Editorial

# Positioning Malaysia as an International Hub for Shariah-Compliant Regenerative Medicine and Bioprocessing

Abu Hassan Asaari Abdullah[1], Mohd Fauzi Mh Busra[2,3], Qi Hao Looi[2,4]

**Submitted:** 6 Aug 2026
**Accepted:** 9 Aug 2026
**Online:** 31 Oct 2026

[1] *Department of Emergency and Trauma, Hospital Kuala Lumpur, Jalan Pahang, 50586 Kuala Lumpur, Malaysia*

[2] *Department of Tissue Engineering and Regenerative Medicine, Faculty of Medicine, Universiti Kebangsaan Malaysia, Jalan Yaacob Latif, Bandar Tun Razak, 56000 Cheras, Kuala Lumpur, Malaysia*

[3] *Centre for Innovation and Technology Transfer, Universiti Kebangsaan Malaysia, 43600 Bangi, Selangor, Malaysia*

[4] *My Cytohealth Sdn Bhd, 5th Floor, Plaza Hamodal, Lot No. 15, Jalan 13/2, Seksyen 13, 46200 Petaling Jaya, Selangor, Malaysia*



To cite this article: Abdullah AHA, Mh Busra MF, Looi QH. Positioning Malaysia as an international hub for Shariah-compliant regenerative medicine and bioprocessing. *Malays J Med Sci.* 2026;**33(5)**:1–10. https://doi.org/10.21315/mjms-08-2026-498

To link to this article: https://doi.org/10.21315/mjms-08-2026-498

## Abstract

**Cell and gene therapy products (CGTPs) are moving from experimental interventions towards regulated therapeutic platforms, yet their translation remains constrained by complex manufacturing, variable clinical evidence and demanding lifecycle oversight. Malaysia has progressively established CGTP regulation through National Pharmaceutical Regulatory Agency guidance, biologics registration pathways and national clinical guidance. A review of publicly available instruments as of July 2026, however, indicates that Malaysia does not yet have a dedicated CGTP development designation that integrates early regulatory engagement, product-specific clinical advice and coordinated post-authorisation evidence generation. The same review did not identify a national CGTP-specific Shariah assurance instrument that translates Islamic principles into operational bioprocessing controls. Malaysia's established halal ecosystem and healthcare travel platform provide a strategic foundation, but credible hub status must be built on regulatory and scientific assurance rather than branding alone. This editorial proposes a complementary framework covering lawful and ethical tissue procurement, religiously sensitive but scientifically complete consent, ancillary-material source mapping, justified replacement of porcine- or animal-derived reagents, validated segregation and contamination control, traceability**

 © Penerbit Universiti Sains Malaysia, 2026
This work is licensed under the terms of the Creative Commons Attribution (CC BY) (http://creativecommons.org/licenses/by/4.0/).

**and a formally governed necessity pathway when no technically suitable alternative exists. Such an integrated model could enable Malaysia to pursue first-mover international leadership in Shariah-compliant regenerative medicine without weakening Good Manufacturing Practice, product quality or patient protection.**

***Keywords:*** *cell and gene therapy products, good manufacturing practice, halal pharmaceuticals, Malaysia, regenerative medicine, Shariah*

## Introduction

Cell and gene therapy products (CGTPs) offer the prospect of durable benefit for conditions that remain inadequately managed by conventional medicines. Their manufacture is nevertheless inseparable from donor variability, living starting materials, complex ancillary reagents, aseptic processing and uncertain long-term effects. Malaysia should therefore view CGTP governance not only as a patient-safety obligation, but also as an opportunity for strategic leadership. The next competitive step is to integrate regulatory maturity with a credible Shariah-compliant bioprocessing system.

