

## DAFTAR PUSTAKA

- Ahmed M., dan Ahmad N., 2011, An Application of Pareto Analysis and Cause-and-Effect Diagram (CED) For Minimizing Rejection of Raw Materials in Lamp Production Process, *Management science and engineering*, 5(3): 87-95.
- Alatas, A. H., dan Putri, R. J. K., 2017, Identifikasi Human Error Pada Proses Produksi Cassava Chips dengan Menggunakan Metode Sherpa dan Heart di PT. Indofood Fritolay Makmur, *Jurnal PASTI*, XI(1): 98–110.
- Ammerman, M., 1998, *The Root Cause Analysis Handbook*, Gramedia.
- Andersen, B., dan Fagerhaug, T., 2006, *Root cause analysis: simplified tools and techniques*, Quality Press.
- Bell, J., dan Holroyd, J., 2009, *Review of Human Reliability Assessment Methods*, Health & Safety Laboratory, 78.
- BPOM, 2018, *Peraturan Badan Pengawas Obat dan Makanan Nomor 34 Tahun 2018 Pedoman Cara Pembuatan Obat yang Baik*, BPOM RI, Jakarta.
- British Retail Consortium, 2012, *Understanding Root Cause Analysis*, British Retail Consortium, UK.
- Corcoran, Jacqueline, dan Ann N.C., 2004, Risk and Resilience Ecological Framework for Assessment and Goal Formulation, *Child and Adolescent Social Work Journal*, 21(3): 211-235.
- Coccia, M., 2018, The Fishbone Diagram to Identify, Systematize and Analyze the Sources of General Purpose Technologies, *Journal of Social and Administrative Sciences*, 4(4):291-303.
- De-Mast, J., Lokkerbol, J., 2012, An Analysis of The Six Sigma DMAIC Method from the Perspective of Problem Solving, *International Journal of Production Economics*, 139(2):604-14.
- Dewi, H., Maryam, M., dan Sutyarno, D., 2018, Analisa Produk Cacat Menggunakan Metode Peta Kendali P dan Root Cause Analysis, *Jurnal Teknologi Pertanian*, 7(2), 10–18.
- Ding, S.H., Muhammad, N.A., Zulkurnaini, N.H., Khaider, A.N., dan Kamaruddin, S., 2013, Production System Improvement by Integration of FMEA with 5-WHYS Analysis, *InAdvanced Materials Research*, 748:1203-1207.
- Dogget, A.M., 2005, Root Cause Analysis: A Framework for Tool Selection, *The Quality Management Journal*, 34.
- Ershadi, M.J., Aiasi, R., dan Kazemi, S., 2018, Root cause analysis in quality problem solving of research information systems: a case study, *International Journal of Productivity and Quality Management*, 24(2):284-99.
- European Medicines Agency, 2018, *Guidance on good manufacturing practice and good distribution practice: Questions and answers*, <https://www.ema.europa.eu/en/human-regulatory/research/development/compliance/good-manufacturingpractice/guidance-good-manufacturing-practice-good-distribution-practice-questions-answers>, 20 Mei 2018.

