

DAFTAR PUSTAKA

- Adiputra, I. M. S., Marsono, S., Pramana, A. A., & Wirawan, I. M. (2021). *Metodologi penelitian kesehatan*. Yayasan Kita Menulis.
- Agustyani, V., Utami, W., Sumaryono, W., Athiyah, U., & Rahem, A. (2017). Evaluation of CDOB implementation as quality assurance system at PBF in Surabaya. *Jurnal Ilmu Kefarmasian Indonesia*, 15(1), 70–76.
- Aliefiani, M. P., Maharani, S. P., & Nisrina, G. (2022). LITERATURE VIEW PENGORGANISASIAN: SDM, Tujuan Organisasi dan Struktur Organisasi. *Jurnal Ekonomi Manajemen Sistem Informasi*, 3(3), 286–299.
- Ananda, D. (2021). Pelaksanaan Cara Distribusi Obat yang Baik di pedagang besar farmasi X di Kota Jambi. *Jurnal Dunia Farmasi*, 6(1), 21–25.
- Alemayehu, C., Tadesse, T., & Demis, A. (2020). Assessment of pharmaceutical storage and distribution practices in public health facilities. *Journal of Pharmaceutical Policy and Practice*, 13(1), 1–9. <https://doi.org/10.1186/s40545-020-00222-0>.
- Alshakka, M., Ibrahim, M. I. M., Hassali, M. A., & Shafie, A. A. (2021). Quality assurance systems in pharmaceutical distribution: A review. *Saudi Pharmaceutical Journal*, 29(5), 456–463. <https://doi.org/10.1016/j.jsps.2021.03.003>.
- Alshammari, T. M., Alharbi, M. F., Alshammari, A. M., & Alenzi, K. A. (2023). Implementation challenges of pharmaceutical quality systems and good distribution practices in healthcare supply chains: A systematic review. *Healthcare*, 11(8), 1–18.
- Badan POM RI. (2025). *Peraturan Badan Pengawas Obat dan Makanan Nomor 20 Tahun 2025 tentang Standar Cara Distribusi Obat yang Baik*. Jakarta: BPOM RI.
- Barney, J., 1991. Firm resources and sustained competitive advantage. *Journal of Management*, 17(1), pp.99–120
- Boadu, M., et al. (2020). Evaluation of good distribution practices compliance in pharmaceutical supply chains. *International Journal of Pharmacy Practice*, 28(6), 560–568.
- Boonstra, A., Versluis, A., & Vos, J. F. J. (2021). Implementing risk management in pharmaceutical supply chains. *Health Policy*, 125(7), 890–897. <https://doi.org/10.1016/j.healthpol.2021.04.002>

- Cahyaningrum, Y. A. (2023). *Evaluasi penerapan cara distribusi obat yang baik sebagai sistem manajemen mutu pada pedagang besar farmasi di wilayah Madiun* (Tesis Magister, Universitas Gadjah Mada). Universitas Gadjah Mada.
- Carucci, R., & Shappell, J. (2022). Design your organization to match your strategy. *Harvard Business Review*.
- Chinajitphan, P., & Kittithreerapronchai, O. (2024). Implementation of good distribution practice in a Thai pharmaceutical manufacturer. *Science, Engineering and Health Studies*, 18, 24040003.
- CIOMS. (2016). *International Ethical Guidelines for Health-related Research Involving Humans*. Geneva: Council for International Organizations of Medical Sciences.
- Creswell, J. W., & Plano Clark, V. L. (2018). *Designing and conducting mixed methods research* (3rd ed.). SAGE Publications.
- Creswell, J. W., & Poth, C. N. (2018). **Qualitative inquiry and research design: Choosing among five approaches** (4th ed.). Sage Publications.
- Cvetanovski, F., Koccev, N., Tonic-Ribarska, J., & Trajkovic-Jolevska, S. (2020). Good Distribution Practice in preserving the integrity and safety of the supply chain of pharmaceuticals. *Macedonian Pharmaceutical Bulletin*, 66(3), 193–194.
- Deloitte. T.H., (2019). *The role of distributors in the US health care industry*. Healthcare Distribution Alliance, 36.
- Departemen Kesehatan RI. (2009). *Pedoman teknis distribusi obat*. Jakarta: Departemen Kesehatan RI.
- Dewi, A.S., (2019). *Evaluasi Penerapan Pedoman Cara Distribusi Obat Yang Baik (CDOB) Oleh Sarana Distribusi Obat Dengan Pendekatan CIPP*. Universitas Airlangga.
- Ditwas ONPP. (2024). *Laporan tahunan Direktorat Pengawasan Distribusi dan Pelayanan ONPP Tahun 2024*. Jakarta: BPOM RI.
- Deming, W.E., 1986. *Out of the Crisis*. Cambridge, MA: MIT Press.
- Etikan, I., Musa, S. A., & Alkassim, R. S. (2016). Comparison of convenience sampling and purposive sampling. *American Journal of Theoretical and Applied Statistics*, 5(1), 1–4.