## Malaysia's Regulatory Evolution and International Position

Malaysia's CGTP framework progressed from the establishment of a technical working group in 2012 to publication of the first registration guidance in 2016, voluntary implementation in 2017, phased screening from 2021 to 2024 and full registration implementation from January 2025 (1). The second edition of the CGTP guidance was issued in September 2025, and the Drug Registration Guidance Document was revised in July 2026 (2, 3). CGTPs are regulated as biologics under the Sale of Drugs Act 1952 and the Control of Drugs and Cosmetics Regulations 1984, with priority review, conditional registration, facilitated registration and orphan-drug mechanisms available (1–3). Malaysia also has national clinical guidance addressing preclinical evidence, clinical investigation and clinical governance (4). This is meaningful progress, but Malaysia still relies mainly on mechanisms designed for broader pharmaceutical categories. The United States provides Regenerative Medicine Advanced Therapy designation, the European Union regulates advanced therapy medicinal products within a centralised framework and offers priority medicines (PRIME) support, while Japan recognises regenerative medical products as a distinct category with conditional and time-limited approval (5–8). These systems do more than shorten review: they formalise regulator-developer interaction, address manufacturing uncertainty and connect initial access with continuing evidence generation (Table 1).

**Table 1.** Evolution and comparative regulatory architecture for CGTPs in Malaysia and selected major jurisdictions.

| Jurisdiction | Regulatory architecture and development | Dedicated CGTP mechanism | Development support/early access | Strategic lesson for Malaysia |
|---|---|---|---|---|
| Malaysia | 2012 technical working group; 2016 first CGTP guidance; 2017 voluntary phase; 2021–2024 phased implementation; full implementation from January 2025; second-edition CGTP guidance in September 2025. | CGTPs are regulated within biologics pathways; priority review, conditional registration, facilitated registration and orphan-drug designation are available. | A voluntary pre-submission meeting and conditional or reliance mechanisms are available, but these are not integrated into a CGTP-specific development designation. | Consider a dedicated CGTP designation with multidisciplinary regulatory coordination, milestone-based advice and lifecycle evidence planning. |

(*continued on next page*)

**Table 1.** (*continued*)

| Jurisdiction | Regulatory architecture and development | Dedicated CGTP mechanism | Development support/early access | Strategic lesson for Malaysia |
|---|---|---|---|---|
| United States | Cell and gene therapies are regulated by the Food and Drug Administration (FDA) under biological-product and human-cell/tissue frameworks. | Regenerative Medicine Advanced Therapy (RMAT) designation for qualifying therapies addressing serious conditions (5). | More intensive guidance, early multidisciplinary meetings, expedited programmes and potential accelerated approval with post-authorisation commitments. | Formalise early engagement and integrate manufacturing, clinical and post-market advice within one route. |
| European Union | Gene therapies, somatic cell therapies and tissue-engineered products are regulated as advanced therapy medicinal products under a centralised framework (6). | ATMP classification and centralised marketing authorisation; PRIME supports medicines addressing unmet need (6, 7). | Early rapporteur involvement, a dedicated coordinator, scientific advice, development planning and conditional marketing authorisation where justified. | Combine product classification, scientific support and central lifecycle oversight. |
| Japan | The Pharmaceuticals and Medical Devices (PMD) Act recognises regenerative medical products as a distinct product category (8). | A dedicated regenerative medical product pathway includes conditional and time-limited approval. | Pharmaceuticals and Medical Devices Agency (PMDA) consultation, priority support, post-marketing efficacy evaluation and specific guidance for MSC-derived products. | Adaptive evidence generation can be supported without removing safety or confirmatory-evidence obligations. |

CGTP = cell and gene therapy product; MSC = mesenchymal stromal/stem cell; PRIME = PRIority MEdicines

## Where the Present Framework Remains Incomplete

The Malaysian system should not be characterised as lacking clinical guidance, as globally recorded, a total of 25 registered cell-based products are in the commercial pipeline (Table 2). The 2024 national guideline addresses matters including dose selection, informed consent, risk management, long-term follow-up and patient registries (4). The more defensible concern is fragmentation. Product registration, clinical research, professional practice, facility oversight and post-treatment surveillance are distributed across different instruments. Existing clinical guidance is necessarily broad and research-oriented; it does not establish a single indication-specific route connecting investigational development, conditional access, qualified delivery centres, registry obligations and eventual routine practice.

## A Shariah-compliant Bioprocessing Framework

Malaysia combines two useful foundations: a government-supported halal ecosystem and an internationally promoted healthcare travel sector (9, 10). Currently, certain pharmaceutical manufacturing plants have implemented MS 2424:2019, which specifies general requirements for manufacturing and handling halal pharmaceuticals, but not in the scope of biologics (11). Malaysian *fatwa* deliberations, as summarised by the Federal Territories Mufti Department, permit stem-cell use for therapy and research subject to lawful sources, consent, avoidance of harm and other conditions (12); however, a CGTP-specific framework which combines halal assurance with *maqasid al-Shariah*, particularly protection of life, prevention of harm, donor dignity, accountability and public benefit is still lacking.

