Session VII:
Regulatory Change in Europe: *Live or Memorex?*

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Presentation Overview

- Draft regulations, general
  - Reasons for change
  - Process of change
- Highlights of draft regulations
- Next steps

Reason for changes

- PIP Scandal forced Commissioner Dalli to make a list of improvements for CA's, NB's and manufacturers
  - Designation, scopes and assessment of NB's
    - Joint Audits of NB's by CA's
  - Unannounced Audits/Inspections
    - Sample Checks
  - Code of Conduct (Team NB)
    - NB's: qualification personnel, policy on objectivity etc
  - Revised regulations

To restore patients, health care professionals and political confidence in the CE marking system

Process of changes

- Designation, scopes and assessment of NB's
  - In 2013, the first joint audits started. In 2014, a third of NB's will have a joint audit
- Unannounced Audits/Inspections
  - In 2014, all NB's have started their program on unannounced audits
- Code of Conduct
  - Approx 30 NB's have signed….
- Revised regulations
  - Combined MDD and AIMD, separately revised IVD
  - No directive, but regulation: no acceptance needed by Member States
  - Anticipated to be reviewed by new Parliament…2015…with 3 year transition

Highlights of new regulations

- Possible involvement of 4th party for high risk (e.g. combination devices)
- Harmonize quality of NB's by joint audits
- Include Meddev guidances in regulation
- UDI for traceability
- Publicly accessible info on Post market information, suppliers
- Introduction of Medical Device Coordination Group (MDCG)
  - Reviewing preliminary NB assessment
- Qualification requirements for NB auditors and reviewers
- Special rules for devices incorporating nanomaterials
- Pre-Market Approval system ?
- Classification changes for lots of medical devices
- Validity of certificates only 2 years?

Will it Deliver?

- Fewer qualified auditors/reviewers
- Fewer Notified Bodies
- Longer process to CE mark
- Increased cost
- Additional audits
- Innovation??

Unannounced audits

- Inspections, at least 1 day, 2 auditors
- Per Regulation 2013/473/EU (September 2013)
- Device specific, NOT QMS
- Focus on match between Information in technical file (approved by NB), BoM as used in manufacturing of the device, and raw material information
- Vendors may also be audited
- Minimal once per 3 years, up to yearly (high risk, suspicion, noncompliance)
- Report (with findings) at end of audit
- NC's to be addressed as usual
- Product samples may be taken for testing by NB

Review of Vigilance by NB

- Manufacturer to provide all Vigilance reports to NB for review
- Verify whether device is still safe
- If questions, certificate may be suspended, awaiting required corrective actions

Review of technical Documentation

- NB's used to sample technical files within a family of products (e.g. balloon catheters)
- NB is now required to review ALL technical files
- NB's will try to finalize this backlog in next 3 years

Are you still with us?

- Global Health Care is asking to reduce cost
- New regulations will result in:
  - More audits
  - Higher cost for File reviews, more file reviews
  - Shorter certificate validity
  - Longer time to market

All resulting in higher cost…

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Any Questions???

Thank You