

Regulatory Strategy Forum for Medical Devices

1-2 March • Memphis, TN •
Inmotion Musculoskeletal Institute

Hot Topics - Europe

Patrick Johnson
Medtronic Neuromodulation

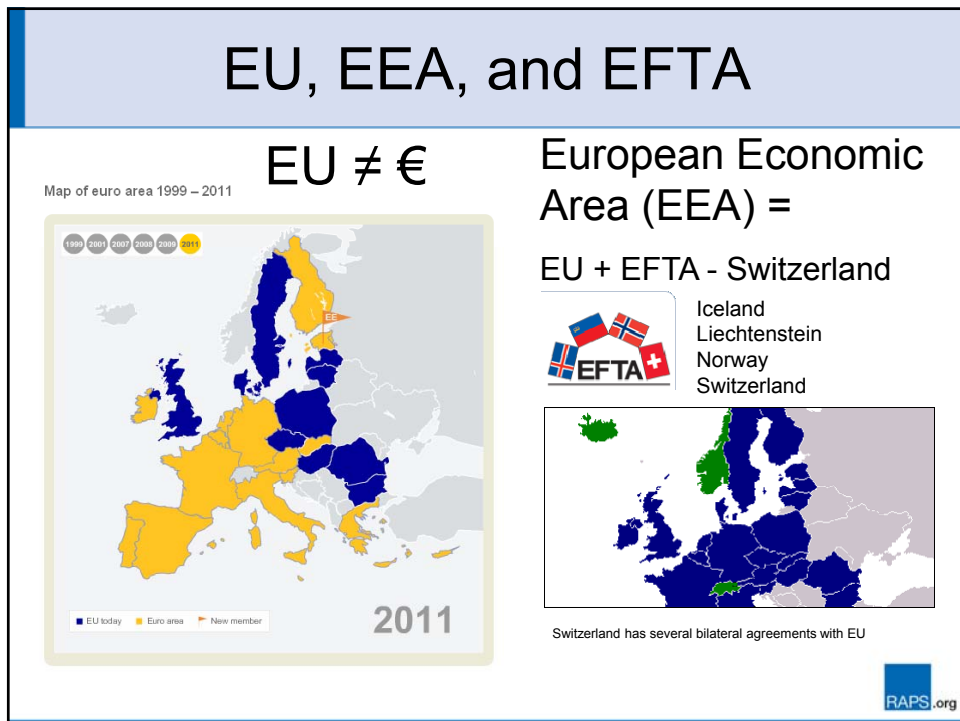
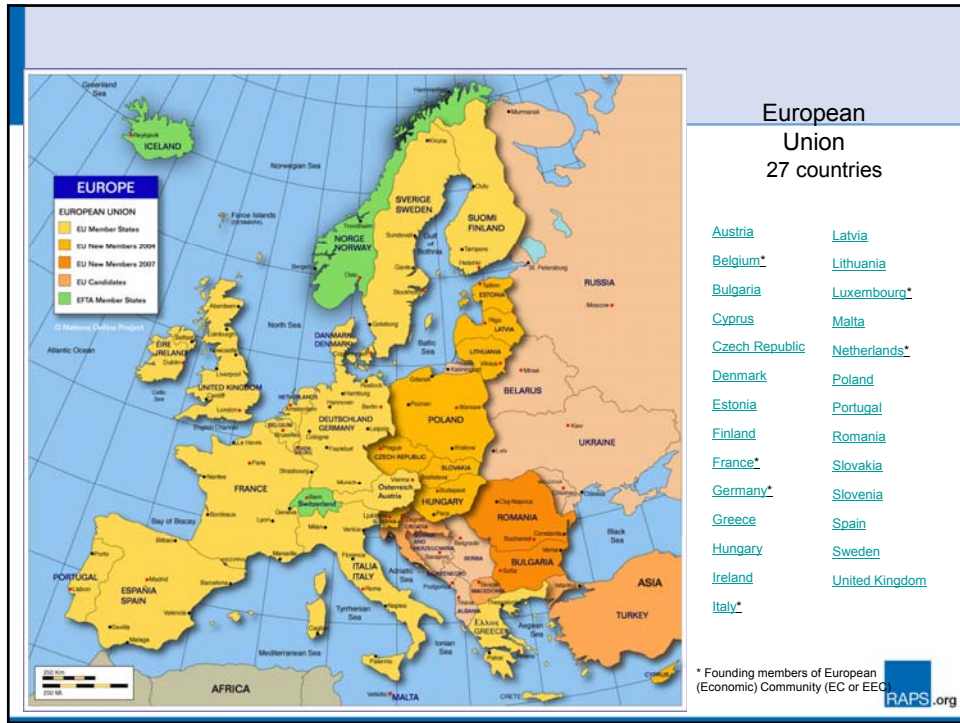


