INTERNATIONAL JOURNAL OF PHARMACEUTICAL SCIENCES
[ISSN: 0975-4725; CODEN(USA): IJPS00]
Journal Homepage: https://www.ijpsjournal.com

Review Article

Erythrocyte-Based Nanotherapeutics: Engineering Strategies, Clinical Translation, and Regulatory Landscape

Waquar Ahsan*[1], Pankaj Musyuni[2], Bharti Mangla[3], Shamama Javed[4], Pankaj Kumar[5]

[1] *Department of Pharmaceutical Chemistry and Pharmacognosy, College of Pharmacy, Jazan University, P. Box No. 114, Jazan, Saudi Arabia*
[2] *Department of Pharmaceutics, School of Pharmaceutical Sciences, Delhi Pharmaceutical Sciences and Research University (DPSRU), New Delhi-110017, India*
[3] *Department of Pharmaceutics, Institute of Pharmaceutical Research, GLA University, Mathura 281406, Uttar Pradesh, India*
[4] *Department of Pharmaceutics, College of Pharmacy, Jazan University, P. Box No. 114, Jazan, Saudi Arabia*
[5] *Department of Pharmaceutics, Faculty of Pharmaceutical Sciences, UCSI University, Kuala Lumpur, Malaysia*

ARTICLE INFO

Published: 13 Mar 2026
Keywords:
Erythrocyte-based drug delivery; Red blood cells; Biomimetic; Nanomedicine; Drug Encapsulation; Targeted Therapy
DOI:
10.5281/zenodo.19008048

ABSTRACT

Erythrocyte-based drug delivery systems (EBDDS) have emerged as promising platforms which are biomimetic and are used for targeted and sustained therapeutic applications. Due to their numerous advantages including inherent biocompatibility, prolonged circulation time, low immunogenicity, and unique membrane architecture, erythrocytes act as natural carriers for encapsulation of drugs and other biological molecules. Recent advances in nanotechnology have led to the development of erythrocyte-derived and erythrocyte-coated nanoparticles that have shown enhanced drug stability, improved immune evasion, and better site-specific delivery. Despite their substantial potential, erythrocyte-based therapeutics face numerous challenges which are related to their structural variability, limited drug loading capacity, immune recognition, large-scale manufacturing and regulatory classification. This review discusses the biological basis of erythrocytes as drug carriers, their engineering strategies, potential therapeutic applications, key challenges, and regulatory considerations.

INTRODUCTION

Among various cell-based approaches, erythrocyte-based systems (EBS) are gaining

***Corresponding Author:** Waquar Ahsan
Address: *Department of Pharmaceutical Chemistry and Pharmacognosy, College of Pharmacy, Jazan University, P. Box No. 114, Jazan, Saudi Arabia*
Email : wmohammad@jazanu.edu.sa

Relevant conflicts of interest/financial disclosures: The authors declare that the research was conducted in the absence of any commercial or financial relationships that could be construed as a potential conflict of interest.

significant interest for their potential applications in drug delivery, immune modulation, and regenerative medicine [1, 2]. The use of natural biological carriers for disease management has garnered significant attention from researchers and scientists. Beyond proteins, peptides, enzymes, and other macromolecules, erythrocytes, commonly known as red blood cells, have been explored as potential drug carriers, for various therapeutic applications, including anticancer, antibacterial, antiviral, and anti-inflammatory treatments [3, 4]. Red blood cells generate small, bubble-like nanovesicles that play both diagnostic and therapeutic roles in biomedicine. Their prolonged circulation time, immune system compatibility, controlled drug release mechanisms, and ability to protect pharmaceuticals from endogenous degradation make them highly effective for targeted drug delivery and diagnostics. This technology has been widely utilized in various biomedical applications. The transition of erythrocyte-based drug delivery systems (EBDDS) from preclinical studies to clinical trials (CTs) demonstrates their potential as innovative and efficient drug delivery platforms. Biomimetic nanoparticles, in particular, have demonstrated exceptional ability in targeting specific sites and enhancing pharmaceutical stability [5, 6]. As a result, they are emerging as a promising approach for the diagnosis and treatment of solid tumors, including gliomas, lung cancer, breast cancer, colon cancer, and stomach cancer.

