

DAFTAR PUSTAKA

- Andersen, P. H., Åberg, S., & Bujac, A. (2023). Corporate Sustainable Brand Identity Work And Network Embeddedness: Learnings From Better Place (2007–2013). *Industrial Marketing Management*, 115, 526–538. <https://doi.org/10.1016/j.indmarman.2023.10.014>
- Anonim. (t.t.). *PT Bifarma Adiluhung: Overview* | *LinkedIn*. Diambil 8 Desember 2022, dari <https://www.linkedin.com/company/pt-bifarma-adiluhung/?originalSubdomain=id>
- ANTARA. (2021, Juni 11). *Biaya Terapi Sel Punca Bisa Seratusan Juta Tergantung Berat Badan*. *www.antaranews.com*. <https://www.antaranews.com/berita/2205910/biaya-terapi-sel-punca-bisa-seratusan-juta-tergantung-berat-badan>
- ANTARA. (2022, Maret 24). *Industri farmasi nasional tumbuh 10,81 persen selama pandemi - ANTARA News*. <https://www.antaranews.com/berita/2780309/industri-farmasi-nasional-tumbuh-1081-persen-selama-pandemi>
- ASQ. (2023). *What are Stakeholders?* <https://asq.org/quality-resources/stakeholders>
- Badan Pengembangan dan Pembinaan Bahasa. (2016). *KBBI VI Daring*. <https://kbbi.kemdikbud.go.id/entri/cemar>
- Barney, J. (1991). Firm Resources and Sustained Competitive Advantage. *Journal of Management*, 17(1), 99–120. <https://doi.org/10.1177/014920639101700108>
- Baxter, D., Trott, P., & Ellwood, P. (2023). Reconceptualising innovation failure. *Research Policy*, 52(7), 104811. <https://doi.org/10.1016/j.respol.2023.104811>
- Bifarma Adiluhung. (2023). *Bifarma Adiluhung*. <https://bifarma.co.id/id/about/#about-bifarma>
- BKPM. (2021). *Potensi Menjanjikan di Industri Farmasi dan Kesehatan Indonesia* | *BKPM*. <https://www.bkpm.go.id/id/publikasi/detail/berita/potensi-menjanjikan-di-industri-farmasi-dan-kesehatan-indonesia>
- Boushey, H., & Knudsen, H. (2021, Juli 9). *The Importance of Competition for the American Economy*. The White House - CEA. https://www.whitehouse.gov/cea/written-materials/2021/07/09/the-importance-of-competition-for-the-american-economy/#_ftn1
- BPOM. (2015). *Peraturan Kepala Badan Pengawas Obat dan Makanan Nomor 16 Tahun 2015 tentang Tata Laksana dan Penilaian Obat Pengembangan Baru* (Nomor 16 Tahun 2015). <https://jdih.pom.go.id/download/product/719/16/2015>. <https://jdih.pom.go.id/download/product/719/16/2015>

- BPOM. (2017). *Peraturan Kepala Badan Pengawas Obat dan Makanan Nomor 24 Tahun 2017 tentang Kriteria dan Tata Laksana Registrasi Obat*.
<https://jdih.pom.go.id/download/product/769/24/2017>
- BPOM. (2020). *Peraturan Badan Pengawas Obat dan Makanan Nomor 18 tahun 2020 tentang Pedoman Penilaian Obat Berbasis Sel Manusia*.
<https://jdih.pom.go.id/download/product/1124/18/2020>
- BPOM. (2022a). *Keputusan Kepala BPOM Nomor 4 Tahun 2022 tentang Perubahan Keempat atas Keputusan Kepala BPOM Nomor HK.02.02.1.2.11.20.1126 Tahun 2020 tentang Petunjuk Teknis Pelaksanaan Persetujuan Penggunaan Darurat (Eergency Use Authorization)*.
- BPOM. (2022b). *Peraturan Badan Pengawas Obat dan Makanan Nomor 18 Tahun 2022 tentang Pedoman Cara Pembuatan Obat yang Baik di Sarana Pengolahan Produk Berbasis Sel dan Jaringan Manusia*.
