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What are the regulatory aspects surrounding nanopharmaceuticals development?

Ruba Ismail[1,2], Ildikó Csóka[1,2]

[1]Institute of Pharmaceutical Technology and Regulatory, Faculty of Pharmacy, University of Szeged, Szeged, Hungary
[2]Department of Applied and Environmental Chemistry, Institute of Chemistry, Faculty of Science and Informatics, University of Szeged, Szeged, Hungary

Tremendous effort has been devoted over the last two decades for developing nanomedicine-based products particularly in the field of drug delivery systems. Nanopharmaceuticals, due to their special their physiochemical characteristics and behaviour, have proved to hold fantastic potential for addressing the questions of unmet clinical needs. But still and all, nanopharmaceuticals R&D needs a complex and comprehensive global critical thinking not to mention that there are still many challenges in their regulations. Hence, this presentation aims at providing an overview on the regulatory needs and risks of nanopharmaceuticals with a focus on the Food and Drug Administration (FDA) and European Medicine Agency (EMA) regulations. Towards boosting the translation of nanopharmaceuticals to clinical applications, Quality by Design (QbD), as a risk-based methodology, is greatly recommended to be followed. In addition to considering the risk assessment focused design, the whole research needs to be performed with great attention to its complexity and multidisciplinary character.

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