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ATMPs, GMP and Risk Management

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Abstract

In the development and manufacture of cell-based medicinal products,the promise of extensive pre- clinical research is being translated into encouraging clinical responses.However,some of the most impressive clinical responses have also been complicated by significant adverse reactions. The need for a highly controlled and costly environment as given by the standards of good manufacturing practice (GMP) aims to allow for a trace ability and reproducibility in an attempt to control for risks that are hitherto only partially understood. In this highly dynamic field, academic institutions fill an ill-defined gap where commercialisation is improbable, such as rare diseases or highly patient-specific therapies. Especially here, standards of GMP pose various challenges that are often critizised to impede scientific and therapeutic progress; also, the obvious differences in risk perception and management lead to difficulties in translational research that will always coincide with increasing regulatory demands. In this complex field of cell-based therapies defined by innovation, regulation and risk control, this presentation will draft an appropriate balance,that will control and endorse therapeutic innovation, with a focus on academia as the major source of ATMP development. Further, an emerging Network of Academic GMP facilities will be presented that, by sharing competences, by collaborating, and by interaction with patients, regulatory bodies and the industry, will establish new trajectories for ATMP development and contribute to faster access to therapeutic innovation in rare and complex diseases.