<https://jdih.pom.go.id/download/product/1397/18/2022>
- BRIN. (2021). *Riset dan Inovasi Penanganan Covid-19*. <https://pendanaan-risnov.brin.go.id/program/eyJpdil6IjRTbGNwWFRoRklxaDh6eWJkNW42RUE9PSIsInZhbHVlIjoibzF1Yi9mbiZDaitsYWZaK21mVTV0Zz09IiwibWFjIjoiiNzYzNWVhMzVhMzE1ZTBiYzk5MmYzNTkwZDExOTIxM2NhNGNmMTY5M2FkOTM4NDdkOGEzYWVhMmNlY2ZjMGNiNCIsInRhZyI6IiJ9>
- Burhan, E., Dwi Susanto, A., Isbaniah, F., Aman Nasution, S., Ginanjar, E., Wicaksono Pitoyo, C., Susilo, A., Firdaus, I., Santoso, A., Arifa Juzar, D., Kamsul Arif, S., Lolong Wulung, N. G., Muchtar, F., Pulungan, A. B., Basarah Yanuarso, P., Ambara Sjakti, H., Prawira, Y., Dwi Putri TIM PENYUSUN Erlina Burhan, N., Adityaningsih, D., ... Dharmawan, I. (2020). *Pedoman Tatalaksana COVID-19 Edisi 4*.
- Capelli, C., Frigerio, S., Lisini, D., Nava, S., Gaipa, G., Belotti, D., Cabiati, B., Budelli, S., Lazzari, L., Bagnarino, J., Tanzi, M., Comoli, P., Perico, N., Introna, M., & Golay, J. (2022). A Comprehensive Report Of Long-Term Stability Data For A Range ATMPs: A Need To Develop Guidelines For Safe And Harmonized Stability Studies. *Cytotherapy*, 24(5), 544–556. <https://doi.org/10.1016/j.jcyt.2021.12.004>
- Chen, J., Yin, X., & Mei, L. (2018). Holistic Innovation: An Emerging Innovation Paradigm. *International Journal of Innovation Studies*, 2(1), 1–13.
<https://doi.org/10.1016/j.ijis.2018.02.001>
- Chen, X., Liu, B., Li, C., Wang, Y., Geng, S., Du, X., Weng, J., & Lai, P. (2023). Stem Cell-Based Therapy For COVID-19. *International Immunopharmacology*, 124, 110890. <https://doi.org/10.1016/j.intimp.2023.110890>
- Cooper, R. G. (2010). The Stage-Gate Idea to Launch System. Dalam *Wiley International Encyclopedia of Marketing*. Wiley.
<https://doi.org/10.1002/9781444316568.wiem05014>

- Cooper, R. G. (2021). Accelerating Innovation: Some Lessons From The Pandemic. *Journal of Product Innovation Management*, 38(2), 221–232.
<https://doi.org/10.1111/jpim.12565>
- Delgado-Hito, P., & Romero-García, M. (2021). ELABORATION OF A RESEARCH PROJECT USING QUALITATIVE METHODOLOGY. Dalam *Enfermería Intensiva* (Vol. 32, Nomor 3, hlm. 164–169). Ediciones Doyma, S.L.
<https://doi.org/10.1016/j.enfi.2021.03.001>
- Derbyshire, J., & Giovannetti, E. (2017). Understanding The Failure To Understand New Product Development Failures: Mitigating The Uncertainty Associated With Innovating New Products By Combining Scenario Planning And Forecasting. *Technological Forecasting and Social Change*, 125, 334–344.
<https://doi.org/10.1016/j.techfore.2017.02.007>
- EMA. (2009). *ICH guideline Q8 (R2) on pharmaceutical development*.
www.ema.europa.eu/contact
- EMA. (2023). *Scientific Recommendations On Classification Of Advanced Therapy Medicinal Products | European Medicines Agency*.
