



TITOLO  
(maiuscolo)

**Addressing sustainability of ATMPs by innovative platform approaches**

Autore (i)

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Ente  
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Riassunto

*Advanced Therapy Medicinal Products (ATMPs) define a broad category of complex and innovative therapies which encompasses tissue, cell-based products, and gene therapy. These revolutionary medicines offer groundbreaking new opportunities, addressing unmet medical needs for rare and complex diseases.*

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*However, numerous challenges persist. Among these, high costs and resource demand pose significant hurdles especially during the transition from bench to bedside, when the requirement for GMP compliance enters the game. In this context, fostering a shift toward a comprehensive platform approach, that encompasses both analytical and manufacturing endeavors, emerges as an essential strategy to enhance the sustainability and affordability of ATMPs.*

*A platform consists in a analytical or manufacturing solution applicable to multi-products without significant change to its operational conditions, allowing it to be applied to different products that share a pre-defined degree of similarity.*

*Here we will present our platform approaches and related advantages: by consolidating set up and qualification efforts into analytical and manufacturing platforms applicable across multiple drug categories, significant reductions in overall resource needs are possible. Advantages include reduced overall costs and shortened timelines, while ensuring the availability of validated analytical methods and robust manufacturing processes from the earliest stages of development. This help overcoming constraints related to resource allocation and production scale that often hinder such level of robustness.*

**IMPORTANTE: inviare il testo in formato (word o pdf) editabile e NON in formato immagine.**

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