rg

Outline

- General EU Information
- Clinical Evidence
- Additional Changes
 - SAE Reporting
 - eLabeling
 - RoHS





More general EU information

Europa Gateway to the European Union

English (en)

EUROPA > About the EU > Institutions and bodies

Home

About the EU

- Basic information
- Institutions and bodies**
- Member countries
- History
- Work for the EU
- EU terminology explained

Policies and activities

Your life in the EU

Take part!

Publications and documents

Media centre

Quick links for...

Institutions and bodies of the European Union

Find out about the EU's institutions. What do they do and how do they work?

[EU institutions and other bodies explained](#)
Overview explaining the institutions' differing political and administrative functions

EU institutions' websites

- European Council**
Sets the general political direction and priorities of the European Union
- European Parliament**
Members of the European Parliament (MEPs) are directly elected by EU voters every five years
- Council of the European Union**
National ministers meet to discuss and – together with Parliament – adopt EU laws
- Presidency of the Council of the EU**
From 1 January to 30 June, the work of driving the EU agenda lies with Hungary.
- European Commission**
Appointed Commissioners and the EU's civil service. The Commission proposes EU legislation and checks it is properly applied across the EU. **Works in the interests of the EU as a whole.**
- Court of Justice of the European Union**
EU law courts
- European Court of Auditors**
Reviews the financing of the EU's activities
- European Central Bank**
Responsible for European monetary policy
- European Ombudsman

Popular links

- [How EU institutions work together – a guide](#)
- [Free, downloadable brochure on the EU institutions](#)
- [Diplomatic missions accredited to the EU](#)

Help us improve

RAPS.org

European Commission

bc.europa.eu/index_en.html

A-Z Index | Sitemap | Search | About this site | Contact | New on EUROPA | Archives | Legal notice | English (en)

European Commission

EUROPA > European Commission

Headlines

Breakthrough bands
Some of Europe's most promising bands get the recognition they deserve at the European Border Breaker Awards.

- Europe on track with satellite navigation
- Back to school
- Setting the stage for economic recovery
- Tallinn and Turku - 2011 European capitals of culture

[All news](#)

The President

José Manuel Barroso
European Parliament Plenary Session

Commissioners' corner

Michel Barnier
Copyright in the digital era

Slim Kallas
More rights for passengers travelling by bus and coach
Commission 2010-2014 >

Blogs

- Blogs of the Commissioners
- Blogs of the representations

Contact the European Commission

Policies and legislation

- Policies
- Legislation
- Public consultations
- Myths and rumours explained

Contracts and grants

- Public contracts
- Grants
- Microfinance
- Recipients of EU funds
- More about contracts and grants**

About

- The European Commission at work
- Commission President
- Commission 2010-2014
- Departments (Directorates-General) and services
- Directory
- The European Union
- More about the European Commission**

Events

- Data Protection Day
- Civil Protection Info Day 2011
- EU Aviation Safety Management towards 2020
- Conference: Future of the CIP
- ETNO Innovation Day 2011
- European Year of Volunteering
- Find an event with the EU calendar**