<https://www.ema.europa.eu/en/human-regulatory/marketing-authorisation/advanced-therapies/advanced-therapy-classification/scientific-recommendations-classification-advanced-therapy-medicinal-products>
- Emerson, J., & Glassey, J. (2021). Bioprocess Monitoring And Control: Challenges In Cell And Gene Therapy. *Current Opinion in Chemical Engineering*, 34, 100722.
<https://doi.org/10.1016/J.COCHE.2021.100722>
- Engert, S., Rauter, R., & Baumgartner, R. J. (2016). Exploring The Integration Of Corporate Sustainability Into Strategic Management: A Literature Review. *Journal of Cleaner Production*, 112, 2833–2850.
<https://doi.org/10.1016/j.jclepro.2015.08.031>
- Eri, S., Nuraini, R., & Sari, E. I. (2021, Mei 22). *Potensi Besar Industri Kesehatan Dalam Negeri*. Indonesia.go.id. <https://indonesia.go.id/kategori/editorial/2811/potensi-besar-industri-kesehatan-dalam-negeri>
- Eriksson, K., & McConnell, A. (2011). Contingency Planning For Crisis Management: Recipe For Success Or Political Fantasy? *Policy and Society*, 30(2), 89–99.
<https://doi.org/10.1016/J.POLSOC.2011.03.004>
- Fai Poon, H., Wu, F., Shen, L., & De Smet, F. (2019). Quality By Design (QBD) Concept: A Potential Solution To Chinese Current Biomanufacturing Challenges. *Biomedical and Pharmacology Journal*, 12(2), 499–502.
<https://doi.org/10.13005/bpj/1668>
- Fakhreddin, F., & Foroudi, P. (2022). The Impact of Market Orientation on New Product Performance Through Product Launch Quality: A Resource-Based View. *Cogent Business & Management*, 9(1). <https://doi.org/10.1080/23311975.2022.2108220>

- Fischer, P., Reiss, T., Mahlich, J., Gicquel, E., Aichinger, H., Pullmann, L., & Bratan, T. (2023). Unlocking The Value Of Innovative Medicines: Insights From The Advanced Therapy Medicinal Products (ATMP) Innovation Systems In Germany And Sweden. *Health Policy and Technology*, 12(2), 100744. <https://doi.org/10.1016/J.HLPT.2023.100744>
- Fogel, D. B. (2018). *Factors Associated With Clinical Trials That Fail And Opportunities For Improving The Likelihood Of Success: A Review*. <https://doi.org/10.1016/j.conctc.2018.08.001>
- Freeman, R. E., Dmytriiev, S. D., & Phillips, R. A. (2021). Stakeholder Theory and the Resource-Based View of the Firm. *Journal of Management*, 47(7), 1757–1770. <https://doi.org/10.1177/0149206321993576>
- Gurbuz, E. (2018). Theory of New Product Development and Its Applications. Dalam *Marketing*. InTech. <https://doi.org/10.5772/intechopen.74527>
- Halo IOSSMA Edisi 3: Maret 2022. (2022, Maret). <https://iossma.or.id/bulletin-iossma/>
- Han, F., Wang, J., Ding, L., Hu, Y., Li, W., Yuan, Z., Guo, Q., Zhu, C., Yu, L., Wang, H., Zhao, Z., Jia, L., Li, J., Yu, Y., Zhang, W., Chu, G., Chen, S., & Li, B. (2020). Tissue Engineering and Regenerative Medicine: Achievements, Future, and Sustainability in Asia. *Frontiers in Bioengineering and Biotechnology*, 8. <https://doi.org/10.3389/fbioe.2020.00083>
- Hosseini, A. S., Soltani, S., & Mehdizadeh, M. (2018). Competitive Advantage and Its Impact on New Product Development Strategy (Case Study: Toos Nirro Technical Firm). *Journal of Open Innovation: Technology, Market, and Complexity* 2018, Vol. 4, Page 17, 4(2), 17. <https://doi.org/10.3390/JOITMC4020017>
- ICH. (2009). *Guidance for Industry: Q8(R2) Pharmaceutical Development*. <http://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/default.htm>
- Inpres No. 6 (2016). <https://peraturan.bpk.go.id/Details/77336/inpres-no-6-tahun-2016>
- Iskandar, D. (2021). *Metodologi Penelitian Kualitatif: Petunjuk Praktis untuk Penelitian Lapangan, Analisis Teks Media, dan Kajian Budaya* (M. I. Dawami, Ed.; 1 ed.). Maghza Pustaka. https://books.google.co.id/books?id=hHeDEAAAQBAJ&pg=PA78&hl=id&source=gbs_toc_r&pli=1#v=onepage&q&f=false
- Kantabutra, S., & Ketprapakorn, N. (2020). Toward A Theory Of Corporate Sustainability: A Theoretical Integration And Exploration. *Journal of Cleaner Production*, 270, 122292. <https://doi.org/10.1016/j.jclepro.2020.122292>
- Kemendikbud. (2016). *KBBI VI Daring*. <https://kbbi.kemdikbud.go.id/entri/gagal>
- Kemenkes. (2020, Januari 16). *Kementerian Kesehatan Republik Indonesia: Stem Cell Tak Bebas Dijualbelikan*.