- European Medicines Agency. (2021). *Guidelines on good distribution practice of medicinal products for human use*. Amsterdam: European Medicines Agency.
- Getahun, K. T., Bilal, A. I., & Cho, D. J. (2025). Public sector pharmaceutical distribution system and its challenges: A case of a central Ethiopian Pharmaceuticals Supply Service and selected branches. *BMC Health Services Research*, 25, 278.
- Hidayat, R., & Dharma, S.(2020). Evaluasi sistem distribusi sediaan farmasi dan alat kesehatan pada PBF di Jakarta. *Jurnal Kesehatan*.
- ISO. (2015). *ISO 9001:2015 Quality Management Systems – Requirements*. Geneva: International Organization for Standardization.
- International Council for Harmonisation. (2023). *ICH Q9(R1): Quality risk management*. Geneva: ICH.
- Kementerian Kesehatan RI. (2011). *Pedoman pembinaan Pedagang Besar Farmasi*. Jakarta: Kemenkes RI.
- Khoirunnisa, A., & Husni, P. (2023). Pengkajian penerapan cara distribusi obat yang baik mengenai obat golongan psikotropika pada salah satu pedagang besar farmasi di Kota Bandung.
- Kumar, S., Liu, Y., & Scudder, G. (2022). Managing cold chain logistics in pharmaceutical distribution. *Journal of Supply Chain Management*, 58(3), 75–88. <https://doi.org/10.1111/jscm.12278>
- Kwon, I. W. G., Kim, S. H., & Martin, D. (2022). Pharmaceutical recall management systems and quality compliance. *International Journal of Healthcare Management*, 15(4), 345–352.
- Lintogareng, O. J., Lolo, W. A., & Rundengan, G. E. (2022). Implementation of Good Distribution Practices for pharmaceutical wholesalers at PT Parit Padang Global. *JM Pharmacon*, 11.
- Miles, M.B., Huberman, A.M., & Saldaña, J. (2014). *Qualitative data analysis: A methods sourcebook* (3rd ed.). Thousand Oaks: SAGE Publications.
- Mwakyeja, B., & Kimario, H. F. (2024). Save life! Optimization of dynamics for pharmaceutical distribution performance. *Management Matters*, 21(2), 93–116.
- Mughnitiyas, A., & Indradi, R. B. (2025). Evaluasi pemenuhan aspek Cara Distribusi Obat yang Baik (CDOB) pada pedagang besar farmasi (PBF) dan PBF

cabang di bawah pengawasan Balai Besar POM di Bandung periode Januari–Juli 2024. *An Najat*, 3(1), 91–103.

Nebot Giralt, A., Bourasseau, A., White, G., Pouget, C., Tabernero, P., Van Assche, K., & Ravinetto, R. (2020). Quality assurance systems of pharmaceutical distributors in low-income and middle-income countries: Weaknesses and ways forward. *BMJ Global Health*, 5(10), e003147.

Nguyen, T. T., Nguyen, T. H., & Nguyen, T. N. (2021). Workforce capacity and pharmaceutical logistics system performance. *Research in Social and Administrative Pharmacy*, 17(5), 912–918. <https://doi.org/10.1016/j.sapharm.2020.08.012>

Okafor, U. G., Ekeocha, Z., Byrn, S., Clase, K., & Shiihii, S. (2022). Development of an assessment tool for Good Distribution Practice for a regulatory agency in West Africa (BIRS Africa Technical Report Paper No. 16; TR-BIRSAFRICA-2022-2). Purdue University.

Patton, M. Q. (2015). *Qualitative research and evaluation methods* (4th ed.). Sage Publications.

Peek, S. (2022). How do pharmaceutical wholesalers work? *Business.com.* <https://www.business.com/articles/pharmaceutical-wholesalers/>.

Pemerintah Republik Indonesia. 2025. Peraturan Pemerintah Nomor 28 Tahun 2025 tentang Penyelenggaraan Perizinan Berusaha Berbasis Risiko. Jakarta: Lembaran Negara Republik Indonesia Tahun 2025. Tersedia pada: <https://peraturan.bpk.go.id/Details/319773/pp-no-28-tahun-2025>.

PIC/S. (2014). *Guide to good distribution practice for medicinal products*. Geneva: Pharmaceutical Inspection Co-operation Scheme.

