Changing Roles of NB, Designation of NB, Impact of a reduced number of NB

TÜV Süd Product Service
Munich
Hans-Heiner Junker
International Affairs
Our Role

- After all discussions, meetings, controversial disputes: Europe will not introduce a EFDA
- Audit and certifying a quality management system and assessment of the medical device will still be in the hands of one body: the Notified Body
- However, for high-risk devices additional impact will be made by European expert panels and/or expert laboratories
Our roles

Audit & certify QMS according to regulations

Assessment of medical devices (testing, TD reviews)

Notified Body

Unannounced Audits w/o cause

Increased responsibilities in the market surveillance
More Information from PMS

Periodic Safety Update Report

Summary of Safety & Clinical Performance Report

Market Surveillance

Unannounced Audits for cause

Reports about serious incidents
Additional Roles and Tasks

- Certification process of certain medical devices will need involvement of further authorities, like expert panel or reference labs
- More special procedures, like consultation on clinical evaluation
- Scrutiny Procedure
Designation Process; Principles

- Remember: one goal of the new MDR is to improve designation process and surveillance of Notified Bodies
- Joint Assessment Team will include special trained auditors
- Commission together with MDCG will appoint an audit team
- Team consists of:
  - At least three experts
    - One from the commission (coordinator)
    - One from two member states, different from the one responsible for the Notified Body
  - Audit team of the member state responsible for the Notified Body
  - Translators
  - Circumstances may require more
- For many steps of this process minimum working days are defined – all together more than 300 days, plus time needed for defining and accepting CAPA
- Designation process will use the NANDO database
General Designation Process

Application to national authority from November 26, 2017

In the course of this process, national authorities, the Commission, and the MDCG have to coordinate their activities

Before designation is possible all member states have the right to raise objections

Designation becomes valid one day after publication in NANDO

Notified Bodies may perform activities of a notified body only after the designation has become valid.
Impact ! What Impact ?

- Nobody knows:
  - how many organizations will apply
  - who will apply at what time
- Some countries have only one applicant, others more
- Authorities explain duration:
  - average time between application and designation is 18 months
- But what will happen if some 50 organizations apply on one day in November 2017?
- Not all applicants will receive designation before the date of application of the MDR in May 2020, very unlikely
  - Most applicants will receive designation in 2019 or later
- Question: what tasks may an organization perform before official designation to shorten time after designation for the certification process?
  - How to be prepared for an audit by the „new“ Notified Body?
- Expect extremely busy Notified Bodies in the last 12 months of the transition time until May 2020
What to do?

Close communication with Notified Body of choice

Prepare a transition plan, determine priorities

Analyze quality of your clinical data, now. Especially for implantable devices.

Strengthen your clinical procedures and competence

Be prepared to apply renewal of MDD/AIMD certificates in order to make use of the extended transition time until May 2024
Thank you

Contact us:
www.tuv-sud.com
info@tuv-sud.com

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