RAPS.org

European Legislation

- **Regulations:** similar to a national law with the difference that it is applicable in all EU countries
- **Directives:** general rules to be transferred into national law by each country as they deem appropriate
- **Decisions:** only deal with a particular issue and specifically mentioned persons or organizations

There are many Directives...

ec.europa.eu/enterprise/newapproach/handbook/index.cfm?luseaction=directive.man

European Commission
Enterprise and Industry

European Commission > Enterprise and Industry > Policies > ... > New legislative framework
> Notified bodies > Nando

Enterprise and Industry

Notified bodies

Handbook

Country
Directive
Body
Face search
Mutual Recognition
Agreements
Bodies for Approval
Accreditation Body
Glossary
Print

Directives

Found : 38

• 88/378/EEC Safety of toys	PDF
• 89/106/EEC Construction products	PDF
• 89/686/EEC Personal protective equipment	PDF
⇒ • 90/385/EEC Active implantable medical devices	PDF
• 92/42/EEC Hot-water boilers	PDF
• 93/15/EEC Explosives for civil uses	PDF
⇒ • 93/42/EEC Medical devices	PDF
• 94/9/EEC Equipment and protective systems intended for use in potentially explosive atmospheres	PDF
• 94/25/EEC Recreational craft	PDF
• 95/16/EEC Lifts	PDF
• 96/98/EEC Marine equipment	PDF
• 97/23/EEC Pressure equipment	PDF
⇒ • 98/79/EC In vitro diagnostic medical devices	PDF
• 99/5/EC Radio and telecommunications terminal equipment	PDF
• 99/36/EC Transportable pressure equipment	PDF
• 2000/9/EC Cableway installations designed to carry persons	PDF
• 2000/14/EC Noise emission in the environment by equipment for use outdoors	PDF
• 2004/22/EC Measuring Instruments Directive	PDF
• 2004/40/EC Electromagnetic compatibility	PDF

rg

There are many Notified Bodies...

Enterprise and Industry

Notified bodies

Hando

Country

Directive

Body

Free search

Mutual Recognition Agreements

Notifying Authority

Accreditation Body

Glossary

Print

Found : 64

Bodies

Search criteria :
Body type : 0101-0200

Withdrawn/Expired Notifications/NBs are not displayed in this list, you can find them in the Body module under the hyperlink "Withdrawn/Expired Notifications/NBs"

Body type	Name	Country
▶ NB 0102	PHYSIKALISCH-TECHNISCHE BUNDESANSTALT - (PTB)	Germany
▶ NB 0103	REGIERUNGSPRÄSIDIUM TÜBINGEN - ABTEILUNG 10 MESS- UND EICHWESEN	Germany
▶ NB 0104	BAYERISCHES LANDESAMT FÜR MAß UND GEWICHT	Germany
▶ NB 0106	LANDESAMT FÜR DAS MESS- UND EICHWESEN BERLIN-BRANDENBURG	Germany
▶ NB 0107	Landeseichdirektion Bremen	Germany
▶ NB 0108	EICHDIREKTION NORD	Germany
▶ NB 0109	HESSISCHE EICHDIREKTION	Germany
▶ NB 0111	MESS- UND EICHWESEN NIEDERSACHSEN	Germany
▶ NB 0112	LANDESBETRIEB MESS- UND EICHWESEN NORDRHEIN-WESTFALEN	Germany
▶ NB 0113	Landesamt für Mess- und Eichwesen Rheinland-Pfalz	Germany
▶ NB 0114	Landesamt für Umwelt- und Arbeitsschutz - FB 4.3 Gesetzliches Mess- und Eichwesen	Germany
▶ NB 0115	SÄCHSISCHES LANDESAMT FÜR MESS- UND EICHWESEN	Germany
▶ NB 0116	LANDESEICHAMT SACHSEN-ANHALT	Germany
▶ NB 0118	LANDESAMT FÜR MESS- UND EICHWESEN THÜRINGEN	Germany
▶ NB 0120	SGS United Kingdom Limited	United Kingdom
▶ NB 0121	DGUV Test Prüf- und Zertifizierungsstelle Institut für Arbeitsschutz der Deutschen Gesetzlichen Unfallversicherung (IFA)	Germany
▶ NB 0122	NMI CERTIN B.V.	Netherlands
▶ NB 0123	TÜV SÜD Product Service GmbH	Germany
▶ NB 0124	DEKRA Certification GmbH	Germany
▶ NB 0125	LGA QualiTest GMBH	Germany
▶ NB 0126	NATIONAL WEIGHTS AND MEASURES LABORATORY	United Kingdom
▶ NB 0128	DUDLEY METROPOLITAN BOROUGH COUNCIL	United Kingdom
▶ NB 0129	WEST SUSSEX TRADING STANDARDS DEPARTMENT	United Kingdom


