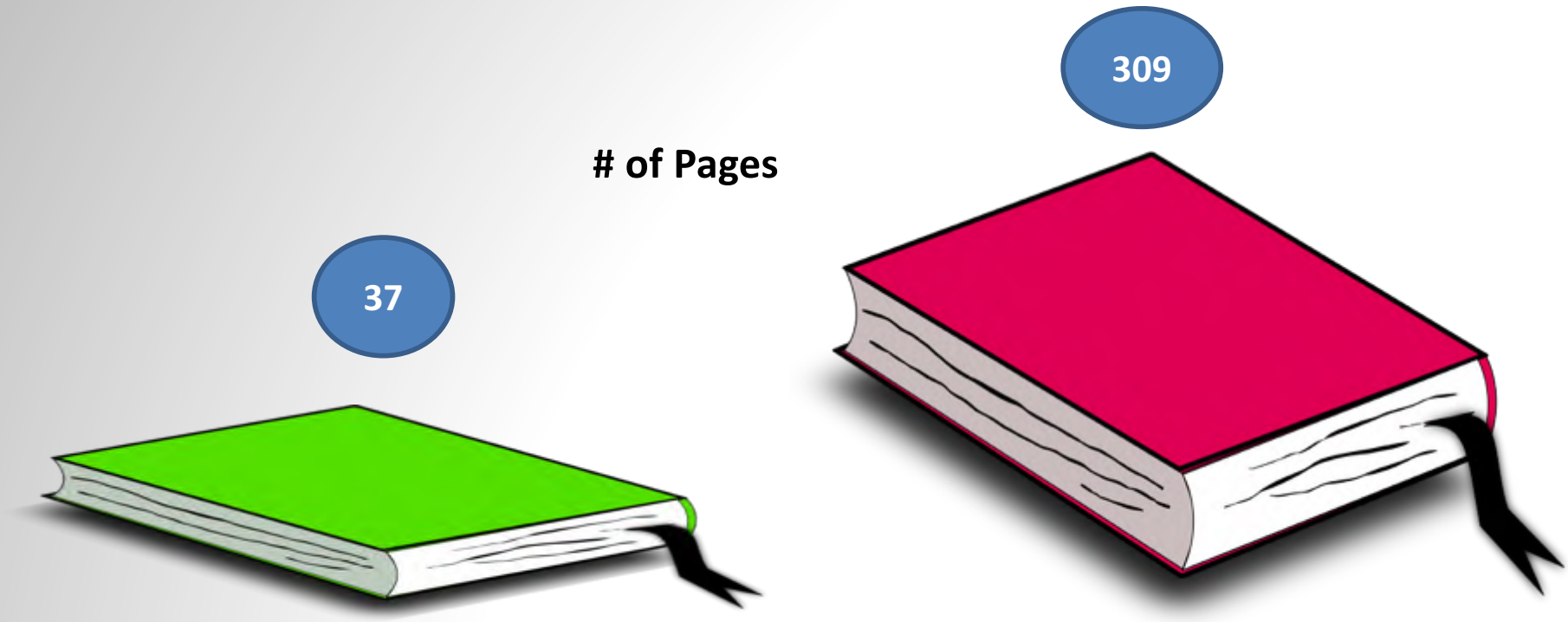
The objective remains

CE mark = business

no CE mark = no sales

High increase of requirements

# of Pages



Consolidated IVDD / 98/79/EC

Consolidated IVDR

William Edwards Deming
(1900 – 1993)

Laws and regulations need control – counting solely on «Best Practice» and professionalism of stakeholders does not work as evidenced by several problems with medical devices and the system for market clearance implemented in EU. Regulations get more stringent, scrutiny gets much more stringent.

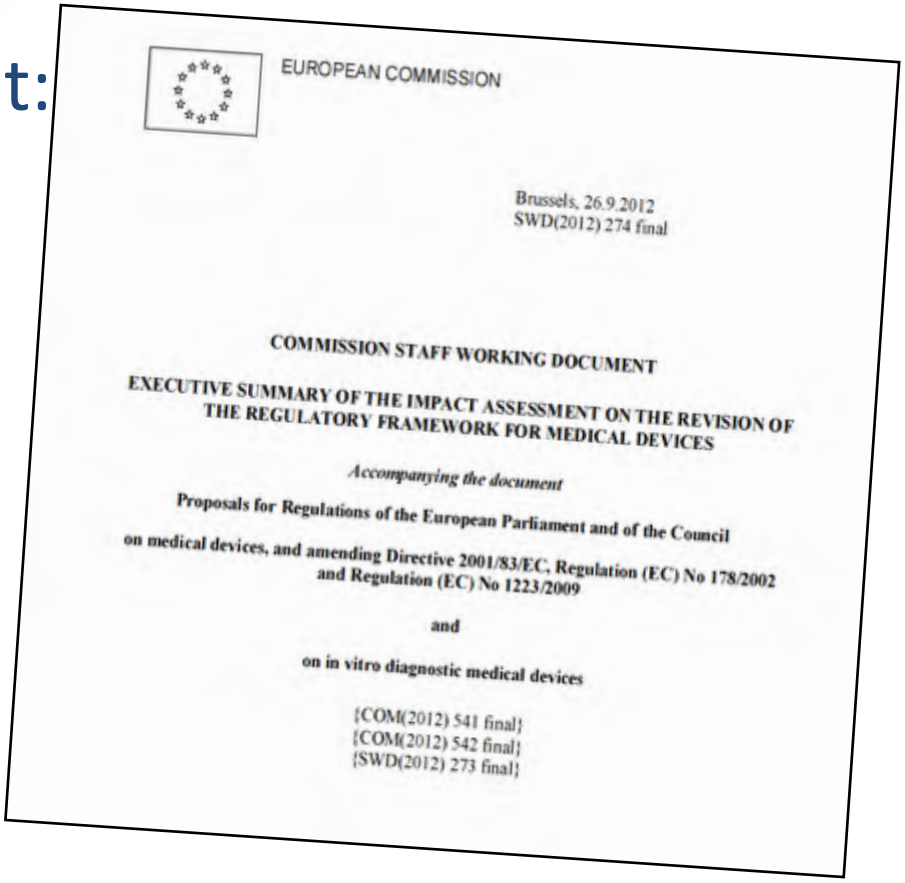
It has been said by William Edwards Deming:

