Critical issues of the regulatory pathway for nanostructured medical devices

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The increasing diffusion of nanomaterials (NM) is being observed also in the domain of medical devices (MD). Hence, nanostructured MDs are becoming common, even though the associated risks must be carefully considered in order to demonstrate safety. The biological effect of NMs require the consideration of methodological issues, since already established methods for, e.g., cytotoxicity can be subject to loss of accuracy in presence of certain NMs.

The need for oversight of MD containing NM is reflected by the Regulation 2017/745 on MD, which states that MD incorporating or consisting of NM are in class III, at highest risk, unless the NM is encapsulated or bound in such a manner that the potential for its internal exposure is low or negligible (Rule 19). Our experience with electrical cell-sensing impedance spectroscopy (ECIS) showed the usefulness of complementing traditional assays (MTT, Neutral Red) with an innovative, real-time cell viability measurement technique. The results were very sensitive to NM concentration, showing the necessity of defining a clear threshold for each NM and each contact type.