European Medical Device Directives

- 90/385/EEC AIMD Council Directive
- 93/42/EEC MDD Council Directive
- 98/79/EC In Vitro Diagnostic Directive
- NEW:** 2007/47/EC Council Directive amending AIMD and MDD Directives - became effective March 21, 2010

21.9.2007
EN
Official Journal of the European Union
L 247/21

DIREKTIVE 2007/47/EC OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL
of 5 September 2007

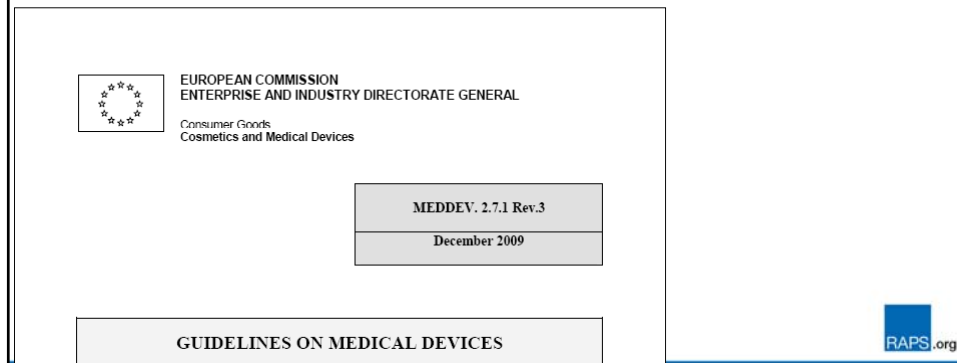
amending Council Directive 90/385/EEC on the approximation of the laws of the Member States relating to active implantable medical devices, Council Directive 93/42/EEC concerning medical devices and Directive 98/8/EC concerning the placing of biocidal products on the market



Clinical Evaluation - Guidance Documents

Guidance on Clinical Evaluation

- MEDDEV 2.7.1 Evaluation of Clinical Data
- GHTF SG5/N2R8:2007 Clinical Evaluation



Essential Requirements Annex 1

Annex 1, section 1 – General Requirements:

- MDD ER 6a
- AIMD ER 5a

“Demonstration of conformity with the essential requirements must include a clinical evaluation in accordance with Annex X (MDD) / Annex 7 (AIMD)”