**Table 2.** List of approved cell-based therapy products worldwide.

| Product, Manufacturer (country) | Main indication | Approval authority/ date | Dose/form (summary) | Therapy basis/ source | Reported price |
|---|---|---|---|---|---|
| Provenge (sipuleucel-T)<br>Dendreon Corp. (US) | Asymptomatic or minimally symptomatic metastatic castration-resistant prostate cancer | US FDA, Apr 2010; EMA, Sep 2010 | Minimum 50 million activated CD54+ cells in 250 mL; infusion bag | Autologous peripheral blood mononuclear cells, mainly dendritic cells activated with 5-(4-phenoxybutoxy) psoralen (PAP) and granulocyte–macrophage colony-stimulating factor (GM-CSF) | $93,000 for three infusions |
| Prochymal (BM-MSCs)<br>Mesoblast Ltd. (Australia) | Acute and refractory graft-versus-host disease | Health Canada, May 2012; US FDA, Jun 2015 (as reported) | IV: 2 million cells/kg (low dose) or 8 million cells/kg (high dose); bag | Allogeneic human bone marrow-derived MSCs | $200,000 per treatment |
| Alofisel/ Alofisell (Cx601; darvadstrocel)<br>TiGenix (US)/ Takeda (UK) | Complex perianal fistulas in Crohn's disease | EMA, Mar 2018 | 5 million MSCs/ mL; four vials per treatment | Allogeneic human adipose tissue-derived MSCs | Approx. $47,485 per treatment |
| KeraHeal<br>Biosolution Co. Ltd. (South Korea) | Deep second-degree burns (> 30% TBSA) and third-degree burns (> 10% TBSA) | South Korea MFDS, May 2006 | 1 mL keratinocyte suspension per 100–400 $cm^2$; vial | Autologous human skin-derived keratinocytes | Approx. $3,561 per vial |
| Queencell<br>Anterogen (South Korea) | Subcutaneous tissue defects | South Korea MFDS, Mar 2010 | At least $1.0 \times 10^6$ adipose-derived cells/vial (1 mL); volume based on defect size | Autologous, minimally manipulated adipose-derived cells | Not available |
| CureSkin<br>S. Biomedics (South Korea) | Depressed acne scars | South Korea MFDS, May 2010 | 50–100 µL of $2.0 \times 10^7$ cells/mL per intradermal injection; three biweekly injections | Autologous human dermal fibroblasts | Approx. $6,300 for coin-sized scar; $11,700 for whole face |
| KeraHeal-Allo<br>Biosolution Co. Ltd. (South Korea) | Deep second-degree burns | South Korea MFDS, Oct 2015 | $2.0 \times 10^7$ keratinocytes in 1.5 mL per 100 cm2; prefilled syringe | Allogeneic skin-derived keratinocytes in thermosensitive hydrogel | Approx. $628 per 1.5 mL |
| Rosmir<br>Tego Science (South Korea) | Nasojugal groove | South Korea MFDS, Dec 2017 | $2.0 \times 10^7$ fibroblasts per pack; single intradermal administration | Autologous human fibroblasts | More than approx. $81.38 per injection |

(*continued on next page*)

