Setting standards: European and international standardization landscape in the field of medical devices utilizing tissues

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Abstract

Standards generate economic benefits which have been estimated at 16 billion euros a year for Germany alone. They facilitate trade, spread knowledge, disseminate innovative advances in technology, and share good management and conformity assessment practices. The poster provides an overview on the portfolio of European and International Standards available from the work of Technical Committee CEN/TC 316 „Medical devices utilizing tissues“ of the European Standardization Organization (CEN) and its sister Technical Committees, ISO/TC 194/SC 1 „Biological evaluation of medical devices“, „Tissue product safety“ and ISO/TC 150/SC 7 „Surgical implants“, „Tissue engineered medical products“ of the International Organization for Standardization (ISO). Standardization provides excellent opportunities for shaping the business environment of current and future markets for tissue engineered medical devices and advanced therapy medicinal products both on the European scale and worldwide. Current projects and potential areas of future activities of the relevant CEN and ISO Technical Committees will be outlined and information given on how to get involved, be it by joining in current activities or by submitting proposals for new projects. The standardization toolkit comprises a variety of publication types. The range of publication types available within the European and International Standardization systems with their particularities will be described and an introduction to the mechanisms of consensus-based standardization given. Standardization is a strategic instrument for economic success. Learn more about how standards are made and how to get involved in CEN/TC 316 and/or its international counterparts to gain a competitive lead through timely access to information and knowledge. Join in to prepare the grounds which form an integral part of the business environment for the market success of your innovative products for application in regenerative medicine. For interested parties based in Germany, the German Standards Institute DIN Deutsches Institut für Normung e. V. can offer financial support for participation in standardization activities, within the framework of a BMBF funded project.