IN GOD WE TRUST, ALL OTHERS BRING DATA*

*Quelle: http://en.wikipedia.org/wiki/W._Edwards_Deming#cite_note-learning-34 - Hastie, Trevor; Tibshirani, Robert; Friedman, Jerome (2009). *The Elements of Statistical Learning* (2nd ed.). Springer.

The MDD and AIMDD: experience and lessons learned

- Current regulatory framework not fundamentally unsound but:
  - 20 years old – not any more adapted to recent innovation
  - Disparities in interpretation between member states
  - Shortcomings of the existing regulations recognized by commission



EUROPEAN COMMISSION

Brussels, 26.9.2012
SWD(2012) 274 final

COMMISSION STAFF WORKING DOCUMENT

EXECUTIVE SUMMARY OF THE IMPACT ASSESSMENT ON THE REVISION OF THE REGULATORY FRAMEWORK FOR MEDICAL DEVICES

Accompanying the document

Proposals for Regulations of the European Parliament and of the Council

on medical devices, and amending Directive 2001/83/EC, Regulation (EC) No 178/2002 and Regulation (EC) No 1223/2009

and

on in vitro diagnostic medical devices

{COM(2012) 541 final}
{COM(2012) 542 final}
{SWD(2012) 273 final}

History of the EU regulatory framework for medical devices

1990	AIMDD
1993	MDD
1998	IVDD
2003	Commission communication on the functioning of MD Directives
2005	Public consultation on revision
2005	Proposal for a directive amending AIMDD / MDD
2007	2007/47 EC amending MDD & AIMDD

History of the EU reg work for medical devi

2007 Commission launches "Recast" of ives

2009 - oject

- Publi
- Enha AMED
- Impr arket by U
- Stren dies
- Switc roach ("recast" to "ong

