

PL 8: How to deal with complexity of nanomedicines in practice (DDRS 2021 Conference Budapest– Plenary Presentations)

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No Abstract available; description:

Headings: Introduction; Nanomedicine opportunities and characteristics; Nanosimilars: regulatory consequences for substitution and interchange; Conclusion. Ref. (11)
Nanomedicine is a promising innovation path for drug research and development with increasing reality over the last decades; a high number of nanomedicines is in clinical evaluation. Copies of the first generation innovator nano products, called nanosimilars in the EU, aim for market access to substitute or being interchanged with reference nanopharmaceuticals. Biological and nonbiological complex drugs (NBCDs) belong to these nano drug products. They are highly complex regarding the non-homogenous composition, and structure. Critical Quality Attributes (CQA) define the profile in vitro and in vivo, ultimately dependent on specific not fully understood structure-function correlations originating from a critical drug manufacturing process (fig. 1). In contrast to biologicals, the regulatory evaluation and approval of the synthetic NBCDs is highly jeopardized by the not defined equivalence assessment for their copies and a globally not harmonized approach. Selection and use of such nanosimilars in practice has revealed unexpected equivalence problems asking for guidance, knowledge-based standards, and practice to guarantee safe, reliable, and consistent nanopharmaceuticals and similars based on a sufficient regulatory similarity/comparability exercise to allow only switching or interchange for therapeutically equivalent products (2-5).

Keywords: Nanomedicine and nanopharmaceuticals, NBCDs, regulatory challenges, educational need

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