1. Erythrocytes as biocompatible carriers

Erythrocytes are highly biocompatible and remain in the bloodstream for extended periods, making them effective carriers for targeted drug delivery and regenerative medicine applications. Their adaptability allows for modifications tailored to patient-specific needs, ensuring drug release in response to specific stimuli such as changes in pH or temperature. This versatility makes erythrocytes promising carriers for a wide range of therapeutic agents. Integrating erythrocytes into regenerative medicine and drug delivery systems showed immense potential, including patient safety, improved treatment efficacy, precise dose monitoring, and overall quality of life [7, 8]. To maximize the therapeutic effectiveness, and to minimize the side effects, researchers have successfully loaded anti-cancer drugs onto erythrocytes, engineering them to release the drugs selectively within tumor cells. In regenerative medicine, erythrocytes serve as carriers for growth factors and stem cells, facilitating tissue repair and regeneration [9].

2. Drug loading strategies

There are multiple strategies that exist to formulate therapeutic agents using erythrocytes. These include embedding drugs within erythrocyte membrane, modifying cell surfaces to target specific tissues, and encapsulating therapeutic agents within the cytoplasm. In the field of bio-delivery, red blood cells (RBC) have attracted significant interest due to their unique biological and physicochemical features. RBCs, which are responsible for oxygen transport, are the most abundant cells in the human body. They originate from erythroblasts in the bone marrow and circulate in the bloodstream for approximately 70 - 140 days. RBCs constitute nearly 70% of all adult human cells, providing an extensive surface area for drug delivery. Their distinctive membrane structure combines cytoskeletal flexibility with internal viscosity, allowing them to navigate capillaries while withstanding shear stress. This unique composition grants RBCs exceptional deformability [10, 11].

The erythrocyte membrane contains numerous proteins that regulate redox homeostasis, respond

to neurotransmitter stimulation and metabolism, from macrovesicles, and mediate the uptake and degradation of bioactive compounds. Due to their biocompatibility, low immunogenicity, and extended lifespan, RBCs are ideal for applications in nanomedicine. These properties make them particularly suitable for encapsulating drugs at targeted organ sites [12, 13]. Additionally, RBC-based drug delivery systems enhance pharmacokinetics by prolonging therapeutic activity following surgical procedures. The most common technique for drug encapsulation within the RBCs is the hypotonic method, in which cells expand under hypnotic conditions, creating temporary pores in their membranes. This allows drugs and nanomaterials to enter the erythrocytes and accumulate. To ensure biocompatibility and controlled drug release, the encapsulated payload must undergo a carefully regulated sealing process.

3. Challenges in erythrocyte-based drug delivery (EBDD)

Variations in erythrocyte morphology and structural integrity can pose challenges for synthetic RBC-based carriers, potentially limiting their interaction with living systems and this factor posed a challenge in generating an effective database for regulatory submission [14, 15]. Despite these challenges, RBC-based drug formulations enable precise drug delivery to targeted tissues, with controlled and monitored release rates that prevent premature degradation or systemic exhaustion. EBDD has revolutionized regenerative medicine by introducing new strategies to treat a wide range of diseases and injuries. Researchers have successfully loaded anti-cancer drugs into erythrocytes, engineering them to selectively adhere to malignant cells for targeted therapy. This approach enhances therapeutic efficacy by modifying erythrocyte surfaces to ensure precise binding to cancer cells, enabling localized drug action [16].

Several challenges remain in using erythrocytes for cell-based therapies as the immune system may recognize and reject modified erythrocytes, limiting their circulation lifespan. Additionally, drug-loading capacity constraints and potential cell degradation may reduce their long-term effectiveness. Addressing these challenges is critical for optimizing EBDD. Red blood cell membrane-coated nanoparticles provide solutions by enhancing the drug-loading efficiency and extending circulation times in the bloodstream. Another innovative approach involves genetically modified erythrocytes with extended survival and immune evasion properties, increasing their suitability for prolonged treatment [17, 18].

