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**Analisis Risiko Potensi Kegagalan Dalam Implementasi CDOB Pada PBF X Di Yogyakarta Dengan Metode
Failure Mode And Effects Analysis**
Martsom Putra Sulung Sayang Langga, Prof. Dr. apt. Teuku Nanda Saifullah Sulaiman, M.Si. ; Prof. Dr. apt. Satibi, M
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# INTISARI

Pedagang Besar Farmasi (PBF) berperan penting dalam menjamin mutu, keamanan, dan ketertelusuran obat selama proses distribusi. Namun, implementasi CDOB masih menghadapi berbagai kendala, terutama pada aspek Bangunan dan Peralatan, Operasional, serta Keluhan, Obat dan/atau Bahan Obat Kembalian, Diduga Palsu, dan Penarikan Kembali. Evaluasi administratif berbasis *checklist* belum cukup menggambarkan tingkat risiko dari setiap potensi kegagalan, sehingga diperlukan pendekatan manajemen risiko yang lebih proaktif. Penelitian ini bertujuan mengidentifikasi mode kegagalan potensial dalam implementasi CDOB pada PBF X di Yogyakarta, menganalisis tingkat risikonya menggunakan FMEA, serta menyusun rekomendasi perbaikan berdasarkan prioritas risiko.

Penelitian ini merupakan penelitian *mix-method* deskriptif dengan pendekatan kualitatif-kuantitatif. Data diperoleh melalui wawancara, FGD, dan pengisian kuesioner oleh tim FMEA. Identifikasi mode kegagalan dilakukan melalui wawancara, sedangkan penilaian risiko dilakukan melalui FGD menggunakan parameter *Severity*, *Occurrence*, dan *Detection*. Ketiga parameter tersebut digunakan untuk menghitung RPN sebagai dasar pengelompokan tingkat risiko.

Hasil penelitian menunjukkan terdapat 50 mode kegagalan potensial, terdiri atas 32 mode kegagalan kategori rendah, 12 kategori sedang, dan 6 kategori tinggi. Risiko tertinggi ditemukan pada aspek Operasional, khususnya subaspek penyimpanan, pemisahan obat dan/atau bahan obat, dan penyaluran, serta pada subaspek penarikan kembali. Rekomendasi perbaikan difokuskan pada penguatan pemantauan kondisi penyimpanan, pemisahan dan pelabelan produk berdasarkan status, verifikasi akhir sebelum pengiriman, pencegahan salah kirim, serta penguatan pelaksanaan penarikan kembali. FMEA membantu menetapkan prioritas perbaikan CDOB secara lebih sistematis dan aplikatif.

**Kata kunci**: PBF, CDOB, Distribusi Obat, *Failure Mode and Effects Analysis*, Risiko, Mitigasi.

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# ABSTRACT

Pharmaceutical wholesalers play an important role in ensuring the quality, safety, and traceability of medicines during the distribution process. However, the implementation of Good Drug Distribution Practice (CDOB) still faces several challenges, particularly in the aspects of Buildings and Equipment, Operations, and Complaints, Returned Medicines, Suspected Counterfeit Medicines, and Recalls. Administrative evaluation using a checklist is not sufficient to describe the level of risk of each potential failure. Therefore, a more proactive risk management approach is needed. This study aimed to identify potential failure modes in the implementation of CDOB at PBF X in Yogyakarta, analyze their risk levels using Failure Mode and Effects Analysis (FMEA), and develop improvement recommendations based on risk priority.

This study used a descriptive mixed-methods design with qualitative and quantitative approaches. Data were collected through interviews, Focus Group Discussions (FGDs), and questionnaires completed by the FMEA team. Potential failure modes were identified through interviews, while risk assessment was conducted through FGDs using three parameters: Severity, Occurrence, and Detection. These parameters were used to calculate the Risk Priority Number (RPN) as the basis for risk classification.

The results identified 50 potential failure modes, consisting of 32 low-risk, 12 medium-risk, and 6 high-risk failure modes. The highest risks were found in the Operational aspects, particularly the subaspects of storage, destruction of drugs and/or drug materials, and distribution, as well as in the sub-aspect of recall. Improvement recommendations focused on strengthening storage condition monitoring, product segregation and labeling based on status, final verification before shipment, prevention of incorrect delivery, and strengthening recall implementation. FMEA helped determine CDOB improvement priorities in a more systematic and practical manner.

**Keywords**: PBF, CDOB, medicine distribution, Failure Mode and Effects Analysis, risk, mitigation.