Device or Not Device: challenges in the development of products containing mechanically and pharmacologically active components

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Recent years witnessed a remarkable increase in the development and clinical use of Medical Devices (MDs). To date about 500,000 different types of MDs are commercialised in the EFTA area, with a global turn-over of about € 100 billion. More and more frequently, manufacturers develop sophisticated products that act through mechanically and pharmacologically active components. For such products the border between MDs and Medicinal Products (MPs) is often difficult to define. At the same time, the classification, and the decision about the development strategy is crucial. Matter of fact the Pre-Clinical and Clinical Development Plan, the size and number of studies, the reference guidelines and even the Competent Authorities (CAs) are different for MDs and MPs. This is especially important for independent developers who are willing to define a correct development strategy in order to transfer the product to a bigger industrial partner later in the development process. The Authors will present case studies of development of such products, with an overview of the differences in terms of development time and methodology. Special attention will be devoted to: a) the methodology for clinical evaluation (ISO 14155) b) the classification of the products according to the relevant European Guidelines (e.g. EC Directive 93/42 and Med. Dev 2.4/1); b) the interaction with the relevant CAs.

Ref.
1.Dir 93/42 CE
2.Dir 90/385 CEE
3.ISO 14155
4.Med. Dev 2.4/1