Annex X / Annex 7 - Clinical Evaluation

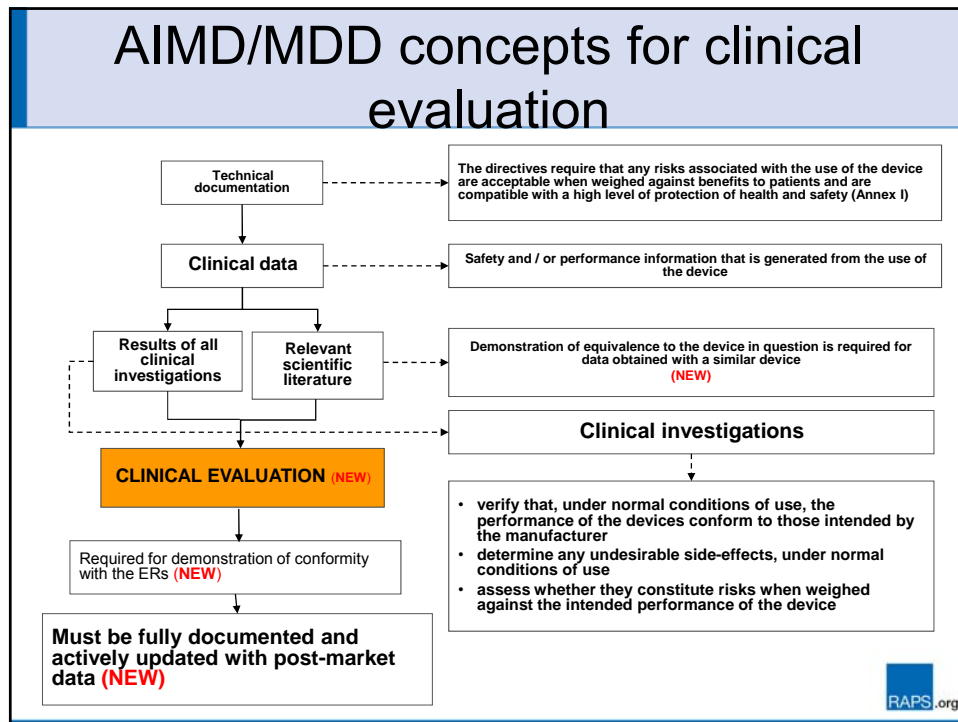
- Conformity to Essential Requirements must be based on clinical data (1.1)
 - Focus on risk management and risk/benefit ratio
- Clinical evaluation must follow a methodologically sound procedure (1.1)
 - A **critical** evaluation of scientific literature (1.1.1)
 - or
 - A **critical** evaluation of the results of a clinical Investigation (1.1.2)
 - or
 - Or a **critical** evaluation of combined literature and clinical investigation data (1.1.3)



Annex X / Annex 7 - Clinical Evaluation

- Clinical Investigations shall be performed for Class III and implantable devices, unless duly justified (1.2)
- Clinical evaluation shall be documented and included/referenced in device technical documentation (1.3)
- Clinical Evaluation must be actively updated with PMS data → justification if Post-Market Clinical Follow-up not deemed necessary (1.4)
- If clinical data not deemed necessary → justification based on risk management output (1.5)





MEDDEV 2.7.1 Rev 3: Scope

Scope of the clinical evaluation:

- comprehensive analysis of available pre-and post market clinical data relevant to the intended use of the device in question, including clinical performance data and safety data, including:
 1. data specific to the device in question
 2. any data relating to devices claimed as equivalent by the manufacturer
 3. any clinical claims made
 4. adequacy of product labeling/suitability of instructions for use

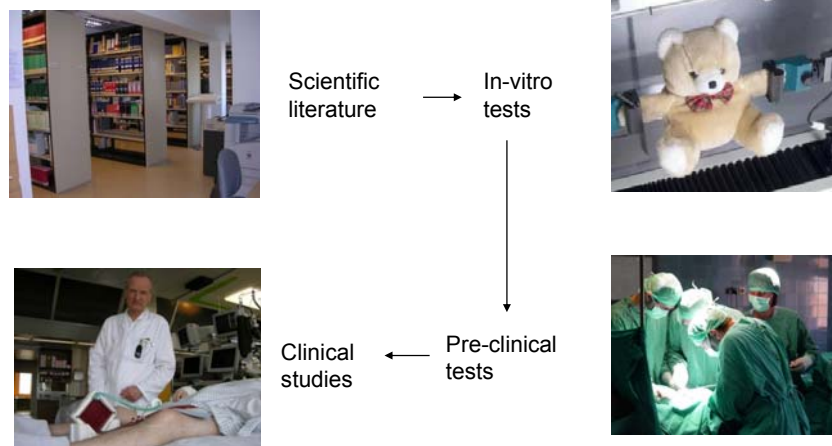
MEDDEV 2.7.1 Rev 3: Scope

Items to be evaluated from a clinical perspective:

- any design features of the device or target treatment populations that require specific attention
 - intended purpose and application of the device (e.g., target treatment group and disease, proposed warnings, contraindications and method of application)
 - specific claims about clinical performance and safety
- whether data from equivalent devices can be used
- data source(s) and type(s) of data to be used, including:
 - design, intended use, risks of the device, developmental context of the technology (i.e., novelty).
- All these aspects shall be defined prior to starting the evaluation
- „*The manufacturer will need to give consideration to the*



What is Clinical Data



Clinical Evidence

- No clinical data
 - Adequate justification, based on risk management, assessment of device-body interaction, Intended Use, claims
- Demonstration of conformity to harmonized performance standards
- Literature
- Bench-testing
- Animal studies
 - Transferability of data to the intended use in humans
- Clinical studies

Equivalence

Equivalence approach

- Evaluation of usability of data from equivalent devices:
 - same Intended Use,
 - technical and biological equivalence, and
 - no clinically significant difference regarding safety and performance
- Assessment must address:
 - Evaluation of any equivalence aspect
 - Evaluation of degree of transferability of any data
 - Availability of adequate data for the predecessor device

Equivalence aspects

Intended Use

- Clinical condition being treated
- Severity and stage of disease
- Site of application to/ in the body + patient population

Biological characteristics

- Biocompatibility of materials in contact with same body fluids/ tissues

Technical characteristics

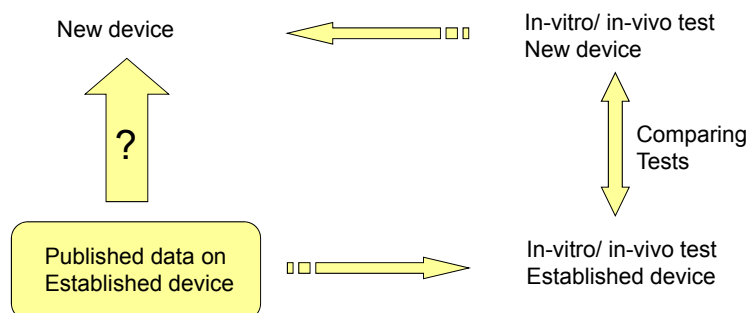
- Design
- Specifications
- Physicochemical properties
- Deployment methods
- Critical performance requirements
- Principles of operation
- Conditions of use