**Table 2.** (*continued*)

| Product, Manufacturer (country) | Main indication | Approval authority/ date | Dose/form (summary) | Therapy basis/ source | Reported price |
|---|---|---|---|---|---|
| Chondron<br>Sewon Cellontech Corp. (South Korea) | Focal knee cartilage defect | South Korea MFDS, Jan 2001 | 1–6 vials; > 12 million cultured chondrocytes per vial | Autologous human chondrocytes | Approx. $5,890 per treatment |
| RMS-Ossron<br>Sewon Cellontech Co. Ltd. (South Korea) | Bone defects | South Korea MFDS, Aug 2009 | 1–6 vials; > 12 million cultured osteoblasts per 0.4 mL vial | Autologous human osteoblasts | Not available |
| Cartistem<br>Medipost (South Korea) | Knee osteoarthritis, International Cartilage Repair Society (ICRS) grade IV | South Korea MFDS, Jan 2012 | 500 μL/cm²; 7.5 × $10^6$ cells in 1.5 mL; vial | Allogeneic human umbilical cord blood-derived MSCs | $19,000–$21,000 standard treatment; + $10,000 per extra treatment |
| CreaVax-RCC<br>JW CreaGene (South Korea) | Metastatic renal cell carcinoma after nephrectomy | South Korea MFDS, May 2007 | 8 doses over 14 weeks; 5.0 × $10^7$ dendritic cells in 2 mL per vial | Autologous human dendritic cells | Approx. $27,000 for eight treatments |
| Immuncell-LC<br>Green Cross Cell Corp. (South Korea) | Prevention of post-surgical recurrence of hepatocellular carcinoma | South Korea MFDS, Aug 2007 | 16 doses; each administration contains 1.0 × $10^9$ to 2.0 × $10^{10}$ activated T cells | Autologous activated human T lymphocytes | More than $4,500 per dose |
| Cupistem<br>Anterogen (South Korea) | Crohn's fistula | South Korea MFDS, Jan 2012 | 3.0 × $10^7$ cells in 1 mL for fistula ≤ 1 cm; 6.0 × $10^7$ in 2 mL for 1–2 cm | Autologous human adipose tissue-derived MSCs | $3,000–$5,000 per treatment |
| Cellgram-AMI<br>FCB Pharmicell (South Korea) | Acute myocardial infarction | South Korea MFDS, Jul 2011 | Weight-based: 5.0 × $10^7$ to 9.0 × $10^7$ BM-MSCs in 10–18 mL; prefilled syringe | Autologous human bone marrow-derived MSCs | $15,000 for one injection |
| Neuronata-R<br>Corestem (South Korea) | Amyotrophic lateral sclerosis (ALS) | South Korea MFDS, Jul 2014 | 1.0 × $10^6$ BM-MSCs in 4 mL autologous CSF; twice at 4-week interval | Autologous human bone marrow-derived MSCs | Approx. $55,000 annually (24 treatments, as reported) |
| Cartigrow<br>Regrow Biosciences Pvt. Ltd. (India) | Knee or ankle cartilage loss | India Drugs Controller General of India (DCGI), Apr 2017 | 48 million chondrocytes; vial | Autologous human chondrocytes | $1,988 per treatment |

(*continued on next page*)

**Table 2.** (*continued*)

| Product, Manufacturer (country) | Main indication | Approval authority/ date | Dose/form (summary) | Therapy basis/ source | Reported price |
|---|---|---|---|---|---|
| Ossgrow<br>Regrow Biosciences Pvt. Ltd. (India) | Early-stage avascular necrosis of the hip | India DCGI, Apr 2017 | $1.2 \times 10^7$ autologous bone cells in 0.4 mL; vial | Autologous human osteoblasts | $1,988 per treatment |
| Apceden (AMDDC)<br>APAC Biotech (India) | Prostate, ovarian, colorectal and non-small cell lung cancers | India DCGI, Mar 2017 | 6 doses of 4–5 million mature dendritic cells over 14 weeks | Autologous monocyte-derived mature dendritic cells | $7,100–$9,940 per treatment |
| Stempeucel<br>Stempeutics Research (India) | Critical limb ischaemia due to thromboangiitis obliterans (Buerger's disease) | India DCGI, May 2016 | Intramuscular injection of 1 or 2 million cells/ kg | Allogeneic human bone marrow-derived MSCs | $2,200 per treatment |
| Chondrocytes-T-Ortho-ACI (Cartogen)<br>Orthocell (Australia) | Cartilage damage (chondromalacia patella or osteochondritis dissecans), age 18–55 | Australia Therapeutic Goods Administration, Mar 2017 | 2–5 million chondrocytes in 1.0 mL assembly medium; bag | Autologous human chondrocytes | $4,500 per treatment |
| Temcell HS<br>JCR Pharmaceuticals (Japan) | Acute and refractory graft-versus-host disease | Japan PMDA, Sep 2015 | 2 million cells/ kg IV; 72 million cells/18 mL bag; twice weekly for 4 weeks | Allogeneic human bone marrow-derived MSCs | $7,600 per bag |
| RenuDermcell<br>Cell Tech Pharmed (Iran) | Facial wrinkles, acne scars and atrophic skin lesions after trauma | Iran FDA, Jan 2018 | At least $3.0 \times 10^7$ cells intradermally; usually repeated three times | Autologous human dermal fibroblasts | Not available |
| MesestroCell<br>Cell Tech Pharmed (Iran) | Osteoarthritis and knee joint arthritis | Iran FDA, Jan 2018 | At least $2.0 \times 10^7$ cells per knee; $4.0 \times 10^7$ for both knees | Autologous bone marrow-derived MSCs | Not available |
| RecolorCell<br>Cell Tech Pharmed (Iran) | Focal, segmental or generalised vitiligo | Iran FDA, Feb 2019 | Approx. 70,000 cells/$cm^2$; indicated for patches < 200 $cm^2$ | Autologous human keratinocytes and melanocytes | Not available |