The potential of EBDD extends to the management of chronic diseases, where long-term, personalized treatment strategies are essential. Erythrocyte-based therapeutics offer promising avenues for improving treatment specificity and efficacy in various disorders. Furthermore, advancements in bioengineering and nanotechnology enable the development of personalized medicine, allowing erythrocyte-based therapies to be customized for individual patients [30]. These erythrocyte-based formulations are an attractive option for medical treatment by improving drug administration and minimizing systemic side effects. Researchers are actively developing EBDDS to target tumor sites while minimizing off-target toxicity. Additionally, gene-editing tools could potentially be delivered via erythrocytes to address hereditary diseases, offering a novel approach to precision medicine [19, 20].

4. Ethical and regulatory considerations

Regulatory framework govern the approval and commercialization of pharmaceuticals and therapeutic agents, ensuring safety and efficacy. However, safety concerns also raise ethical challenges. In recent years, significant advancements in cancer treatment have led to the development of novel therapies, such as the immunotherapy (both active and passive), stem cell treatments, and nanocarrier-based delivery systems [21, 22]. Conventional cancer treatments, such as the chemotherapy and radiation therapy, often suffer from adverse effects and lack of specificity. The introduction of biocompatible EBDDS aims to address these limitations by improving drug targeting and circulation longevity while minimizing immune system clearance [23, 24]. Owing to their ability to deliver therapeutics with high specificity, erythrocytes have emerged as a valuable tool in both therapy and diagnostics. They can function as bioreactors, carrying a wide range of therapeutic agents. However, despite these advancements, the erythrocyte-based therapies present significant ethical, legal, and regulatory challenges owing to the complexity in developing formulation, establishing it's stability and testing for application. Legal barriers surrounding marketing approval could delay or obstruct the commercialization of many promising treatments, even the highly advanced ones [25, 26].

5. Global regulatory frameworks for erythrocytes-based formulations

International regulatory frameworks play a crucial role in the approval and commercialization of novel drug delivery systems. Regulatory considerations greatly affect the licensing and development process and should be considered while new approaches to drug distribution are developed and approved. These technologies have to follow the prescribed guidelines and regulations established by regulatory authorities across different countries if they are to be accessible to stakeholders and patients everywhere [27]. This covers establishing that the treatment is safe and efficient as well as ensuring that it conforms with international laws and guidelines thereof. International regulatory sanctions facilitate the distribution and production of a wide range of treatments, thereby simplifying their convenience for patients. Global cooperation and interaction among researchers, developers, and regulatory authorities is essential for the successful creation and application of these innovative treatments [28, 29]. For instance, to collect information on how safe and effective a new gene treatment is for a rare genetic disease, a pharmaceutical company needs to conduct CTs at multiple locations. To ensure that the treatment meets the required standards, it is important to work closely with the regulatory officials in each country. This teamwork will speed up the approval process and ensure global accessibility of these life-saving treatments. [30, 31].

Global coordination is important in the development and acceptance of novel therapeutic approaches. The evolution of medical technology benefits significantly from international CTs and regulatory partnerships. Understanding the advantages and limitations of global cooperation in the pharmaceutical industry can provide valuable insights for future drug development initiatives [32]. For instance, a pharmaceutical company doing research on a novel cancer treatment might collaborate with research centres across multiple countries to diversify patient enrolment and collect comprehensive efficacy data. By addressing specific legal and regulatory challenges while adhering to international standards, companies can accelerate the development and availability of life-saving medical treatments [33].

Technological advancements are driving the development of various treatments, including cell, tissue, and gene therapies. These innovations have garnered significant interest due to their potential to address numerous medical conditions and physical disorders. Examples include enhanced donor cells, engineered oncolytic viruses, hematopoietic stem cells, skin grafts, novel gene-editing techniques, and customized tissues [34, 35]. These therapies have proven beneficial in treating a wide range of diseases and conditions, including blood cancers, burns, thalassemia, sickle cell disease, spinal muscular atrophy, certain tumors, and specific genetic disorders. As the number of cell, tissue, and gene therapy products continues to grow, regulatory oversight is essential to ensure their ethical production and compliance with quality, safety, and efficacy standards. Effective regulation requires robust classification systems and in-depth understanding of their origins, manufacturing processes, and intended applications of these products. Additionally, regulatory frameworks must balance oversight with innovation, ensuring that rules do not hinder the development or accessibility of these therapies. In this context, the World Health Organization (WHO) strongly advocates for regulatory harmonization and reliance to facilitate global access to these advancements [36].

