Continuing regulatory changes and their impact

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Disclosure

Speaker name:
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I have the following potential conflicts of interest to report:

☐ Consulting
☐ Employment in industry
☐ Stockholder of a healthcare company
☐ Owner of a healthcare company
☐ Other(s)

☑ I do not have any potential conflict of interest
Status & trends

++ regulations

++ changes

++ pre-clinical data required

++ clinical data required
Status & trends

regulations
Status & trends

Guidance document Medical Devices

**MEDDEV 2.7/3 rev. 3** (166 kB) Clinical investigations: serious adverse reporting under directives 90/385/EEC and 93/42/EC - SAE reporting form (87 kB)  
**May 2015**

The new SAE reporting form will be taken in use 1 September 2016 at the latest.

**MEDDEV 2.7/2 rev. 2** (37 kB) Guidelines for Competent Authorities for making a validation/assessment of a clinical investigation application under directives 90/385/EEC and 93/42/EC  
**September 2015**

**MEDDEV 2.1/6** (325 kB) Qualification and Classification of stand alone software  
**July 2016**

**MEDDEV 2.7/1 rev. 4** (631 kB) Clinical evaluation: Guide for manufacturers and notified bodies  
**June 2016**

Past 2 years only; full overview available on http://ec.europa.eu/growth/sectors/medical-devices/guidance_en
Status & trends

ICH E6(R2) – November 2016

EU: Adopted by CHMP, 15 December 2016, issued as EMA/CHMP/ICH/135/1995

CH: Human Research Act requires amendment (Q2 2017), however Swissmedic will use it as a reference with immediate effect (20 December 2016)
Status & trends

ISO 14155:2011

June 2016: preparation phase of the revision started. Updated version expected 2018
Medical Device Regulation (MDR)

- Revision of the medical device and in vitro diagnostic medical device directives
- Main objectives:
  - To consistently ensure a high level of health and safety protection
  - To address the technological and scientific progress of the past 20 years
  - To support the free and fair trade in the EU
More EU coordination relative to vigilance and market surveillance

Stricter control of high risk devices

EU database to improve transparency

Reinforcement of NB oversight

Inclusion of non-medical (e.g., esthetics)

Real-life data collection requirement

New classification for IVD

EU authorization of clinical trial

MDR
MDR status

- 2012: adoption of the Commission proposals on medical devices and IVDs
- 2014: European Parliament adopts its first reading
- 2015: Council agrees on a "general approach"
- 15 June 2016: Council and Parliament reach political agreement on the two Regulations, endorsed by Health Ministers on 17 June 2016

Source: Erik Hansson, Deputy Head of Unit European Commission, DG Internal Market, Industry, Entrepreneurship and SMEs
MDR status

Publication expected Q2 2017; entry into force on the 20th day after its publication in the Official Journal

Date of application: from 3 (MD) / 5 (IVD) years after entry into force.

**NOTE 1:** Regulatory bodies (CA & NB) strongly advice to take immediate action to ensure data is available when needed

**NOTE 2:** Notified Bodies: From 87 to 57 now, but only 15% will be allowed to provide certification for the high risk devices
Consequences

Knowledge & expertise

✓ All claims must be proven!
✓ Clinical research regulation
✓ Contracting requirements
✓ Other approvals applicable? Eg radiation
✓ Data protection, eg US database for EU study (privacy shield)
✓ Safety reporting requirements
Consequences

Procedures

✓ Standard Operating Procedures are required for ALL activities relative to devices intended for human use
✓ Outsourcing can be performed under own SOPs or of the contracted vendor but must be defined
Conclusion

✓ More detailed, more defined regulations
✓ Requiring more defined procedures
✓ More proof needed, can’t claim that something is new AND the same as other products
✓ More experts needed
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