Pharmaceutical Inspection Co-operation Scheme. (2021). *Guide to good distribution practice for medicinal products*. Geneva: PIC/S.

Putra, A. A. P., & Hartini, Y. S. (2012). *Implementasi cara distribusi obat yang baik pada pedagang besar farmasi di Yogyakarta*.

Putri, M. F. F. D., & Dandan, K. L. (2023). Implementasi kepatuhan pelaksanaan Cara Distribusi Obat yang Baik terkait produk khusus psikotropika dan obat mengandung prekursor farmasi di PBF PT “X” di Kota Tasikmalaya. *Majalah Farmasetika*, 8(3), 224.

Pratiwi, R., et al. (2024). Traceability systems in pharmaceutical distribution: A systematic review. *Journal of Pharmaceutical Policy and Practice*, 17(1),

1–12.

Rachmayanti, A. S., Badar, M., Wulandari, C., Sammulia, S. F., Haryani, R., & Hasan, N. (2023). Gambaran pelaksanaan penyimpanan Cara Distribusi Obat yang Baik dan Benar (CDOB) di PBF BUMN dan non-BUMN Kota Batam. *Jurnal General Health and Pharmaceutical Science Research*, 1(2), 20–30.

Rahman, M., et al. (2023). Transport validation and pharmaceutical distribution quality systems. *International Journal of Pharmacy Practice*, 31(4), 400–408

Sari, D., et al. (2023). Evaluation of distribution facilities compliance with CDOB standards in Indonesia. *Jurnal Manajemen Farmasi*, 13(1), 22–30.

Setiawan, A., et al. (2022). Documentation and traceability challenges in pharmaceutical supply chains. *Jurnal Farmasi Indonesia*, 19(2), 101–110

Sastroasmoro, S., & Ismael, S. (2014). *Dasar-dasar metodologi penelitian klinis* (5th ed.). Jakarta: Sagung Seto.

Sembiring, D., & Wathoni, N. (2021). Evaluasi pelaksanaan pendistribusian cold chain product (CCP) oleh pedagang besar farmasi (PBF) di Kota Bandung. *Majalah Farmasetika*, 6(4), 300.

Sutrisno, E., et al. (2022). Internal audit practices in pharmaceutical distribution facilities. *Jurnal Manajemen Kesehatan*, 10(2), 101–110.

Shargel, L., (2016). *Applied biopharmaceutics & pharmacokinetics*, 7th ed. McGraw- Hill, New York.

Silverman, D. (2020). *Qualitative research* (5th ed.). Sage Publications.

Sugiyono. (2019). *Metode penelitian kuantitatif, kualitatif, dan R & D*. Bandung: Alfabeta.

Sugiyono. (2017). *Metode penelitian kuantitatif, kualitatif, dan R&D*. Alfabeta.

Tandililing, R ., (2024). Quality assurance system for pharmaceutical wholesalers (PBF) by implementing Good Drug Distribution Methods (CDOB) in Jayapura City. *Formosa Journal of Science and Technology*, 3(7), 1511–1520.

Tashakkori, A., & Teddlie, C. (2010). *Mixed methods in social and behavioral research* (2nd ed.). Sage Publications.

- Van Assche, K., Nebot Giral, A., Caudron, J. M., Schiavetti, B., Pouget, C., Tsoumanis, A., Meessen, B., & Ravinetto, R. (2018). Pharmaceutical quality assurance of local private distributors: A secondary analysis in 13 low- income and middle-income countries. *BMJ Global Health*, 3(3), e000771.
- World Health Organization. (2010). *WHO good distribution practices for pharmaceutical products* (Annex 5, WHO Technical Report Series, No. 957). Geneva: WHO.
- World Health Organization. (2018). *WHO Technical Report Series: Good Distribution Practices*. Geneva: WHO.
- Wijaya, M., & Chan, A. (2019). Evaluasi pelaksanaan Cara Distribusi Obat di PBF Rajawali Nusindo. *Jurnal Dunia Farmasi*, 2(3), 148–159.
- Yin, R. K. (2018). *Case study research and applications: Design and methods* (6th ed.). Sage Publications.
- Yadav, P., Tata, H. L., & Babaley, M. (2021). Improving public health supply chains through effective logistics management. *Global Health Science and Practice*, 9(2), 300–312. <https://doi.org/10.9745/GHSP-D-20-00426>
- Yusuf, M., & Avanti, C. (2020). CDOB dan implementasinya oleh PBF di Kota Banjarbaru dan Banjarmasin. *Jurnal Ilmiah Farmasi*.
- Yin, R. K. (2018). *Case study research and applications: Design and methods* (6th ed.). SAGE Publications.