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SPECTARIS position

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SPECTARIS is the German industry association for the high-tech medium-sized business sector and representative body in the areas of medical technology, consumer optics, analytical, bio and laboratory technology as well as photonics. These industry sectors generated sales of over € 73 billion in 2018. Innovation and growth characterizes them and their 320,000 strong workforce. Technologies developed here are used in almost all branches of industry, making them an important motor for the German economy.

Recommendations for the Harmonization of Medical Device Regulations between the US and the EU

In order to achieve the regulatory convergence between the US and EU medical device regulation systems, it is crucial to define common standards for regulatory use. The biggest challenge for a medical device manufacturer is the maintenance of different regulatory approvals during product life cycle. Fulfilling different requirements restrains the market entry of innovative devices and thus endangers patient care.

Therefore, the German industry association SPECTARIS welcomes the harmonization efforts initiated by the German Government and its US partners with regard to the regulation of medical devices. We strongly support the intention to include the EU into the Medical Device Single Audit Program (MDSAP) of the International Medical Device Regulators Forum (IMDRF). These are important steps defining joint and high-quality procedures for the approval of medical devices between the US and the EU.

In the context of ongoing consultations in the harmonization process SPECTARIS makes the following recommendations:

First actions to be implemented

- Fast acceptance of the international standard ISO 13485:2016 by the FDA:
  An essential trade barrier is the current non-acceptance of the international quality management standard ISO 13485. Until now, European manufacturers have to additionally install a system according to 21 CFR 820. With the new version of ISO 13485 in 2016, both systems have converged. Unfortunately, the FDA does not yet recognize ISO 13485.
- Harmonization of UDI and databases: The FDA has established and continues to implement a unique device identification system to adequately identify medical devices through their distribution and use. In Europe, new UDI and database requirements in the Medical Device

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Regulation differ from the FDA system (e.g. product labelling with two – human and machine readable – codes). Double labelling does not increase patient safety and increases bureaucratic expenses significantly. Therefore, the systems should be harmonized.

Priorities in the harmonization process

- Full acceptance of MDSAP: Full acceptance of MDSAP provides multiple benefits. It will accelerate market access by decreasing expenses in terms of costs, time and manpower. Due to increased and improved exchange between the participating authorities and administrative bodies, audits will become more harmonized, faster, and product safety will be increased.
- Clinical data: To eliminate duplication of regulatory activities, data already generated in clinical research should be used and recognized based on standardized conduct and reporting of clinical studies. In addition, harmonized reporting criteria for incidents can simplify processes and increase patient safety.
- Product Submissions: To eliminate duplication of regulatory activities, the structure of required submissions should be aligned, eg. following the IMDRF table of content. This will remove redundancies and decreases the effort for maintaining the different files. A common structure of regulatory submissions still supports national approvals before market entry but at the same time allows improved exchange between the participating national authorities.
- Upcoming technologies: Agreements on common standards for e.g. artificial intelligence, physiological closed loops and usage of big data.

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