*e.g. PU material of Ascenda catheter ↔ SCS lead:
intrathecal ↔ epidural use*

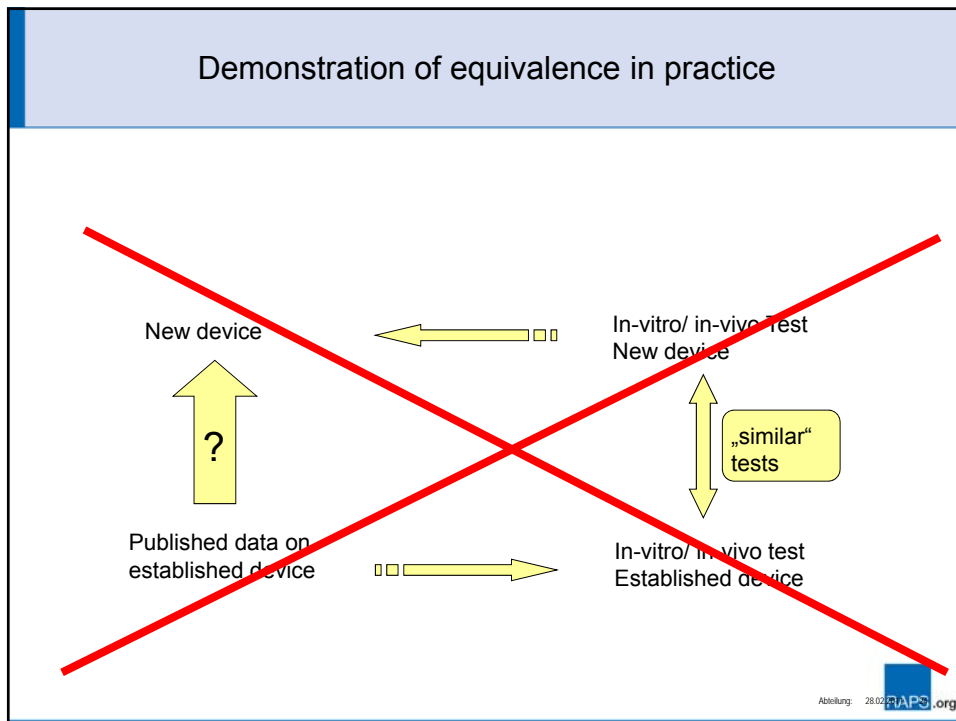
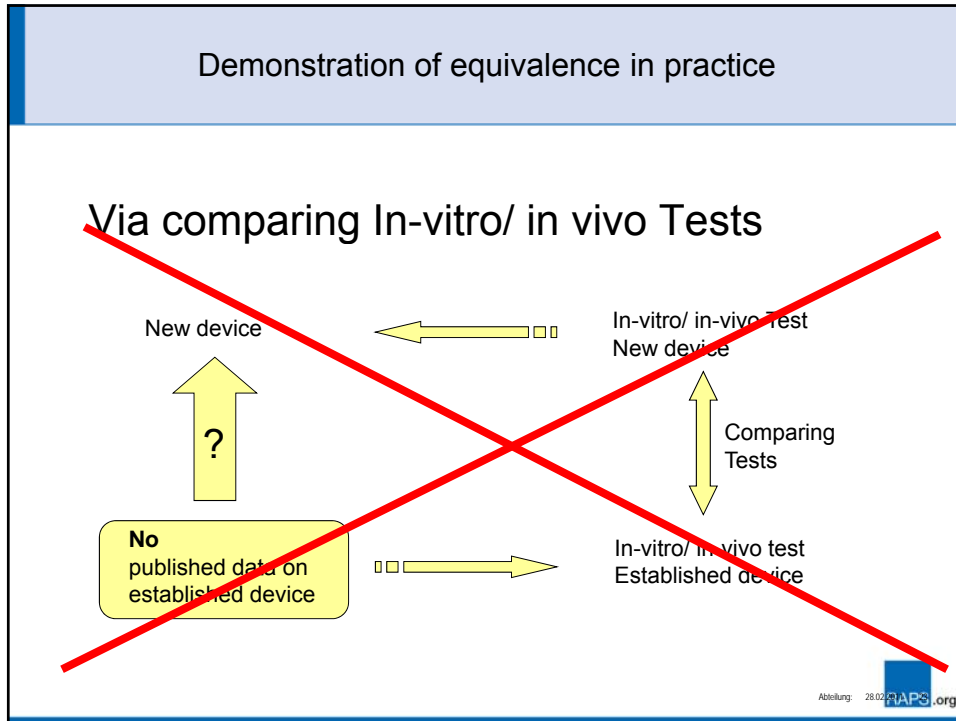
Abteilung: 28.02.2011  FIAPS.org