<https://www.kemkes.go.id/article/view/20011700001/stem-cell-tak-bebas-dijualbelikan.html>

- Keppres RI. (2023). *Keputusan Presiden Republik Indonesia Nomor 17 Tahun 2023 tentang Penetapan Berakhirnya Status Pandemi Corona Virus Desease (COVID-19) di Indonesia*.
- Kharb, M., & Rathore, K. S. (2022). QbD Approach: A Framework for Integrating Quality into Pharmaceutical Products. *Journal of Pharmaceutical Research International*, 1–11. <https://doi.org/10.9734/jpri/2022/v34i12A35854>
- Kimbrel, E. A., & Lanza, R. (2020). Next-generation Stem Sells — Ushering in A New Era of Cell-based Therapies. *Nature Reviews Drug Discovery*, 19(7), 463–479. <https://doi.org/10.1038/s41573-020-0064-x>
- Kotler, P., Armstrong, G., & Opresnik, M. O. (2018). *Principles of Marketing: Global Edition* (17 ed.). Pearson Education.
- Kotler, P., & Keller, K. L. (2016). *Marketing management: Global Edition* (15 ed.). Pearson Education Limited.
- Kurniawan, A., Ivansyah, M. D., Dilogu, I. H., & Hutami, W. D. (2023). Umbilical Cord Mesenchymal Stem Cells Combined With Secretome For Treating Congenital Pseudarthrosis Of The Tibia: A Case Series. *European Journal of Orthopaedic Surgery and Traumatology*, 33(7), 2881–2888. <https://doi.org/10.1007/S00590-023-03511-3/METRICS>
- Kusnandar, V. B. (2022, Maret 29). *Industri Kimia, Farmasi, dan Obat Tradisional Terus Tumbuh di Masa Pandemi Covid-19*. Katadata.co.id. <https://databoks.katadata.co.id/datapublish/2022/03/29/industri-kimia-farmasi-dan-obat-tradisional-terus-tumbuh-di-masa-pandemi-covid-19>
- Kuzma, E., Padilha, L. S., Sehnem, S., Julkovski, D. J., & Roman, D. J. (2020). The Relationship Between Innovation And Sustainability: A Meta-Analytic Study. *Journal of Cleaner Production*, 259, 120745. <https://doi.org/10.1016/j.jclepro.2020.120745>
- Lazar, J., Feng, J. H., & Hochheiser, H. (2017). Analyzing Qualitative Data. Dalam *Research Methods in Human Computer Interaction* (hlm. 299–327). Elsevier. <https://doi.org/10.1016/B978-0-12-805390-4.00011-X>
- Lestari, D., & Nurjanah, S. (2022). Mengukur Kinerja yang Ditinjau Dari Inovasi dan Governance. *Journal of Business and Economics Research (JBE)*, 3(1), 16–22. <https://doi.org/10.47065/jbe.v3i1.1343>
- Lucion, D., Ghinelli, F., Buxton, J., Wright, J., Steeds, C., Hall, S., & Buchholz, P. (2023). HTA256 Identifying Current ATMP Market Access Challenges and Strategies in France, Germany, Italy, and Spain. *Value in Health*, 26(12), S369–S370. <https://doi.org/10.1016/j.jval.2023.09.1939>

- Luo, Q., Zheng, Y., & Zhang, J. (2022). Combination Therapies Against COVID-19. *Front. Biosci. (Landmark Ed)* 2022;, 27(9), 257. <https://doi.org/10.31083/j.fbl2709257>
