

**Translational requirements for nanotechnology enable medical products: a converging model
applied to the SPION case**

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Pre-clinical assessment of nanomaterial is a key process for nanotechnology enabled medical products. To maximise effort and costs, a successful multiparametric pre-clinical assessment cascade is needed. Consideration for similarities between the pre-clinical and clinical screening are drawn up assessing industrially relevant aspects such as safe- and quality- by-design across the critical steps that lead to product market approval. Starting from the physical and chemical characterisation, to the specific theranostics properties, SuperParamagnetic Iron Oxide Nano Particles (SPIONS) are presented as one of the most promising theranostic nanomaterial for clinical application. Thus, the use of screening platforms, based on cell-nanoparticle mechanism of biological interaction, are introduced for cost-effective go/no go assessment; these comprising sterility, endotoxicity, cytotoxicity, and immunotoxicity. In vivo testing strategies, for specific theranostic applications, are fundamental during the translational process. Finally, consideration on past and present clinically translated products highlights the importance in developing multiparametric pre-clinical experimental testing strategies focused on achieving sound and robust dataset for clinical translation.