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Facilitating the translation of nanomedicines to a clinical product: challenges and opportunities

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Highlights:

- Clinical translation and commercialization challenges of nanomedicine products
- Manufacturing or scale-up, characterization, safety, stability and efficacy hurdles
- Impediment of inadequate regulation and socioeconomic acceptance of nanomedicines
- Microfluidics QbD and PAT technologies to accelerate the nanomedicines discovery

Teaser: Understanding of fundamental, characterization, clinical and regulatory aspects of nanomedicines is vital to enhance their translational potential. Hence, challenges and opportunities related to the commercialization of nanomedicines are discussed.

There are numerous hurdles hindering the clinical translation of nanomedicines. The major challenges are: reproducible manufacturing and scale-up, availability of appropriate characterization methods, instability under *in vivo* environments, safety issues, poor understanding of the disease heterogeneity and patient preselection strategies, regulatory barriers and inadequate understanding of the biophysical and chemical interactions of nanoformulations. Technologies such as quality-by-design, process analytical techniques and microfluidics could significantly accelerate the translation of nanomedicines. However, these approaches require further learning and an adequate regulatory background. Overall, to achieve an efficient clinical translation, collaboration among academia, industry and regulatory bodies