- Maillot, C., Sion, C., Isla, N. De, Toye, D., & Olmos, E. (2021). Quality By Design To Define Critical Process Parameters For Mesenchymal Stem Cell Expansion. *Biotechnology Advances*, 50. <https://doi.org/10.1016/j.biotechadv.2021.107765>
- Melani, A. (2021, Juni 26). *Melihat Peta Persaingan Sektor Farmasi di Indonesia*. Liputan6.com. <https://www.liputan6.com/saham/read/4591906/melihat-peta-persaingan-sektor-farmasi-di-indonesia>
- Miles, M. B., Huberman, A. M., & Saldaña, J. (2020). *Qualitative Data Analysis : A Methods Sourcebook Fourth Edition* (S. Helen, Ed.; 4 ed.). SAGE Publications, Inc.
- Müzes, G., & Sipos, F. (2022). Mesenchymal Stem Cell-Derived Secretome: A Potential Therapeutic Option for Autoimmune and Immune-Mediated Inflammatory Diseases. *Cells*, 11(15), 2300. <https://doi.org/10.3390/cells11152300>
- NIH. (2016). *NIH Stem Cell Information: Stem Cell Basic*. NIH Stem Cell Information Home Page. <https://stemcells.nih.gov/info/basics/stc-basics>
- Patel, H., Parmar, S., & Patel, B. (2013). A Comprehensive Review On Quality By Design (Qbd) In Pharmaceuticals. *International Journal of Pharmaceutical Sciences Review and Research*, 21(1), 223–236. www.globalresearchonline.net
- Permenkes Nomor 32, BN.2018/NO.993, kemkes.go.id (2018). <https://peraturan.bpk.go.id/Details/111942/permenkes-no-32-tahun-2018>
- Precedence Research. (2021, Juni 29). *Regenerative Medicine Market Size to Hit US\$ 23.7 Bn by 2027*. <https://www.globenewswire.com/news-release/2021/06/29/2254925/0/en/Regenerative-Medicine-Market-Size-to-Hit-US-23-7-Bn-by-2027.html>
- Rathore, A. S. (2014). QbD/PAT For Bioprocessing: Moving From Theory To Implementation. *Current Opinion in Chemical Engineering*, 6, 1–8. <https://doi.org/10.1016/j.coche.2014.05.006>
- Renwarin, J. M. J., Aji, W. W., Weley, A. B., & Tannady, H. (2022). Does Dynamic Capability, Managerial Competency and Organization Capability Still Relevant on Business Sustainability: Study of Indonesia Freight Forwarding Industry. *Proceeding International Conference on Entrepreneurship (IConEnt) Sustainability Of Cultural Entrepreneurship*, 295–300.
- Research and Market. (2021). *ASEAN Pharmaceutical Manufacturing Market 2017-2027 by Formulation and Country: Trend Forecast and Growth Opportunity*. <https://www.researchandmarkets.com/reports/5310318/asean-pharmaceutical-manufacturing-market-2017>
- Salmikangas, P. (2014). Challenges During The Development Of ATMPs. Dalam *CAT-DGTI Workshop*.

- Sampathkumar, K., & Kerwin, B. A. (2023). Roadmap for Drug Product Development and Manufacturing of Biologics. *Journal of Pharmaceutical Sciences*.