Demonstration of equivalence in practice

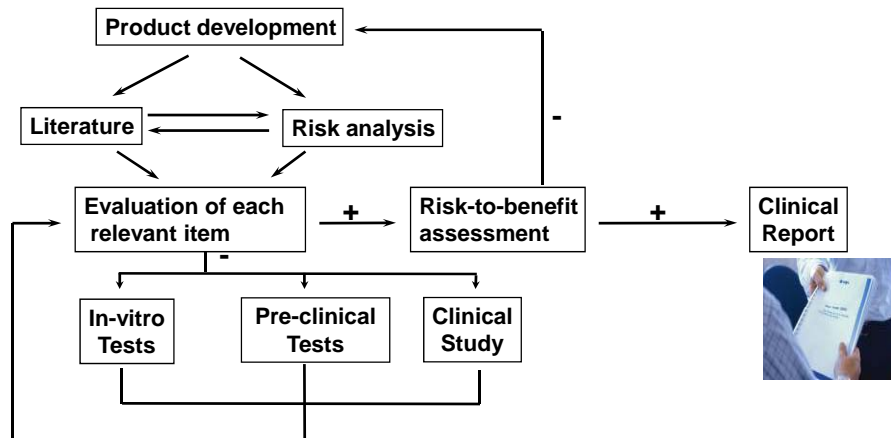
Via comparing In-vitro/ in vivo Tests



Abteilung: 28.02.2011  FIAPS.org



Compilation of clinical data



February RAPS.org

SAE Reporting in Clinical Trials

- MDD/AIMD revisions effective March 21, 2010 requires all SAEs (regardless of device and/or procedure relatedness) be reported to CAs in the countries where the study is being conducted
- Requirements defined in MEDDEV 2.7/3 “Clinical Investigations: Serious Adverse Event Reporting” December 2010
 - Includes SAEs occurring in any country worldwide where the study is conducted under the same clinical investigation plan

RAPS.org

SAE Reporting Timelines

Sponsor to CA:

≤ 2 calendar days for a SAE with imminent risk of death, serious injury, or serious illness that requires prompt remedial action.

≤ 7 calendar days for any other SAE

Investigator to Sponsor:

≤ 3 calendar days for any SAE



eLabeling

- Historical wording of directives specified provision of IFUs in “leaflet supplied”
- IVD Guidance MEDDEV 2.14.3 provides for provision of IFU for clinicians via
 - Different media: other than paper form, e.g. CD-Rom, DVD, etc.
 - Different means of supply: provision of IFU by sales force, fax, internet, etc, rather than by inclusion of paper IFU with the device itself



eLabeling

- 2007/47/EC revisions to AIMD/MDD provides the opportunity for e-labeling of medical devices
 - “In the light of technical progress in information technology and medical devices, a process should be provided to allow information supplied by the manufacturer to be available by other means.”
- Guidance currently in development



Removal of Hazardous Substances (RoHS)

- Directive Publication: exp. April 2011
- EEE Medical Devices included: 3 yrs thereafter (April 2014)
- Scope (exemptions incl. AIMD) to be reviewed in 2014
- Six substances banned
- Time-restricted exemptions for certain applications
- RoHS specific DoC required (lay-out defined in Annex VII, to based on Technical File)
- MDD CE-mark to cover RoHS compliance



RoHS Scope

In scope:

- 'Electrical and Electronic Equipment' (EEE)* means equipment which is
 - dependent on electric currents or electromagnetic fields in order to work properly and
 - equipment for the generation, transfer and measurement of such currents and fields and
 - designed for use with a voltage rating not exceeding 1000 volts for alternating current and 1500 volts for direct current

* various categories – see Annex 1 – covers basically all EEE (No. 8: medical devices)



RoHS Effectiveness Timeline

Effective:

- Placing on the market for the first time:
 - Medical devices: 3 years (April 2014)
 - Monitoring and control instruments: 3 years (April 2014)
 - IVDs: 5 years (April 2016)
- Placing on the market: April 2019



Back-up Slides



CE Mark



- Conformité Européenne
- Conformance to a European Directive
- Affixed on products
 - Conformity Assessment
 - Self assessment
 - Technical assessment by authorized third party
 - Declaration of Conformity
- Product may be brought onto EEA market