Regulations governing erythrocyte-based formulations vary significantly across countries. In the United States (US), the Food and Drug Administration (FDA) requires rigorous preclinical and clinical evaluations before approving these products for human use. Similarly, in the European Union, the European Medicines Agency (EMA) oversees the approval process under a unified regulatory framework. Manufacturers of erythrocyte-based therapeutics must adhere to country-specific regulations to legally market and distribute their products [37, 38]. National regulatory differences influence the production and distribution of these therapies, creating challenges for manufacturers seeking global market entry. Regulatory agencies such as the FDA and EMA, ensure the safety and efficacy of erythrocyte-based products. However, navigating diverse regulatory landscapes presents significant hurdles for manufacturers, as compliance with different national guidelines is necessary for international commercialization. These variations in regulations can impact patient access to novel blood-derived therapies, and future regulatory changes may have profound implications for the industry.

6. Impact of regulatory frameworks on market access

Manufacturers aiming to enter new markets must navigate complex regulatory landscapes, often facing delays in product approval and commercialization. Failure to meet regulatory standards may prevent life-saving treatments from reaching patients in need. To address these challenges, regulatory agencies must work toward aligning and streamlining their guidelines to facilitate the global distribution of erythrocyte-based therapies. For example, the launch of a new blood cell-based medication may be delayed due to varying regulatory requirements in the US, the European Union (EU), and Asia. Pharmaceutical companies may need to conduct additional CTs and comply with region-specific approval processes, increasing costs and limiting global access to the medication. Regulations greatly impact product development timelines and market entry, requiring companies to allocate substantial resources to meet regulatory compliance [39, 40]. These challenges can slow innovation, extend research and development timelines, and increases costs, ultimately limiting patient access to critical therapies [41]. Establishing global regulatory

standards could expedite the approval process, ensuring that patients worldwide benefit from new treatments. A unified regulatory framework would enable pharmaceutical companies to launch erythrocyte-based products more efficiently, improving accessibility and patient outcomes. For instance, a company developing a new blood cell-based therapy may need to conduct multiple CTs and obtain regulatory approvals in different jurisdictions. Harmonizing these regulatory requirements would reduce delays, lower costs, and accelerate patient access to innovative treatments [42, 43].

A well-defined regulatory framework for cell-based therapies has the potential to revolutionize medicine by enabling precise and personalized treatment approaches for various diseases. However, clear and consistent regulations are essential to ensure the safety and efficacy of these therapies. This regulatory system should encompass guidelines for the sourcing, manufacturing, and quality control of cell-based products, as well as post-market surveillance to monitor patient outcomes over time. Regulatory authorities must also maintain open communications with researchers and industry leaders to stay informed of scientific advancements and adapt regulations accordingly.

CONCLUSION

In conclusion, EBDDS represent a promising and evolving platform in nanomedicine and cell-based therapeutics. Numerous advantages associated with erythrocytes make this system highly attractive for the delivery of a variety of therapeutic agents. Advancements in drug loading techniques, membrane engineering, and fabrication of erythrocyte membrane-coated nanoparticles have further expanded their applications in across various domains including oncology, infectious diseases, inflammatory disorders, and regenerative medicine. These biomimetic platforms demonstrate enhanced therapeutic stability, improved pharmacokinetics and reduced systemic toxicity in comparison to the conventional drug delivery systems. However various challenges, in particular, their regulatory classification, quality control standardization, and harmonization are crucial for the acceleration of their clinical translation and commercialization process. Interdisciplinary collaboration is warranted among researchers, clinicians, bioengineers, and regulatory agencies to address these limitations. These therapies have the potential to emerge as safe, efficient, and patient specific treatment strategies in future.

FUNDING

No funding received for this study

AUTHOR CONTRIBUTIONS

Conceptualization: PM, BM; Data curation: SJ, PK, WA; Formal analysis: PM, BM, PK, SJ; Methodology: PM, BM, SJ, WA; Project administration: BM, WA; Resources: SJ, WA; Software: PM, PK, BM; Supervision: WA; Validation: BM, SJ, WA; Visualization: PM, BM, PK; Writing: PM, BM, SJ, PK; Revision: SJ, WA.

