



## PEER-REVIEW REPORT

**Name of journal:** *World Journal of Stem Cells*

**Manuscript NO:** 102788

**Title:** Enhancing the clinical translation of stem cell models by focusing on standardization and international regulatory cooperation

**Provenance and peer review:** Unsolicited manuscript; Externally peer reviewed

**Peer-review model:** Single blind

**Reviewer's code:** 08403476

**Position:** Peer Reviewer

**Academic degree and professional title:** Associate Professor, PhD

**Reviewer's Country/Territory:** China

**Author's Country/Territory:** China

**Manuscript submission date:** 2024-10-28

**Reviewer chosen by:** Hong-Xin Jiang

**Reviewer accepted review:** 2024-11-22 06:48

**Reviewer performed review:** 2024-12-03 02:32

**Review time:** 10 Days and 19 Hours

Scientific quality	Grade B (Very good)
Novelty of this manuscript	Grade B (Very Good)
Creativity or innovation of this manuscript	Grade B (Very Good)
Scientific significance of the conclusion in this manuscript	Grade B (Very Good)
Language quality	Grade B (Very good)
Does this manuscript describe a study of	Yes



the existing knowledge system?	
Does this manuscript report a revolutionary innovation?	No
Does this manuscript report an unconventional innovation?	Yes
Conclusion	Accept
Re-review	No
Peer-reviewer statements	Peer-Review: Anonymous
	Conflicts-of-Interest: No

### SPECIFIC COMMENTS TO AUTHORS

In the letter, the authors reviewed an article by Granjeiro et al., recently published in the World Journal of Stem Cells, titled “Bioengineering breakthroughs: The impact of stem cell models on advanced therapy medicinal product development”. The article explored the critical role that stem cell models play in advanced therapeutic pharmaceutical products (ATMPs), and focused on the need for international regulatory harmonization and the urgent need for standardized protocols in stem cell therapy development. Based on the above, the authors further emphasized the need for standardized stem cell culture and differentiation protocols to enhance the global clinical transformation, safety and consistency of stem cell therapies, focus on these issues makes it a timely and valuable contribution to the ongoing discourse on improving the translational pipeline for stem cell-based treatments, and I think this letter is suitable for publication in the World Journal of Stem Cells. Below are my comments to further improve the article: 1. The authors acknowledge the novelty of the article's focus on the need for international regulatory coordination and the urgent need for standardized protocols in stem cell therapy development. In this regard, the author should put forward his own opinion based on his own professional knowledge, rather than just pointing out its importance in



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general. 2. As far as I know, there have been some achievements and attempts on the standardization of stem cell culture and differentiation protocols, I suggest the authors take these into account for objective discussion. 3. The format of the manuscript should be modified according to the requirements of the journal, such as citation format, reference format, etc. Overall, this letter is well-suited for publication in the World Journal of Stem Cells due to its thoughtful engagement with the critical topics raised in Granjeiro et al.'s article. By incorporating specific professional insights and actionable recommendations, the authors can significantly strengthen their contribution and provide a roadmap for addressing the challenges associated with the development and clinical application of stem cell therapies.



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**Reviewer's code:** 03373482

**Position:** Peer Reviewer

**Academic degree and professional title:** Assistant Professor, MD, PhD

**Reviewer's Country/Territory:** Brazil

**Author's Country/Territory:** China

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**Reviewer chosen by:** Jia-Lin Zhang

**Reviewer accepted review:** 2025-01-25 14:47

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**Review time:** 1 Hour

Scientific quality	Grade A (Excellent)
Novelty of this manuscript	Grade A (Excellent)
Creativity or innovation of this manuscript	Grade B (Very Good)
Scientific significance of the conclusion in this manuscript	Grade B (Very Good)
Language quality	Grade A (Excellent)
Does this manuscript describe a study of	No



the existing knowledge system?	
Does this manuscript report a revolutionary innovation?	No
Does this manuscript report an unconventional innovation?	No
Conclusion	Accept
Re-review	Yes
Peer-reviewer statements	Peer-Review: Anonymous
	Conflicts-of-Interest: No

#### SPECIFIC COMMENTS TO AUTHORS

This paper is a letter to the Editor based on a previously published work. The letter is well written in English and regards the findings of the reference study published by Granjeiro et al. in the World Journal of Stem Cells in 2024, which discussed the role of stem cells in advanced therapy medicinal products (ATMP) for tissue regeneration and drug screening. The authors of the letter focused on what they called two critical aspects that extended beyond the original review: the necessity of international regulatory harmonization and the urgent need for standardized protocols in the development of stem cell-based therapies. The authors reinforced the need to standardize advanced therapy protocols and went further, suggesting this should be done not only by national regulatory agencies but also through international cooperation among international research institutions and regulatory bodies. In summary, the authors concluded that while the original paper by Granjeiro et al. has contributed significantly to understanding the role of stem cell models in ATMP development, they believe that prioritizing international regulatory harmonization and protocol standardization is crucial for realizing the full potential of these therapies. This conclusion is also true, as there are plenty of papers published regarding advanced medicinal therapy products



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without harmonized protocols, which leads to conflicting results, sometimes with bad results, and turning difficult its use by patients in many countries. In fact, all these actions taken together could not only improve the quality of research performed in this field but also to enhance the efficacy and safety of those procedures. That is why I believe this letter is suitable for publication in the World Journal of Stem Cells. Besides, more studies should be stimulated in order to reinforce this information as well as the publication of papers regarding the regulatory aspects of advanced therapy products worldwide.