

# Regulatory challenges and approaches to characterize nanomedicines and their follow-on similars.

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## **Abstract**

Nanomedicines are highly complex products and are the result of difficult to control manufacturing processes. Nonbiological complex drugs and their biological counterparts can comprise nanoparticles and therefore show nanomedicine characteristics. They consist of not fully known nonhomomolecular structures, and can therefore not be characterized by physicochemical means only. Also, intended copies of nanomedicines (follow-on similars) may have clinically meaningful differences, creating the regulatory challenge of how to grant a high degree of assurance for patients' benefit and safety. As an example, the current regulatory approach for marketing authorization of intended copies of nonbiological complex drugs appears inappropriate; also, a valid strategy incorporating the complexity of such systems is undefined. To demonstrate sufficient similarity and comparability, a stepwise quality, nonclinical and clinical approach is necessary to obtain market authorization for follow-on products as therapeutic alternatives, substitution and/or interchangeable products. To fill the regulatory gap, harmonized and science-based standards are needed.

## **KEYWORDS:**

glatiramoids; liposomes; nanocolloidal iron carbohydrates; nanomedicines; nanosimilars; nonbiological complex drugs; stepwise regulatory approach for follow-on versions

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