CONFLICT OF INTEREST: All authors declare no conflict of interest

DATA AND CODE AVAILABILITY: Not Applicable

ETHICAL APPROVAL: Not Applicable

REFERENCES

1. Berikkhanova, K., Taigulov, E., Bokebaev, Z., Kusainov, A., Tanysheva, G., Yedrissov, A., Seredin, G., Baltabayeva, T., & Zhumadilov, Z. (2023). Drug-loaded

erythrocytes: Modern approaches for advanced drug delivery for clinical use. Heliyon, 10(1), e23451.

2. Mansour, A., Romani, M., Acharya, A. B., Rahman, B., Verron, E., & Badran, Z. (2023). Drug delivery systems in regenerative medicine: An updated review. Pharmaceutics, 15(2), 695.
3. Muzykantov, V. R. (2010). Drug delivery by red blood cells: Vascular carriers designed by mother nature. Expert Opinion on Drug Delivery, 7(4), 403–427.
4. Villa, C. H., Cines, D. B., Siegel, D. L., & Muzykantov, V. (2017). Erythrocytes as carriers for drug delivery in blood transfusion and beyond. Transfusion Medicine Reviews, 31(1), 26–35.
5. Beh, C. Y., Prajnamitra, R. P., Chen, L. L., & Hsieh, P. C. (2021). Advances in biomimetic nanoparticles for targeted cancer therapy and diagnosis. Molecules, 26(16), 5052.
6. Al-Hetty, H. R. A. K., Kadhim, M. S., Al-Tamimi, J. H. Z., Ahmed, N. M., Jalil, A. T., Saleh, M. M., Kandeel, M., & Abbas, R. H. (2023). Implications of biomimetic nanocarriers in targeted drug delivery. Emergent Materials, 6(1), 1–13.
7. Koleva, L., Bovt, E., Ataullakhanov, F., & Sinauridze, E. (2020). Erythrocytes as carriers: From drug delivery to biosensors. Pharmaceutics, 12(3), 276.
8. Ding, J., Ding, X., Liao, W., & Lu, Z. (2024). Red blood cell-derived materials for cancer therapy: construction, distribution, and applications. Materials Today Bio, 24, 100913.
9. He, A., Huang, Y., Cao, C., & Li, X. (2024). Advances in drug delivery systems utilizing blood cells and their membrane-derived microvesicles. Drug Delivery, 31(1), 2425156.
10. Villa, C. H., Pan, D. C., Zaitsev, S., Cines, D. B., Siegel, D. L., & Muzykantov, V. R. (2015). Delivery of drugs bound to erythrocytes: new avenues for an old intravascular carrier. Therapeutic delivery, 6(7), 795-826.
11. Wang, S., Han, K., Ma, S., Qi, X., Guo, L., & Li, X. (2022). Blood cells as supercarrier systems for advanced drug delivery. Medicine in Drug Discovery, 13, 100119.
12. Anderson, H. L., Brodsky, I. E., & Mangalmurti, N. S. (2018). The evolving erythrocyte: red blood cells as modulators of innate immunity. The Journal of Immunology, 201(5), 1343-1351.
13. Villa, C. H., Anselmo, A. C., Mitragotri, S., & Muzykantov, V. (2016). Red blood cells: Supercarriers for drugs, biologicals, and nanoparticles and inspiration for advanced delivery systems. Advanced drug delivery reviews, 106, 88-103.
14. Wang, S., Han, K., Ma, S., Qi, X., Guo, L., & Li, X. (2022). Blood cells as supercarrier systems for advanced drug delivery. Medicine in Drug Discovery, 13, 100119.
15. Glassman, P. M., Villa, C. H., Ukidve, A., Zhao, Z., Smith, P., Mitragotri, S., ... & Muzykantov, V. R. (2020). Vascular drug delivery using carrier red blood cells: focus on RBC surface loading and pharmacokinetics. Pharmaceutics, 12(5), 440.
16. Cheng, X., Xie, Q., & Sun, Y. (2023). Advances in nanomaterial-based targeted drug delivery systems. Frontiers in bioengineering and biotechnology, 11, 1177151.
17. Villa, C. H., Pan, D. C., Zaitsev, S., Cines, D. B., Siegel, D. L., & Muzykantov, V. R. (2015). Delivery of drugs bound to erythrocytes: new avenues for an old intravascular carrier. Therapeutic delivery, 6(7), 795-826.