2011 R tion after 2 consultations (on MDD / AIMDD and IVDD between 2008 and 2010)

2010
PIP

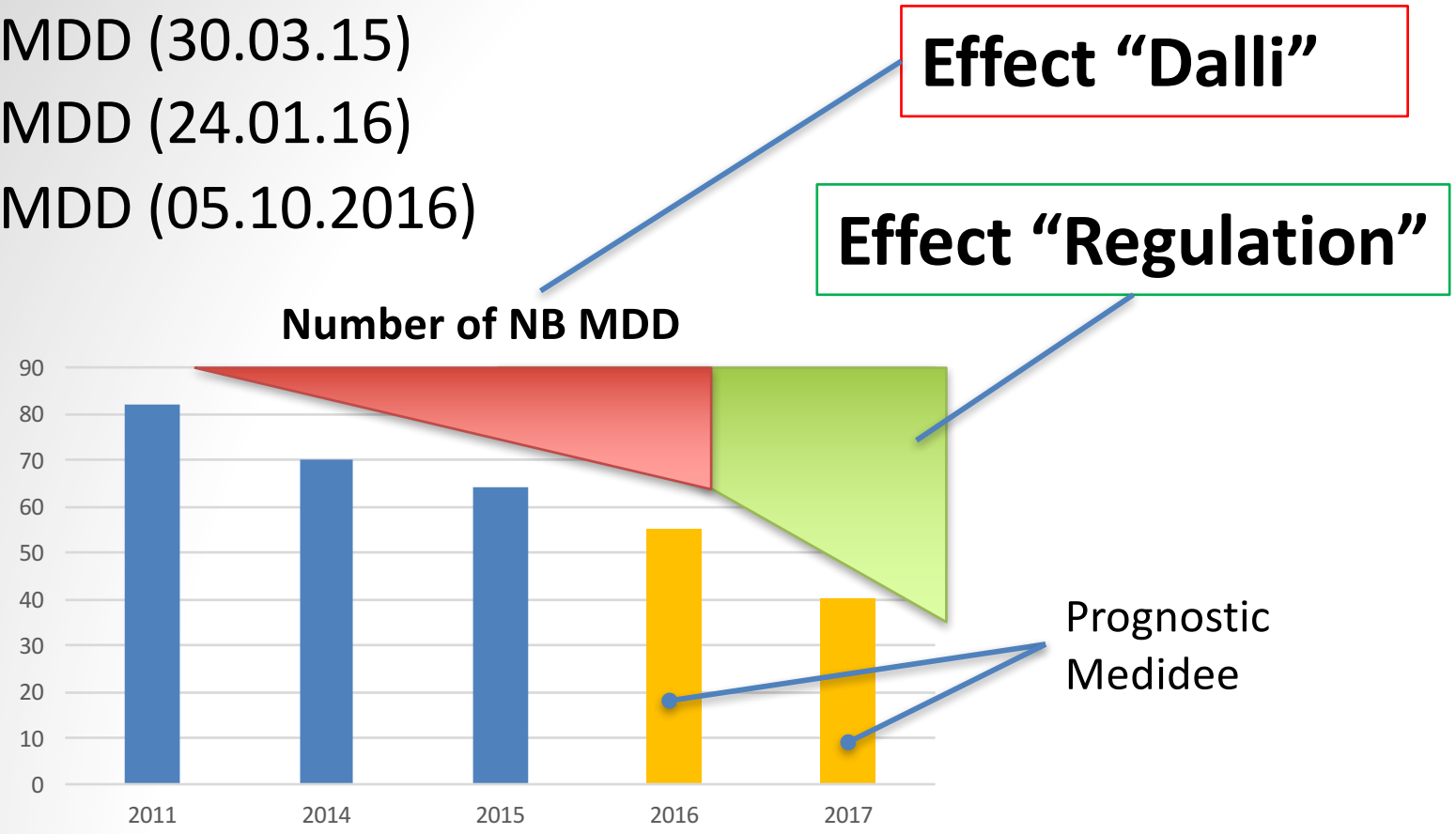
Manufacturers concerns since February 2012 (continued impact of Dalli plan & joint audits)

- Enforced control of NBs
  - Designation and surveillance (**with a real threat to loose designation for competence scopes…**)
  - Much stricter qualification requirements for NB personnel – you will face an expert each time
- Policies ensuring NBs use the powers that have been conferred to them
  - Unannounced audits
  - Mandatory review of TF – especially with regards to change control, PMS, PMCFU

Nando list

- 82 NB in 2011 for MDD
- 75 NB for MDD (21.06.14)
- 70 NB for MDD (11.10.14)
- 64 NB for MDD (30.03.15)
- 61 NB for MDD (24.01.16)
- 58 NB for MDD (05.10.2016)

- IVD 22 NB (05.10.2016) !!!!



Some Key Changes with IVDR

Subject	Change impacting Mfg
Technical documentation	Annex II, aligned to ToC
Classification	More rules, precisions. Change from a positive list to a risk based system: - IVDR: 4 classes of risk A-D (individual / public health risk)
Conformity assessment	- Special procedure: Class D IVD - scrutiny - NB to notify CA along with safety & performance summary, IFU, assessment report and if applicable designated reference lab's scientific opinion
Competence	Article 13: Person responsible for regulatory compliance

Some Key Changes with IVDR

Subject	Change impacting Mfg
IVDR Performance evaluation	**- Performance evaluation report (C+D) to be regularly updated logically interlinked with RM and PMS / Vigilance.**
IVDR Interventional clinical performance studies / other performance studies	**- Always required unless duly justifiable** **- Performance evaluation subject of any NB review**

Some Key Changes with IVDR

Subject	Change impacting Mfg
Standards	**CS (common specifications) may be adopted by the commission in areas where standardization is lacking in addition to standards**
Transparency	**Making results of Performance evaluation (D) publicly available (certain devices)**
PMS	**PMS system, PMS plan**

ISO 13485:2016

- **Most ISO / TR 14969 guidance turned into requirements**
- **More prescriptive, transition Feb 2016 to Feb. 2019 – coexisting of 2nd and 3rd edition.**
- **No more second edition certificates issued after Feb 2018**
- **A working group started to work on handbook to replace ISO / TR 14969**
- **A forth edition will come as an adaption to HLS is projected**
- **A 6 year window of stability is however expected**

Key impact for IVD Manufacturers

- Insufficient « man power » within Notified Bodies
  - Competency
  - Number of reviewers
- Effective need to implement sound technical documentation
- Effective need to demonstrate performance of the product
- Subject to unannounced audits
- Implementation of PMS and Vigilance procedures
- Implementing Unique Device Identification (UDI)

Overall conclusion

Changes will **severely affect business** operations:

- More documentation, more controls
- More costs / Less investors
- More scrutiny

⇒ Real threat for business continuity

Thank you for your attention!
Questions?

Kim Rochat
Medidee Services SA
www.medidee.com