CSF = colony-stimulating factor; DCGI = Drugs Controller General of India; FDA = Food and Drug Administration; MFDS = Ministry of Food and Drug Safety; PMDA = Pharmaceuticals and Medical Devices Agency; MSC = mesenchymal stromal/stem cell

Three operational areas deserve priority (Table 3). First, tissue procurement should document source permissibility, donor welfare, collection risk, storage, secondary use, commercialisation and disposal. Consent for umbilical cord, placenta or paediatric sources should be culturally sensitive without omitting scientific information, privacy protections, chain of identity or chain of custody (4, 12). Second, every ancillary material should undergo source mapping and risk classification. For example, porcine-derived trypsin to avoid clotting of pHPL-supplemented medium is technically effective, but its origin creates a clear Shariah concern, and its use in biological manufacture requires control of adventitious-agent risk (13). Recombinant or animal-origin-free dissociation reagents should be preferred when comparability for cell yield, identity, potency, purity and safety is demonstrated. Another example, the use of qualified human platelet lysate or defined media instead of fetal bovine serum may support clinical-scale mesenchymal stromal cell expansion, but donor screening, pooling strategy, pathogen-risk control and batch qualification remain essential (14–16). When no technically suitable alternative exists, any necessity assessment should be documented and reviewed by scientific, quality and qualified Shariah experts, with referral to competent authorities where certification or *fatwa* implications arise.

Third, facility management should embed Shariah assurance within the manufacturing quality system. Risk-based controls may include approved-material status, supplier qualification, source documentation for cleaning and processing materials, segregated storage, status labelling, line clearance, validated cleaning and

**Table 3.** Proposed operational framework for Shariah-compliant CGTP bioprocessing.

| Bioprocessing checkpoint | Scientific and Shariah issue | Proposed assurance requirement |
|---|---|---|
| Human tissue procurement | Permissibility of the tissue source; donor dignity; collection-related harm; consent for storage, secondary research, genetic use, commercialisation, cross-border transfer and disposal. | Use a source-eligibility matrix and religiously sensitive informed consent that remains scientifically complete. Document donor or authorised-guardian consent, privacy protection, chain of identity and chain of custody (4, 12). |
| Consumables and reagents | Porcine-derived trypsin, fetal bovine serum, animal-derived coatings or supplements and supplier changes may introduce Shariah, adventitious-agent and comparability concerns. | Maintain an ancillary-material register with source declarations and supplier qualification. Prefer validated recombinant or animal-origin-free dissociation reagents; consider qualified human platelet lysate or defined media where suitable. Demonstrate comparability for yield, identity, potency, purity and safety (13–16). |
| Facility and contamination control | Shared equipment, storage, cleaning materials, carryover and unclear material status can compromise product safety and halal integrity. | Apply risk-based material status, segregated storage, line clearance, closed processing where feasible, validated cleaning and disinfection, environmental monitoring, cross-contamination controls and end-to-end traceability. Microbiological efficacy and product safety remain decisive (2, 17). |
| Governance, deviations and product disposition | Blanket prohibition may conflict with clinical necessity, while undocumented exceptions undermine credibility. | Embed a Shariah risk register within the pharmaceutical quality system. Use joint scientific-quality-Shariah review, change control, deviation and CAPA procedures, supplier review and a documented *darurah*/*hajah* pathway. Refer certification or *fatwa* questions to competent authorities. Shariah assurance review must not replace GMP batch disposition or clinical evidence (2, 11, 12). |

CAPA = corrective and preventive action; GMP = Good Manufacturing Practice

disinfection, cross-contamination prevention, closed processing where feasible, deviation management and end-to-end traceability. Microbiological effectiveness, residue control and product safety must remain decisive when disinfectants or processing materials are selected. These measures are compatible with contamination-control and quality-risk-management principles under Pharmaceutical Inspection Co-operation Scheme (PIC/S) Good Manufacturing Practice (GMP) (17). Shariah assurance should therefore function as an additional governance layer, never as a substitute for sterility, identity, potency, GMP batch disposition or clinical evidence.

