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Building the design, translation and development principles of polymeric nanomedicines using the case of clinically advanced poly(lactide(glycolide))–poly(ethylene glycol) nanotechnology as a model: An industrial viewpoint☆

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ABSTRACT

The design of the first polymeric nanoparticles could be traced back to the 1970s, and has thereafter received considerable attention, as evidenced by the significant increase of the number of articles and patents in this area. This review article is an attempt to take advantage of the existing literature on the clinically tested and commercialized biodegradable PLA(G)A-PEG nanotechnology as a model to propose quality building and outline translation and development principles for polymeric nano-medicines. We built such an approach from various building blocks including material design, nano-assembly – i.e. physicochemistry of drug/nano-object association in the pharmaceutical process, and release in relevant biological environment – characterization and identification of the quality attributes related to the biopharmaceutical properties.

More specifically, as envisaged in a translational approach, the reported data on PLA(G)A-PEG nanotechnology have been structured into packages to evidence the links between the structure, physicochemical properties, and the *in vitro* and *in vivo* performances of the nanoparticles. The integration of these bodies of knowledge to build the CMC (Chemistry Manufacturing and Controls) quality management strategy and finally support the translation to proof of concept in human, and anticipation of the industrialization takes into account the specific requirements and biopharmaceutical features attached to the administration route. From this approach, some gaps are identified for the industrial development of such nanotechnology-based products, and the expected improvements are discussed. The viewpoint provided in this article is expected to shed light on design, translation and pharmaceutical development to realize their full potential for future clinical applications.

Contents

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