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EXTRACTABLES & LEACHABLES CONSIDERATIONS FOR ATMPS: CHALLENGES AND POSSIBLE STRATEGIES

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Riassunto

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ATMPs (Advanced Therapy Medicinal Products) is a broad and innovative category of biological products that encompasses GPTs (Gene Therapy Products), SCTPs (Somatic Cell Therapy Products) and TEPs (Tissue-engineered products).
These therapies are notably complex and often customized to address the specific needs of individual patients or targeted patient niches which implies that developers and manufacturers have to deal with unique risks and challenges.
The use of single-use systems (SUS) offers several benefits to overcome challenges in ATMPs production in terms of flexibility, modularity, costs and contamination control but, on the other hand, the impact on product quality, safety and efficacy should be carefully assessed.
Recent studies have reported that substances that leach from SUS may have a negative impact on cells. Thus, considering that cells are usually employed to manufacture ATMPs or even they are part of the final product, alteration in cell physiology and functionality raises patient safety concerns as well as drug substance (DS)/drug product (DP) quality concerns.
Thus, Extractables&Leachables (E&L) studies are required before submitting Biologics License Application (BLA)/marketing authorisation applications (MAA) but their role in early stages may be crucial for selecting the appropriate materials and preventing changes that may occur in the late stages of clinical development.
In this poster, the contrasts between traditional E&L and unique requirements of ATMPs are presented and discussed.

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

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