18. Koleva, L., Bovt, E., Ataullakhanov, F., & Sinauridze, E. (2020). Erythrocytes as carriers: From drug delivery to biosensors. Pharmaceutics, 12(3), 276.
19. Berikkhanova, K., Taigulov, E., Bokebaev, Z., Kusainov, A., Tanysheva, G., Yedrissov, A., ... & Zhumadilov, Z. (2024). Drug-loaded erythrocytes: Modern approaches for advanced drug delivery for clinical use. Heliyon, 10(1).
20. Guido, C., Maiorano, G., Gutiérrez-Millán, C., Cortese, B., Trapani, A., D'Amone, S., ... & Palamà, I. E. (2021). Erythrocytes and nanoparticles: new therapeutic systems. Applied Sciences, 11(5), 2173.
21. Vincy, A., Mazumder, S., Amrita, Banerjee, I., Hwang, K. C., & Vankayala, R. (2022). Recent progress in red blood cells-derived particles as novel bioinspired drug delivery systems: challenges and strategies for clinical translation. Frontiers in Chemistry, 10, 905256.
22. Yao, Y., Zhou, Y., Liu, L., Xu, Y., Chen, Q., Wang, Y., Wu, S., Deng, Y., Zhang, J., & Shao, A. (2020). Nanoparticle-based drug delivery in cancer therapy and its role in overcoming drug resistance. Frontiers in Molecular Biosciences, 7, 193.
23. Chehelgerdi, M., Chehelgerdi, M., Allela, O. Q. B., Pecho, R. D. C., Jayasankar, N., Rao, D. P., Thamaraikani, T., Vasanthan, M., Viktor, P., Lakshmaiya, N., Saadh, M. J., Amajd, A., Abo-Zaid, M. A., Castillo-Acobo, R. Y., Ismail, A. H., Amin, A. H., & Akhavan-Sigari, R. (2023). Progressing nanotechnology to improve targeted cancer treatment: Overcoming hurdles in its clinical implementation. Molecular Cancer, 22(1), 169.
24. Koleva, L., Bovt, E., Ataullakhanov, F., & Sinauridze, E. (2020). Erythrocytes as carriers: From drug delivery to biosensors. Pharmaceutics, 12(3), 276.
25. Glassman, P. M., Villa, C. H., Ukidve, A., Zhao, Z., Smith, P., Mitragotri, S., Russell, A. J., Brenner, J. S., & Muzykantov, V. R. (2020). Vascular drug delivery using carrier red blood cells: Focus on RBC surface loading and pharmacokinetics. Pharmaceutics, 12(5), 440.
26. Barrios, C., de Lima Lopes, G., Yusof, M. M., Rubagumya, F., Rutkowski, P., & Sengar, M. (2023). Barriers in access to oncology drugs - a global crisis. Nature Reviews Clinical Oncology, 20(1), 7–15.
27. Villa, C. H., Seghatchian, J., & Muzykantov, V. (2016). Drug delivery by erythrocytes: "Primum non nocere". Transfusion and Apheresis Science, 55(3), 275–280.
28. National Academy of Medicine, Finkelman, E. M., McGinnis, J. M., McClellan, M. B., et al. (Eds.). (2017). Vital directions for health & health care: An initiative of the National Academy of Medicine. National Academies Press (US). https://www.ncbi.nlm.nih.gov/books/NBK595181/ (Accessed on March 23, 2025).
29. Ranganathan, P., Chinnaswamy, G., Sengar, M., Gadgil, D., Thiagarajan, S., Bhargava, B., Booth, C. M., Buyse, M., Chopra, S., Frampton, C., Gopal, S., Grant, N., Krailo, M., Langley, R., Mathur, P., Paoletti, X., Parmar, M., Purushotham, A., Pyle, D., … Pramesh, C. S. (2021). The International Collaboration for Research methods Development in Oncology (CReDO) workshops: Shaping the future of global oncology research. The Lancet Oncology, 22(8), e369–e376.
30. Kumar, J., Ramkishan, A., & Venkatesh, M. P. (2024). Navigating Global Regulatory Requirements for Generic Drugs: A Comparative Study of MIST, BRICS, and

ICH Countries. International Journal of Pharmaceutical Investigation, 14(1).