- Haleem, M.R., Saleem, Y.M., Fatahallah, F.A., dan Abdelfattah, E.L., 2013, Quality in the pharmaceutical industry, *Saudi Pharmaceut J.*
- Hajiagha, S.H., Hashemi, S.S., Mohammadi, Y., Zavadskas, E.K., 2016, Fuzzy belief Structure Based VIKOR Method: An Application for Ranking Delay Causes of Tehran Metro System by FMEA Criteria, *Transport*, 31(1):108-118.
- Kaushik, P., 2011, Relevance of Six Sigma Line of Attack in SMEs: A Case Study of a Die Casting Manufacturing Unit, *Journal of Engineering dan Technology*, 1(2): 107- 113.
- Kumbhar, K.N., 2018, *Brainstorming Technique: Innovative Quality Management Tool for Library*, Current Trends in Library Management.
- Kuswardana, A., Eka, N., dan Natsir, H., 2017, *Analisis Penyebab Kecelakaan Kerja Menggunakan Metode RCA (Fishbone Diagram Method And 5 – Why Analysis) di PT. PAL Indonesia*, Conference on Safety Engineering and Its Application.
- Liu, H.C., Li, P., You, J.X., dan Chen, Y.Z., 2015, A Novel Approach for FMEA: Combination of Interval 2-Tuple Linguistic Variables and Gray Relational Analysis, *Quality and Reliability Engineering International*, 31(5):761-72.
- Mas'idah, E., Syakhroni, A., dan Rachmawati, A. A., 2019, Analisis Kesalahan Manusia pada Pengemudi Bus Rapid Transit (BRT) Menggunakan Metode Human Error Assessment And Reduction Technique (HEART) dan Systematic Human Error Reduction And Prediction (Studi Kasus : Brt Koridor I, Trans Semarang), *Opsi*, 12(2): 77.
- Mufid, H. A., dan Mahachandra, M., 2019, *Penerapan Human Error Assessment Reduction Technique Dan Systematic Human Error Reduction Prediction pada Pt Sri Rejeki Isman Tbk*, Workshop dan Seminar PEI 2019, ISBN 978-623-92057-0-6, 345–352.
- Ningrum, M. C., dan Ananta, R., 2020, *Penerapan Pengkajian Mutu Produk (PMP) atau Product Quality Review (PQR) untuk Menghasilkan Obat Berkualitas pada Era Digitalisasi*, Program Studi Profesi Apoteker Universitas Pancasila, Fakultas Farmasi Universitas Pancasila.
- Nurmesa, 2019, Tahapan Pembuatan Laporan Product Quality Review Sebagai Evaluasi Mutu Produk di PT Kalbe Farma Tbk, *Farmaka - Jurnal Unpad*, 17(1): 1-10.
- Perera, A.A., Navaratne, S.B., 2016, Application of Pareto principle and Fishbone diagram for Waste Management in a Powder Filling Process, *International Journal of Scientific and Engineering Research*, 7(11): 181-184.
- Putra, B. P., 2019, Analisis Human Error Pada Bagian Jaing Di PT Arteria Daya Mulia Menggunakan Metode Human Error Assesment And Reduction Technique (HEART) dan Systematic Human Error Reduction And Prediction (SHERPA), *Laporan Tugas Akhir Teknik Industri*, Fakultas Teknologi Industri, Universitas Islam Sultan Agung Semarang.
- QBD Group, 2022, *Annual Product Quality Review (APQR) in Pharma: importance, benefits dan challenges*, <https://qbdgroup.com/en/blog/annual-product-quality-review-apqr-in-pharma/>, 15 November 2022.
- Qotrunnada, L., 2022, Analisis Human Error pada Proses Pemintalan Benang di

- Ring Spinning Frame Menggunakan Metode Human Error Assessment and Reduction Technique (HEART) dan Root Cause Analysis (RCA), *Skripsi*, Program Studi Teknik Industri, Fakultas Teknologi Industri, Universitas Islam Sultan Agung Semarang.
- Rachmawati, A. A., 2019, *Human Error Assessment And Reduction Technique (HEART) dan Systematic Human Error Reduction And Prediction (Studi Kasus : Brt Koridor I, Trans Semarang)*, Universitas Islam Sultan Agung.
- Raman, R.S., dan Basavaraj, Y., 2019, Quality Improvement of Capacitors Through Fishbone and Pareto Techniques, *International Journal of Recent Technology and Engineering*, 8(2):2248-52.
- Rana, S., dan Belokar, R.M., 2017, Quality Improvement Using FMEA: A Short Review, *International Research Journal of Engineering and Technology*, 4(6):263-7.
- Safitri, D. M., Astriaty, A. R., dan Rizani, N. C., 2015, Human Reliability Assessment dengan Metode Human Error Assessment and Reduction Technique pada Operator Stasiun Shroud PT. X, *Jurnal Rekayasa Sistem Industri*, 4(1): 1–7.
- Sondalini, M., 2013, Understanding How to Use The 5-Whys For Root Cause Analysis, *Plant, Equipment and Reliability Improvement*, 1.
- Sugiyono, 2017, *Metode Penelitian Kuantitatif, Kualitatif, dan R&D* (26th ed), Alfabeta.
- Susendi, N., Suparman, A., dan Sopyan, I., 2021, Kajian Metode Root Cause Analysis yang Digunakan dalam Manajemen Risiko di Industri Farmasi, *Majalah Farmasetika*, 7(1), 1-10.
- Yuniarto, H., Akbari, A., dan Masruroh, N., 2013, Perbaikan pada Fishbone Diagram Sebagai Root Cause Analysis Tool, *Jurnal Teknik Industri*, 3(3).
- Zubair, M., 2022, Product Quality Reviews and Its Importance in Product Lifecycle, *Research and Reviews: Journal of Pharmaceutical Analysis*, 11(3).