## Conclusion

Malaysia should refine its CGTP pathway through structured early engagement, coordinated clinical guidance and lifecycle evidence planning. In parallel, the Ministry of Health, National Pharmaceutical Regulatory Agency (NPRA), Department of Islamic Development Malaysia (JAKIM), Standards Malaysia, clinicians, scientists, manufacturers and qualified Islamic scholars should evaluate a CGTP-specific Shariah bioprocessing annex. The proposed framework is not a halal certification ruling or *fatwa*; it is a policy and quality-management proposition for expert development. If implemented without compromising scientific requirements, it could provide Malaysia with a credible first-mover strategy for international leadership in Shariah-compliant regenerative medicine and bioprocessing.

## Declaration of Generative AI and AI-assisted Technologies in the Writing Process

During preparation of this manuscript, the authors used OpenAI ChatGPT to support literature organisation, an early working draft and language refinement. The authors defined the central thesis and substantive recommendations, reviewed the cited primary and official sources, critically revised the manuscript and accept full responsibility for its originality, accuracy and integrity.

## Acknowledgements

The authors thank members of the National Committee of Guideline on Clinical Practice of Regenerative Medicine and Stem Cells, Ministry of Health Malaysia, for advice and critical review during the preparation of this editorial. Their input helped inform the discussion of Shariah-compliant regenerative medicine and bioprocessing in Malaysia. The views and recommendations presented are those of the authors.

## Authors' Contributions

Conception and design: AHAA, MFMB, QHL
Analysis and interpretation of the data: MFMB, QHL
Drafting of the article: AHAA, MFMB, QHL
Critical revision of the article for important intellectual content: AHAA
Final approval of the article: AHAA
Administrative, technical, or logistic support: MFMB, QHL
Collection and assembly of data: MFMB, QHL

## Correspondence

Professor Dato' Sri Dr. Abu Hassan Asaari bin Abdullah
MD (UM), FRCS (Ed), FAMM, FAMS (Spore), FASEM (ASIA), FIMMA (Indo)
Department of Emergency and Trauma,
Hospital Kuala Lumpur,
Jalan Pahang,
50586 Kuala Lumpur, Malaysia
Tel: +603-2615 5555
Email: dsdraha@gmail.com

## References

1. Halimi HM, Meor Mohd Affandi MMR, Karuppannan M, Ab Ghani A. Cell and gene therapy regulation in Malaysia: current pathways and international comparison. *J Appl Pharm Sci*. 2026;**16(3)**:58–74. https://doi.org/10.7324/JAPS.2026.248204

2. National Pharmaceutical Regulatory Agency. Guidance document and guidelines for registration of cell and gene therapy products (CGTPs) in Malaysia. 2nd ed. [Internet]. Petaling Jaya: Ministry of Health Malaysia; 2025 [Retrieved 2026 Jul 23]. Available at: https://www.npra.gov.my/index.php/en/guideline-bio.html

3. National Pharmaceutical Regulatory Agency. Drug registration guidance document (DRGD), 3rd edition, 12th revision July 2026 [Internet]. Petaling Jaya: Ministry of Health Malaysia; 2026 [Retrieved 2026 Jul 23]. Available at: https://www.npra.gov.my/index.php/en/drug-registration-guidance-documents-drgd-e-book

4. Ministry of Health Malaysia. Guidelines on stem cell and cell-based research and therapy. 3rd ed. [Internet]. Putrajaya: Medical Development Division, Ministry of Health Malaysia; 2024 [Retrieved 2026 Jul 23]. Available at: https://www.moh.gov.my/en/publications-and-reports/policies-act-policies-guide-lines/penerbitan-klinikal/senarai-penerbitan-klinikal/perkhidmatan-o-g-dan-pediatrik