31. Hassanaly, P., & Dufour, J. C. (2021). Analysis of the regulatory, legal, and medical conditions for the prescription of mobile health applications in the United States, the European Union, and France. Medical Devices: Evidence and Research, 389-409.
32. Lezotre, P. L. (2014). Value and influencing factors of the cooperation, convergence, and harmonization in the pharmaceutical sector. International Cooperation, Convergence and Harmonization of Pharmaceutical Regulations, 171–219.
33. Institute of Medicine (US). (2010). Extending the spectrum of precompetitive collaboration in oncology research: Workshop summary. National Academies Press (US). https://www.ncbi.nlm.nih.gov/books/NBK210038/ (Accessed on March 23, 2025).
34. Hasanzadeh, A., Ebadati, A., Dastanpour, L., Aref, A. R., Sahandi Zangabad, P., Kalbasi, A., Dai, X., Mehta, G., Ghasemi, A., Fatahi, Y., Joshi, S., Hamblin, M. R., & Karimi, M. (2023). Applications of innovation technologies for personalized cancer medicine: Stem cells and gene-editing tools. ACS Pharmacology & Translational Science, 6(12), 1758–1779.
35. Anurogo, D., Yuli Prasetyo Budi, N., Thi Ngo, M. H., Huang, Y. H., & Pawitan, J. A. (2021). Cell and gene therapy for anemia: Hematopoietic stem cells and gene editing. International Journal of Molecular Sciences, 22(12), 6275.
36. Shukla, V., Seoane-Vazquez, E., Fawaz, S., Brown, L., & Rodriguez-Monguio, R. (2019). The landscape of cellular and gene therapy products: authorization, discontinuations, and cost. Human gene therapy clinical development, 30(3), 102-113.
37. Kalantar-Zadeh, K. (2017). History of erythropoiesis-stimulating agents, the development of biosimilars, and the future of anemia treatment in nephrology. American journal of nephrology, 45(3), 235-247.
38. Devi, S. K., Joga, R., Srivastava, S., Nagpal, K., Dhamija, I., Grover, P., & Kumar, S. (2024). Regulatory landscape and challenges in CAR-T cell therapy development in the US, EU, Japan, and India. European Journal of Pharmaceutics and Biopharmaceutics, 114361.
39. Villa, C. H., Cines, D. B., Siegel, D. L., & Muzykantov, V. (2017). Erythrocytes as carriers for drug delivery in blood transfusion and beyond. Transfusion medicine reviews, 31(1), 26-35.
40. Villa, C. H., Cines, D. B., Siegel, D. L., & Muzykantov, V. (2017). Erythrocytes as carriers for drug delivery in blood transfusion and beyond. Transfusion medicine reviews, 31(1), 26-35.
41. Miller, J. E., Mello, M. M., Wallach, J. D., Gudbranson, E. M., Bohlig, B., Ross, J. S., ... & Bach, P. B. (2021). Evaluation of drug trials in high-, middle-, and low-income countries and local commercial availability of newly approved drugs. JAMA Network Open, 4(5), e217075-e217075.
42. Dinçkol, D., Ozcan, P., & Zachariadis, M. (2023). Regulatory standards and consequences for industry architecture: The case of UK Open Banking. Research Policy, 52(6), 104760.
43. Korea Development Institute. (2021). Case Studies on the Regulatory Challenges Raised by Innovation and the Regulatory Responses. OECD Publishing.

HOW TO CITE: Waquar Ahsan, Pankaj Musyuni, Bharti Mangla, Shamama Javed, Pankaj Kumar, Erythrocyte-Based Nanotherapeutics: Engineering Strategies, Clinical Translation, and Regulatory Landscape, Int. J. of Pharm. Sci., 2026, Vol 4, Issue 3, 1466-1475. https://doi.org/10.5281/zenodo.19008048