<https://doi.org/10.1016/J.XPHS.2023.11.004>
- Serra, M., Cunha, B., Peixoto, C., Gomes-Alves, P., & Alves, P. M. (2018). Advancing Manufacture Of Human Mesenchymal Stem Cells Therapies: Technological Challenges In Cell Bioprocessing And Characterization. Dalam *Current Opinion in Chemical Engineering* (Vol. 22, hlm. 226–235). Elsevier Ltd.
<https://doi.org/10.1016/j.coche.2018.11.003>
- Setiabudy, R. (2021, Juli 10). *Penelitian Berbasis Pelayanan dalam Pengembangan Obat*. *kompas.id*. <https://www.kompas.id/baca/opini/2021/07/10/penelitian-berbasis-pelayanan-dalam-pengembangan-obat>
- Setyahadi, R. R., & Narsa, I. M. (2020). Corporate Governance and Sustainability in Indonesia. *The Journal of Asian Finance, Economics and Business*, 7(12), 885–894.
<https://doi.org/10.13106/jafeb.2020.vol7.no12.885>
- Seyhan, A. A. (2019). Lost In Translation: The Valley Of Death Across Preclinical And Clinical Divide – Identification Of Problems And Overcoming Obstacles. *Translational Medicine Communications* 2019 4:1, 4(1), 1–19.
<https://doi.org/10.1186/S41231-019-0050-7>
- Shanley, A. (2021). Can Cell and Gene Therapies Achieve Their Full Potential? *BioPharm International*, 34(01). <https://www.biopharminternational.com/view/can-cell-and-gene-therapies-achieve-their-full-potential->
- Soetjahjo, B., Malueka, R. G., Nurudhin, A., Purwoko, Sumardi, Wisaksana, R., Adhiputri, A., Sudadi, Soeroto, A. Y., Sidharta, B. R. A., Thobari, J. A., Murni, T. W., Soewondo, W., Herningtyas, E. H., Sudjud, R. W., Trisnawati, I., Ananda, N. R., & Faried, A. (2023). Effectiveness And Safety Of Normoxic Allogenic Umbilical Cord Mesenchymal Stem Cells Administered As Adjunctive Treatment In Patients With Severe COVID-19. *Scientific Reports*, 13(1), 12520.
<https://doi.org/10.1038/s41598-023-39268-2>
- Stacey, G. N., Connon, C. J., Coopman, K., Dickson, A. J., Fuller, B., Hunt, C. J., Kemp, P., Kerby, J., Man, J., Matejtschuk, P., Moore, H., Morris, J., Oreffo, R. O. C., Slater, N., Ward, S., Wiggins, C., & Zimmermann, H. (2017). Preservation And Stability Of Cell Therapy Products: Recommendations From An Expert Workshop. *Regenerative Medicine*, 12(5), 553–564. <https://doi.org/10.2217/rme-2017-0073>
- Statista. (2023, Januari). *Pharmaceuticals - ASEAN | Statista Market Forecast*. Health Market Insight. <https://www.statista.com/outlook/hmo/pharmaceuticals/asean>
- Sun, D., Gao, W., Hu, H., & Zhou, S. (2022). Why 90% Of Clinical Drug Development Fails And How To Improve It? *Acta Pharmaceutica Sinica B*, 12(7), 3049–3062.
<https://doi.org/10.1016/j.apsb.2022.02.002>
- Tempo. (2021, Juni 13). *FKUI: Biaya Terapi Stem Cell untuk Pasien Covid-19 Kritis Seratus Jutaan*. *tempo.co*. <https://tekno.tempo.co/read/1472024/fkui-biaya-terapi-stem-cell-untuk-pasien-covid-19-kritis-seratus-jutaan>

- Thompson, A. A., Gamble, J. E., Peteraf, M. A., & Strickland, A. J. (2022). *Crafting And Executing Strategy: The Quest For Competitive Advantage, Concepts and Cases* (23 ed.).
- Yang, C.-L., & Hsu, H.-K. (2019). Optimized New Product Development Strategy. Dalam *The International Journal of Organizational Innovation* (Vol. 12). <http://www.ijoi-online.org/>