5. US Food and Drug Administration. Regenerative Medicine Advanced Therapy designation [Internet]. Silver Spring (MD): US FDA; [Retrieved 2026 Jul 23]. Available at: https://www.fda.gov/vaccines-blood-biologics/cellular-gene-therapy-products/regenerative-medicine-advanced-therapy-designation

6. European Medicines Agency. Advanced therapy medicinal products: overview [Internet]. Amsterdam: EMA; [Retrieved 2026 Jul 23]. Available at: https://www.ema.europa.eu/en/human-regulatory-overview/advanced-therapy-medicinal-products-overview

7. European Medicines Agency. PRIME: priority medicines [Internet]. Amsterdam: EMA; [Retrieved 2026 Jul 23]. Available at: https://www.ema.europa.eu/en/human-regulatory-overview/research-development/prime-priority-medicines

8. Pharmaceuticals and Medical Devices Agency. Regenerative medical products [Internet]. Tokyo: PMDA; [Retrieved 2026 Jul 23]. Available at: https://www.pmda.go.jp/english/review-services/reviews/0003.html

9. Halal Development Corporation. About HDC [Internet]. Petaling Jaya: HDC; [Retrieved 2026 Jul 23]. Available at: https://hdcglobal.com/about-hdc/

10. Malaysia Healthcare Travel Council. Malaysia Healthcare Travel Council and Batik Air forge strategic partnership to elevate Malaysia's medical tourism excellence [Internet]. Kuala Lumpur: MHTC; 2025 [Retrieved 2026 Jul 23]. Available at: https://www.mhtc.org.my/malaysia-healthcare-travel-council-and-batik-air-forge-strategic-partnership-to-elevate-malaysias-medical-tourism-excellence/

11. Department of Standards Malaysia. MS 2424:2019 Halal pharmaceuticals-General requirements. Cyberjaya: Department of Standards Malaysia; 2019.

12. Jabatan Mufti Wilayah Persekutuan. Bayan Linnas Siri Ke-227: penggunaan sel stem dalam perubatan menurut perspektif syarak [Internet]. Putrajaya: Jabatan Mufti Wilayah Persekutuan; 2020 [Retrieved 2026 Jul 23]. Available at: https://muftiwp.gov.my/en/artikel/bayan-linnas/4362-bayan-linnas-siri-ke-227-penggunaan-sel-stem-dalam-perubatan-menurut-perspektif-syarak

13. European Medicines Agency. Guideline on the use of porcine trypsin used in the manufacture of human biological medicinal products [Internet]. Amsterdam: EMA; 2014 [Retrieved 2026 Jul 23]. Available at: https://www.ema.europa.eu/en/use-porcine-trypsin-used-manufacture-human-biological-medicinal-products-scientific-guideline

14. Schallmoser K, Bartmann C, Rohde E, Reinisch A, Kashofer K, Stadelmeyer E, et al. Human platelet lysate can replace fetal bovine serum for clinical-scale expansion of functional mesenchymal stromal cells. *Transfusion*. 2007;**47(8)**:1436–1446. https://doi.org/10.1111/j.1537-2995.2007.01220.x

15. Becherucci V, Piccini L, Casamassima S, Bisin S, Gori V, Gentile F, et al. Human platelet lysate in mesenchymal stromal cell expansion according to a GMP grade protocol: a cell factory experience. *Stem Cell Res Ther*. 2018;**9**:124. https://doi.org/10.1186/s13287-018-0863-8

16. European Medicines Agency. Guideline on the use of bovine serum in the manufacture of human biological medicinal products. Revision 1. EMA/CHMP/BWP/457920/2012 Rev.1 [Internet]. Amsterdam: EMA; 2013 [Retrieved 2026 Oct 13]. Available at: https://www.ema.europa.eu/en/use-bovine-serum-manufacture-human-biological-medicinal-products-scientific-guideline

17. National Pharmaceutical Regulatory Agency. Publication of revised PIC/S Annex 1 [Internet]. Petaling Jaya: Ministry of Health Malaysia; 2022 [Retrieved 2026 Jul 23]. Available at: https://www.npra.gov.my/index.php/en/industry/more-regulations/recent-updates/427-english/announcement-main/announcement-2022/1527399-publication-of-revised-pic-s-annex-1.html